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NUCLEAR REGULATORY COMMISSION

10 CFR Parts 9 and 35

[NRC–2018–0303]

RIN 3150–AK27

Social Security Number Fraud Prevention

AGENCY: Nuclear Regulatory Commission.

ACTION: Direct final rule.

SUMMARY: The U.S. Nuclear Regulatory Commission (NRC) is amending its regulations to implement the Social Security Number Fraud Prevention Act of 2017. This statute directed agencies to issue regulations that prohibit the inclusion of an individual's Social Security account number (Social Security number or SSN) on any document sent through the mail unless the head of the agency deems it necessary and the appropriate precautions are taken to protect the SSN. Applicants, licensees, and members of the public who are required to submit a form containing a SSN may be affected.

DATES: This direct final rule is effective August 17, 2020, unless significant adverse comments are received by July 2, 2020. If this direct final rule is withdrawn as a result of such comments, timely notice of the withdrawal will be published in the **Federal Register**. Comments received after this date will be considered if it is practical to do so, but the NRC is able to ensure consideration only for comments received on or before this date. Comments received on this direct final rule will also be considered to be comments on a companion proposed rule published in the Proposed Rules section of this issue of the **Federal Register**.

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

- *Federal Rulemaking Website:* Go to *https://www.regulations.gov* and search for Docket ID NRC–2018–0303. Address questions about NRC dockets to Carol Gallagher; telephone: 301–415–3463; email: *Carol.Gallagher@nrc.gov.* For technical questions contact the individuals listed in the **FOR FURTHER INFORMATION CONTACT** section of this document.
- *Email comments to: Rulemaking.Comments@nrc.gov.* If you do not receive an automatic email reply confirming receipt, then contact us at 301–415–1677.
- *Mail comments to:* Secretary, U.S. Nuclear Regulatory Commission, Washington, DC 20555–0001, ATTN: Rulemakings and Adjudications Staff.

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: Alexa Sieracki, Office of Nuclear Materials Safety and Safeguards, U.S. Nuclear Regulatory Commission, Washington, DC 20555–0001; telephone: 301–415–7509, email: *Alexa.Sieracki@nrc.gov.*

SUPPLEMENTARY INFORMATION:

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I. Obtaining Information and Submitting Comments

A. Obtaining Information

Please refer to Docket ID NRC–2018–0303 when contacting the NRC about the availability of information for this action. You may obtain publicly-available information related to this action by any of the following methods:

- *Federal Rulemaking Website:* Go to *https://www.regulations.gov* and search for Docket ID NRC–2018–0303.
- *NRC's Agencywide Documents Access and Management System (ADAMS):* You may obtain publicly-available documents online in the ADAMS Public Documents collection at *https://www.nrc.gov/reading-rm/adams.html.* To begin the search, select ''Begin Web-based ADAMS Search.'' For problems with ADAMS, please contact the NRC's Public Document Room (PDR) reference staff at 1–800–397–4209, 301–415–4737, or by email to *pdr.resource@nrc.gov.*
- *Attention:* The Public Document Room (PDR), where you may examine and order copies of public documents is currently closed. You may submit your request to the PDR via email at *PDR.Resource@nrc.gov* or call 1–800–397–4209 between 8:00 a.m. and 4:00 p.m. (EST), Monday through Friday, except Federal holidays.

B. Submitting Comments

Please include Docket ID NRC–2018–0303 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 *https://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. Procedural Background

Because the NRC anticipates that this action will be non-controversial, the NRC is using the ''direct final rule procedure'' for this rule. The amendments to the rule will become effective on August 17, 2020. However, if the NRC receives significant adverse comments on this direct final rule by July 2, 2020, then the NRC will publish a document that withdraws this action and will subsequently address the

comments received in a final rule as a response to the companion proposed rule published in the Proposed Rules section of this issue of the **Federal Register**. Absent significant modifications to the proposed revisions requiring republication, the NRC will not initiate a second comment period on this action.

A significant adverse comment is a comment where the commenter explains why the rule would be inappropriate, including challenges to the rule's underlying premise or approach, or would be ineffective or unacceptable without a change. A comment is adverse and significant if it meets the following criteria:

(1) The comment opposes the rule and provides a reason sufficient to require a substantive response in a notice-and-comment process. For example, a substantive response is required in the following circumstances:

(a) The comment causes the NRC to reevaluate (or reconsider) its position or conduct additional analysis;

(b) The comment raises an issue serious enough to warrant a substantive response to clarify or complete the record; or

(c) The comment raises a relevant issue that was not previously addressed or considered by the NRC.

(2) The comment proposes a change or an addition to the rule, and it is apparent that the rule would be ineffective or unacceptable without incorporation of the change or addition.

(3) The comment causes the NRC to make a change (other than editorial) to the rule. For detailed instructions on filing comments, please see the **ADDRESSES** section of this document.

III. Discussion

The President signed into law the Social Security Number Fraud Prevention Act of 2017 (the Act) on September 15, 2017, to reduce the risk of identity theft by directing agencies to ''issue regulations specifying the circumstances under which inclusion of a social security account number on a document sent by mail is necessary.'' [1] The Act restricts the inclusion of an SSN on any document sent by mail ''unless the head of the agency determines that the inclusion of the [SSN] on the document is necessary.'' [2] The Act directs agencies to issue regulations that specify when inclusion of an SSN is necessary, include instructions for the partial redaction of SSNs where feasible, and provide a requirement that SSNs not be visible on the outside of any package sent by mail.[3] These regulations must be issued no later than 5 years after the date of enactment of the Act.

The NRC determined that rulemaking was necessary because the Act requires the NRC to amend its regulations. This effort could not be achieved through issuing guidance, as guidance documents are not legally binding and cannot be used to amend regulations. The NRC's rulemaking is narrowly tailored to address the requirements specifically set forth in the Act; therefore, the NRC determined that a direct final rule was appropriate, because the amendments are required by statute, expected to be non-controversial, and unlikely to yield public comment resulting in a significant change to the NRC's proposal. A direct final rule is preferable to a final rule because it allows for the opportunity for public comment, should there be any additional regulations that the public identifies as needing amendment or any additional considerations the NRC needs to evaluate to implement the Act.

To comply with the Act, the NRC examined whether SSNs are necessary in any of the written communications to the NRC required by regulation. The Act only applies to written communications sent or received via mail by the NRC that include SSNs. The Act does not apply to a licensee's validation of an individual's SSN because the SSN would not be included in written communications with the NRC in those cases. If inclusion of SSNs is not necessary, then each associated regulation would need to be amended to remove the inclusion of the SSN in the required documents. If inclusion of SSNs is necessary, the NRC must consider whether partial redaction of the SSN is feasible and amend the regulations accordingly to meet the ''requirement that [SSNs] not be visible on the outside of any package sent by mail.'' [4]

Based on its review, the agency has concluded that, in all instances where it requires full or partial SSNs to be included in written communications, this information is necessary for identity confirmation. Reasons for this include instances when individuals have similar or same names and cases where outside factors require the NRC to collect either a full or partial SSN. For example, the collection may be required by law or by another agency. The NRC already requests SSNs to be partially redacted in documents sent by mail whenever feasible. Therefore, the NRC concluded that minimal changes to its regulations are needed to reduce the inclusion of full or partial SSNs. However, the agency determined that the following amendments are needed to fully implement the Act:

- In § 9.1, a new Subpart E needs to be added concerning the use of SSNs in documents sent by mail.
- In §§ 35.3045 and 35.3047, language should be revised to prioritize the use of identification numbers that are not SSNs when identifying patients.

In anticipation of the above revisions, all applicable NRC forms have been proactively modified to include language that SSNs must not be visible on the outside of any package sent by mail.

IV. Section-by-Section Analysis

The following paragraphs describe the specific changes in this direct final rule.

Section 9.1 Scope and Purpose

This direct final rule adds new paragraph (e).

Subpart E—Social Security Number Fraud Prevention Act Requirements

This direct final rule adds new subpart E—Social Security Number Fraud Prevention Act Requirements.

Section 35.3045 Report and Notification of a Medical Event

This direct final rule revises paragraph (g)(1)(ii) to replace ''social security number or identification number'' with ''identification number or if no other identification number is available, the social security number.''

Section 35.3047 Report and Notification of a Dose to an Embryo/Fetus or a Nursing Child

This direct final rule revises paragraph (f)(1)(ii) to replace ''social security number or identification number'' with ''identification number or if no other identification number is available, the social security number.''

V. Regulatory Flexibility Certification

Under the Regulatory Flexibility Act (5 U.S.C. 605(b)), the NRC certifies that this rule will not, if issued, have a significant economic impact on a substantial number of small entities. This direct final rule affects a number of ''small entities'' as defined by the Regulatory Flexibility Act or the size standards established by the NRC (10 CFR 2.810). However, as indicated in the regulatory analysis contained in this document, these amendments do not have a significant economic impact on the affected small entities.

[1] Public Law 115–59, Section 2(b).

[2] Public Law 115–59, Section 2(a).

[3] Public Law 115–59, Section 2(b)(1)–(2).

[4] Public Law115–59, Section 2(b)(2).

VI. Regulatory Analysis

The NRC has prepared a final regulatory analysis for this direct final rule. The analysis examines the costs and benefits of the alternatives considered by the NRC. The key findings are as follows:

• Benefits. This final rule ensures that the NRC is in compliance with the Act by doing the following:

(1) Revising regulations in 10 CFR part 9, § 35.3045(g)(1)(ii), and § 35.3047(f)(1)(ii) to address the intent of the Act; and

(2) Ensuring that NRC forms comply with the intent of the Act.

In accordance with the Act, the NRC requests that a SSN be included in documents sent by mail only when necessary and partially redacted whenever feasible. The redacted SSN should list only the number of digits necessary and must not be visible from the outside of packages sent to and from the NRC.

• Cost to the Industry. This direct final rule results in no incremental costs to material or reactor licensees.

• Cost to the Public. This direct final rule results in no incremental costs to the public.

• Cost to the NRC. This direct final rule results in no incremental costs to the NRC beyond those necessary to prepare and issue this direct final rule and make conforming changes to NRC forms, which are considered costs that have already been incurred.

VII. Backfitting and Issue Finality

This direct final rule modifies the NRC regulations to implement the requirements of the Act to use SSNs only where necessary and to partially redact SSNs to the extent practicable. These regulations relate solely to information collection and reporting requirements. The NRC has long taken the position that information collection and reporting requirements are not subject to the NRC's backfitting and issue finality regulations in 10 CFR 50.109, 10 CFR 70.76, 10 CFR 72.62, 10 CFR 76.76, and 10 CFR part 52. Therefore, the NRC has determined that the various backfitting and issue finality provisions do not apply to this final rule and has not prepared a backfit analysis.

VIII. Plain Writing

The Plain Writing Act of 2010 (Pub. L. 111–274) requires Federal agencies to write documents in a clear, concise, and well-organized manner. The NRC has written this document to be consistent with the Plain Writing Act as well as the Presidential Memorandum, ''Plain Language in Government Writing,'' published June 10, 1998 (63 FR 31883).

IX. Environmental Assessment and Final Finding of No Significant Environmental Impact

The Commission has determined under the National Environmental Policy Act of 1969, as amended, and the Commission's regulations in subpart A of 10 CFR part 51, that this direct final rule, if adopted, would not be a major Federal action significantly affecting the quality of the human environment and, therefore, an environmental impact statement is not required.

This direct final rule amends NRC's regulations in 10 CFR parts 9 and 35. These amendments are necessary to comply with the Social Security Number Fraud Prevention Act of 2017, which directed agencies to issue regulations that prohibit the inclusion of an individual's SSN on any document sent through the mail unless the head of the agency deems it necessary and the appropriate precautions are taken to protect the SSN. These amendments do not increase any effect on the environment.

The determination of this environmental assessment is that there will be no significant environmental impacts from this action.

X. Paperwork Reduction Act

This direct final rule does not contain any new or amended collections of information subject to the Paperwork Reduction Act of 1995 (44 U.S.C. 3501 *et seq.*). Existing collections of information were approved by the Office of Management and Budget (OMB), approval numbers 3150–0043, 3150–0014, 3150–0046, and 3150–0010.

Public Protection Notification

The NRC may not conduct or sponsor, and a person is not required to respond to, a collection of information unless the document requesting or requiring the collection displays a currently valid OMB control number.

XI. Congressional Review Act

This direct final rule is not a rule as defined in the Congressional Review Act (5 U.S.C. 801–808).

List of Subjects

10 CFR Part 9

Administrative practice and procedure, Courts, Freedom of information, Government employees, Privacy, Reporting and recordkeeping requirements, Sunshine Act.

10 CFR Part 35

Biologics, Drugs, Health facilities, Health professions, Labeling, Medical devices, Nuclear energy, Occupational safety and health, Penalties, Radiation protection, Reporting and recordkeeping requirements.

For the reasons set out in the preamble and under the authority of the Atomic Energy Act of 1954, as amended; the Energy Reorganization Act of 1974, as amended; and 5 U.S.C. 552 and 553, the NRC is adopting the following amendments to parts 9 and 35:

PART 9—PUBLIC RECORDS

■ 1. The authority citation for part 9 continues to read as follows:

Authority: Atomic Energy Act of 1954, sec. 161 (42 U.S.C. 2201); Energy Reorganization Act of 1974, sec. 201 (42 U.S.C. 5841); 44 U.S.C. 3504 note.

Subpart A also issued under 31 U.S.C. 9701.

Subpart B also issued under 5 U.S.C. 552a.

Subpart C also issued under 5 U.S.C. 552b.

■ 2. In § 9.1, add paragraph (e) to read as follows:

§ 9.1 Scope and purpose.

* * * * *

(e) Subpart E implements the provisions of the Social Security Number Fraud Prevention Act of 2017, Public Law 115–59, concerning the use of Social Security account numbers in documents sent by mail.

■ 3. Add subpart E, consisting of §§ 9.300 and 9.301, to read as follows:

Subpart E—Social Security Number Fraud Prevention Act Requirements

§ 9.300 Scope of subpart.

This subpart implements the Social Security Number Fraud Prevention Act of 2017, Public Law 115–59, with respect to the use of Social Security account numbers in documents sent by mail and requirements applicable to NRC personnel for redacting Social Security account numbers in documents sent by mail.

§ 9.301 Social Security account numbers in documents sent by mail.

(a) Social Security account numbers shall not be visible on the outside of any package sent by mail.

(b) A document sent by mail may only include the Social Security account number of an individual if it is determined by the head of the agency that the inclusion of a Social Security account number is necessary.

(c) The inclusion of a Social Security account number of an individual on a document sent by mail is necessary when—

(1) Required by law; or

(2) Necessary to identify a specific individual and no adequate substitute is available.

(d) Social Security account numbers must be partially redacted in documents sent by mail whenever feasible.

PART 35—MEDICAL USE OF BYPRODUCT MATERIAL

■ 4. The authority citation for part 35 continues to read as follows:

Authority: Atomic Energy Act of 1954, secs. 81, 161, 181, 182, 183, 223, 234, 274 (42 U.S.C. 2111, 2201, 2231, 2232, 2233, 2273, 2282, 2021); Energy Reorganization Act of 1974, secs. 201, 206 (42 U.S.C. 5841, 5846); 44 U.S.C. 3504 note.

■ 5. In § 35.3045, revise paragraph (g)(1)(ii) to read as follows:

§ 35.3045 Report and notification of a medical event.

* * * * *

(g) * * *

(1) * * *

(ii) Identification number or if no other identification number is available, the social security number of the individual who is the subject of the event; and

* * * * *

■ 10. In § 35.3047, revise paragraph (f)(1)(ii) to read as follows:

§ 35.3047 Report and notification of a dose to an embryo/fetus or a nursing child.

* * * * *

(f) * * *

(1) * * *

(ii) Identification number or if no other identification number is available, the social security number of the individual who is the subject of the event; and

* * * * *

Dated: May 28, 2020.

For the Nuclear Regulatory Commission.

Annette L. Vietti-Cook,

Secretary of the Commission.

[FR Doc. 2020–11899 Filed 6–1–20; 8:45 am]

BILLING CODE 7590–01–P

DEPARTMENT OF THE TREASURY

Office of the Comptroller of the Currency

12 CFR Parts 7 and 160

[Docket ID OCC–2019–0027]

RIN 1557–AE73

Permissible Interest on Loans That Are Sold, Assigned, or Otherwise Transferred

AGENCY: Office of the Comptroller of the Currency, Treasury.

ACTION: Final rule.

SUMMARY: Federal law establishes that national banks and savings associations (banks) may charge interest on loans at the maximum rate permitted to any state-chartered or licensed lending institution in the state where the bank is located. In addition, banks are generally authorized to sell, assign, or otherwise transfer (transfer) loans and to enter into and assign loan contracts. Despite these authorities, recent developments have created legal uncertainty about the ongoing permissibility of the interest term after a bank transfers a loan. This rule clarifies that when a bank transfers a loan, the interest permissible before the transfer continues to be permissible after the transfer.

DATES: The final rule is effective on August 3, 2020.

FOR FURTHER INFORMATION CONTACT: Andra Shuster, Senior Counsel, Karen McSweeney, Special Counsel, or Priscilla Benner, Senior Attorney, Chief Counsel's Office, (202) 649–5490, for persons who are deaf or hearing impaired, TTY, (202) 649–5597, Office of the Comptroller of the Currency, 400 7th Street SW, Washington, DC 20219.

SUPPLEMENTARY INFORMATION:

I. Background

On November 21, 2019, the OCC published a notice of proposed rulemaking (proposal or NPR) to codify its conclusion that when a national bank or savings association (bank) sells, assigns, or otherwise transfers (transfers) a loan, interest permissible before the transfer continues to be permissible after the transfer.[1]

As the proposal explained, a bank may charge interest on a loan at the maximum rate permitted to any state-chartered or licensed lending institution in the state where the bank is located. In addition, banks are generally authorized to transfer their loans and to enter into and assign loan contracts. Despite these authorities, recent developments have created legal uncertainty about the ongoing permissibility of the interest term after a bank transfers a loan.

Consistent with the proposal, this regulation addresses that legal uncertainty by clarifying and reaffirming the longstanding understanding that a bank may transfer a loan without affecting the permissible interest term. Based on its supervisory experience, the OCC believes that unresolved legal uncertainty about this issue may disrupt banks' ability to serve consumers, businesses, and the broader economy efficiently and effectively, particularly in times of economic stress. The OCC also believes that enhanced legal certainty may facilitate responsible lending by banks, including in circumstances when access to credit is especially critical.

II. Overview of Comments

The OCC received over sixty comments on its NPR, including comments from industry trade associations, nonbank lenders, community groups, academics, state government representatives, and members of the public. Many commenters expressed support for the rule. Some stated that the legal uncertainty discussed in the proposal has had negative effects on the primary and secondary markets for bank loans. They argued that legal certainty regarding a bank's ability to transfer non-usurious loans without affecting the interest term would benefit banks and markets, including for liquidity and diversification purposes. Many supporting commenters also agreed that the OCC has the authority to address this issue by regulation and that the proposal reflected a permissible interpretation of relevant Federal banking law.

The OCC also received comments opposed to the rule, which raised both legal and policy concerns. Many commenters argued that the OCC does not have the authority to issue this regulation. Several also argued that the OCC's proposal was subject to, but did not comply with, the substantive and procedural provisions in 12 U.S.C. 25b. Opposing commenters also questioned the need for the rule, stating there is no evidence that legal uncertainty has had negative effects on banks or markets. Relying on these and other arguments, some commenters also argued that the OCC's proposal did not comply with the Administrative Procedure Act (APA).[2] Finally, certain commenters stated that the NPR would facilitate predatory lending by promoting rent-a-charter relationships and allowing nonbanks to evade otherwise applicable state law.

Two commenters provided empirical studies analyzing the effects of the *Madden* v. *Midland Funding, LLC*[3] decision (*Madden*), including evidence that *Madden* restricted access to credit for higher-risk borrowers in states

[1] Permissible Interest on Loans That Are Sold, Assigned, or Otherwise Transferred, 84 FR 64229 (Nov. 21, 2019).

[2] 5 U.S.C. 551 *et seq.*

[3] 786 F.3d 246 (2d Cir. 2015). In this case, the U.S. Court of Appeals for the Second Circuit held that a purchaser of a loan originated by a national bank could not charge interest at the rate permissible for the bank if that rate would be impermissible under the lower usury cap applicable to the purchaser.

within the Second Circuit and that it caused a rise in personal bankruptcies due to a decline in marketplace lending, especially for low-income households.

III. Analysis

As noted in the proposal, the OCC is undertaking this rulemaking to clarify that a bank may transfer a loan without impacting the permissibility or enforceability of the interest term in the loan contract, thereby resolving the legal uncertainty created by the *Madden* decision. To support this conclusion, the proposal discussed a bank's authority to lend money, to make contracts, to charge interest consistent with the laws of the state in which it is located, and to subsequently transfer that loan and assign the loan contract. It also discussed the principles of ''valid-when-made'' and the assignability of contracts, which, if applied to the transfer of a loan, would generally produce an outcome consistent with the OCC's conclusion.

Authority

As noted above, although many supporting commenters expressly agreed that the OCC may promulgate this rule, many opposing commenters questioned the OCC's authority, relying on several principal arguments:

- Certain Federal statutes (12 U.S.C. 85 and 1463(g)) are unambiguous and only address the interest a *bank* may charge. Because these statutes are unambiguous, the OCC cannot invoke *National Cable & Telecommunications Ass'n* v. *Brand X internet Services* [4] (*Brand X*) to overturn the result in *Madden.*
- Valid-when-made is not a historical usury principle that supports the OCC's proposal.
- There is no basis to conclude that Federal law should preempt state usury laws based on a bank's power to assign contracts.
- There is no basis to conclude that Federal law should preempt state usury laws based on a bank's authority to transfer loans.

The OCC has carefully considered these comments and believes there is ample authority to issue this regulation. Federal law grants national banks broad authority to engage in the business of banking.[5] Specifically relevant here, the National Bank Act (NBA) provides national banks with enumerated powers, including the ability to lend money, and ''all such incidental powers as shall be necessary to carry on the business of banking.'' [6] By statute, national banks also have the authority to transfer their loans.[7]

Furthermore, the NBA expressly authorizes national banks to make contracts.[8] Among the essential rights associated with this power is the right to assign some or all of the benefits of a contract to a third party.[9] Generally, all contractual rights may be assigned ''in the absence of clear language expressly prohibiting the assignment and unless the assignment would materially change the duty of the obligor or materially increase the obligor's burden or risk under contract or the contract involves obligations of a personal nature.'' [10] In addition, contractual rights generally may not be assigned if the assignment is ''specifically forbidden by statute or . . . void as against public policy.'' [11] All ordinary business contracts are assignable, and a contract for money due in the future is among the types of contracts that normally may be assigned.[12] Therefore, a national bank's authority to enter into loan contracts pursuant to 12 U.S.C. 24(Third) necessarily includes the authority to assign such loan contracts.[13]

When a national bank exercises its authority to lend money and enters into a loan contract, the NBA authorizes the bank to ''charge on any loan . . . interest at the rate allowed by the laws of the State . . . where the bank is located.'' [14] Section 85 is the sole provision that governs the interest permissible on a loan made by a national bank, and it operates primarily by incorporating the usury laws of the state in which the bank is located. Section 85 and 12 U.S.C. 86, which establishes the remedy for a violation of section 85, constitute the comprehensive statutory scheme governing the interest permitted on national bank loans.[15]

The NBA thus clearly establishes that a national bank may (1) lend money, pursuant to a loan contract, with an interest term that is consistent with the laws of the state in which the bank is located and (2) subsequently transfer that loan and assign the loan contract. However, the comprehensive statutory scheme regarding interest permitted on national bank loans does not expressly address how the exercise of a national bank's authority to transfer a loan and assign the loan contract affects the interest term. When Congress enacted the NBA, it understood that loan transfers were a fundamental aspect of the business of banking and that such transfers would play an important role in the national banking system.[16] Therefore, section 85's silence in this regard is ''conspicuous[ ],'' [17] and the OCC may interpret section 85 to resolve this silence.[18]

The OCC is not persuaded by commenters who argued that 12 U.S.C. 1735f–7a forecloses an argument that section 85's silence is ambiguous as to its application to loan transfers. These commenters argued that section 1735f–7a preempts state usury laws and expressly applies to originations and sales of certain loans, and therefore, Congress must be presumed to have intentionally omitted similar language in section 85, thereby precluding the application of section 85 to loan transfers. These commenters argued that this presumption is particularly strong, because several statutory parallels to section 85 were enacted at the same time as section 1735f–7a. At least one commenter also cited 12 U.S.C. 3803 to

[4] 545 U.S. 967 (2005).

[5] The OCC will discuss the authority to issue this rule for national banks before discussing the authority to issue this rule for savings associations.

[6] 12 U.S.C. 24(Seventh) and 371.

[7] 12 U.S.C. 24(Seventh) and 371; 12 CFR 7.4008 and 34.3; *see also Planters' Bank of Miss.* v. *Sharp,* 47 U.S. 301, 322 (1848) (concluding that the authority to transfer a loan is a ''necessarily implied'' corollary to the authority to make a loan). It should be noted that rights authorized by a statute need not be express—they are often implicit in the other rights given by the statute. *See, e.g., Franklin Nat'l Bank* v. *New York,* 347 U.S. 373, 377–78 (1954) (concluding that the right to accept savings deposits implicitly includes the right to advertise).

[8] 12 U.S.C. 24(Third).

[9] Restatement (Second) of Contracts section 317 (Am. Law Inst. 1981).

[10] 29 Williston on Contracts section 74:10 (4th ed.) (footnote omitted).

[11] *Id.* at section 74:23.

[12] *See Bank of Am., N.A.* v. *Rice,* 780 S.E.2d 873 (N.C. Ct. App. 2015).

[13] *See also Franklin Nat'l Bank,* 347 U.S. at 377–78.

[14] 12 U.S.C. 85. Section 85 also allows a national bank to charge ''1 per centum in excess of the discount rate on ninety-day commercial paper in effect at the Federal reserve bank in the Federal reserve district where the bank is located.'' *Id.*

[15] *See Beneficial Nat'l Bank* v. *Anderson,* 539 U.S. 1 (2003).

[16] *See Planters' Bank,* 47 U.S. at 323 (''[Banks] must be able to assign or sell [their] notes when necessary and proper, as, for instance, to procure more specie in an emergency, or return an unusual amount of deposits withdrawn, or pay large debts for a banking-house.'').

[17] *Baldwin* v. *United States,* 921 F.3d 836, 842 (9th Cir. 2019).

[18] *See Chevron U.S.A., Inc.* v. *Nat. Res. Def. Council, Inc.,* 467 U.S. 837, 843 (1984) (''[I]f the statute is silent or ambiguous with respect to the specific issue, the question for the court is whether the agency's answer is based on a permissible construction of the statute.''); *see also Robinson* v. *Shell Oil Co.,* 519 U.S. 337, 341 (1997) (''The plainness or ambiguity of statutory language is determined by reference to the language itself, the specific context in which that language is used, and the *broader context of the statute as a whole.*'') (emphasis added); *Smiley* v. *Citibank (S.D.), N.A.,* 517 U.S. 735 (1996) (*Smiley*) (deferring to the OCC's reasonable interpretation of section 85's ambiguity with respect to meaning of ''interest'').

make a similar argument.[19] The OCC disagrees. First, while the OCC agrees that section 1735f–7a applies to certain loans that have been transferred,[20] this is not by virtue of express statutory language addressing loan transfers. Rather, section 1735f–7a implicitly applies to transferred loans, notwithstanding its silence on this issue, for reasons similar to why the OCC concludes that section 85 applies to transferred loans. Moreover, even if section 1735f–7a expressly applied to loan transfers, it would further highlight the ambiguity created by the silence in section 85.[21] As courts have stated, affirmative language in one provision (section 1735f–7a) and statutory silence in another (section 85) can indicate that Congress intended to provide the administering agency (the OCC) with discretion to interpret the latter statute.[22]

After careful consideration, the OCC continues to conclude that it is appropriate to resolve the silence in section 85 by providing that when a bank transfers a loan, interest permissible before the transfer continues to be permissible after the transfer.

Well before the passage of the NBA, the Supreme Court recognized one of the ''cardinal rules in the doctrine of usury'' and described it as follows: ''a contract, which, in its inception, is unaffected by usury, can never be invalidated by any subsequent usurious transaction.'' [23] Courts have also held the inverse—a loan that is usurious at its inception remains usurious until purged by a new contract.[24] Notwithstanding comments to the contrary, the OCC continues to read the cases cited in the proposal, particularly when considered in light of the court decisions establishing the inverse, to support a broad proposition: The usurious or non-usurious character of a contract endures through assignment.[25]

The OCC's interpretation is also supported by national banks' ability to assign contracts, as discussed above. Commenters argued that the interest term on a loan should be treated differently from other loan terms, including because it derives from a national bank's status under Federal law. For reasons stated in the proposal and herein, the OCC does not agree that the interest term of the contract should be treated differently, nor does it believe that the enforceability of an assigned interest term should depend on the licensing status of the assignor or assignee.[26] Upon assignment, the third-party assignee steps into the shoes of the national bank and may enforce the rights the bank assigned to it under the contract.[27] To effectively assign a loan contract and allow the assignee to step into the shoes of the national bank assignor, a permissible interest term must remain permissible and enforceable notwithstanding the assignment.[28] The loan should not be considered usurious after the assignment simply because a third party is enforcing the contractually agreed-upon interest term.[29] Furthermore, an assignment should not change the borrower's obligation to repay in any material way.[30]

Several commenters argued that, as common law, valid-when-made and the assignability of contracts do not provide the OCC with authority for this regulation. However, the OCC is not citing these tenets as independent authority for this rulemaking but rather as tenets of common law that inform its reasonable interpretation of section 85. Because Congress is presumed to legislate with knowledge of, and incorporate, common law, it is reasonable to interpret section 85 in light of these tenets.[31]

The OCC's interpretation is also consistent with the purpose of section 85. This statute facilitates national banks' ability to operate lending programs on a nationwide basis, a characteristic fundamental to national banks since their inception.[32] Recognizing the value of uniformity in applicable interest law, Congress extended the principles of section 85 to savings associations, state-chartered insured depository institutions, and insured credit unions.[33] Then, in 2010, while carefully examining the application of state law to national banks, Congress expressly preserved the authority conferred by section 85, thereby reaffirming its importance.[34] Reading section 85 as applying only to loans that a national bank holds to maturity would undermine this statutory scheme.[35]

The OCC's interpretation also promotes safe and sound operations, a core component of the OCC's mission as the prudential regulator of national banks. Even in the mid-nineteenth century, the ability to transfer loans was recognized as an important tool to manage liquidity and enhance safety and soundness.[36] As the Supreme Court stated, ''[banks] must be able to assign or sell [their] notes when necessary and proper, as, for instance, to procure more specie in an emergency, or return an

[19] This statute authorizes housing creditors to make, purchase, and enforce alternative mortgage transactions and expressly preempts certain state laws.

[20] *See* S. Rep. No. 96–368, at 19 (1979) (''In connection with the provisions in this section, it is the Committee's intent that loans originated under this usury exemption will not be subject to claims of usury even if they are later sold to an investor who is not exempt under this section.'').

[21] This same conclusion applies to the extent that section 3803 expressly addresses transferred loans.

[22] *Catawba Cty., N.C.* v. *EPA,* 571 F.3d 20, 36 (D.C. Cir. 2009) (''Silence . . . may signal permission rather than proscription.''); *Cheney R. Co., Inc.* v. *ICC,* 902 F.2d 66, 69 (D.C. Cir. 1990) (''[T]he contrast between Congress's mandate in one context with its silence in another suggests not a prohibition but simply a decision *not to mandate* any solution in the second context, *i.e.,* to leave the question to agency discretion. Such a contrast (standing alone) can rarely if ever be the 'direct[]' congressional answer required by *Chevron.*''); *Clinchfield Coal Co.* v. *Fed. Mine Safety & Health Review Comm'n,* 895 F.2d 773, 779 (D.C. Cir. 1990) (''[W]here an agency is empowered to administer the statute, Congress may have meant that in the second context the choice should be up to the agency.'').

[23] *See Nichols* v. *Fearson,* 32 U.S. (7 Pet.) 103, 109 (1833); *see also Gaither* v. *Farmers' & Mechs.' Bank of Georgetown,* 26 U.S. (1 Pet.) 37, 43 (1828).

[24] *See, e.g., Auctus Fund, LLC* v. *Sunstock, Inc.,* 405 F. Supp. 3d 218 (D. Mass. 2019); *Heide* v. *Hunter Hamilton Ltd. P'ship,* 826 F. Supp. 224 (E.D. Mich. 1993); *Matthews* v. *Tripp,* 285 Mich. 705 (1938); *Westman* v. *Dye,* 214 Cal. 28 (1931); *Tribble* v. *Anderson,* 63 Ga. 31 (1879).

[25] This reading has been endorsed by the Solicitor General of the United States. *See Brief for the United States as Amicus Curiae, Midland Funding, LLC* v. *Madden,* No. 15–610 (May 24, 2016). Many commenters also support this reading.

[26] *See Olvera* v. *Blitt & Gaines, P.C.,* 431 F.3d 285, 286, 289 (7th Cir. 2005) (''[T]he assignee of a debt . . . is free to charge the same interest rate that the assignor . . . charged the debtor . . . even if the assignee does not have a license that expressly permits the charging of a higher rate.''). As at least one commenter noted, this case interprets Illinois state law and, therefore, does not directly address the issues raised by this rulemaking. However, the OCC finds the holding and reasoning instructive to its analysis.

[27] *Dean Witter Reynolds Inc.* v. *Variable Annuity Life Ins. Co.,* 373 F.3d 1100, 1110 (10th Cir. 2004) (stating that it was long-established that ''an assignee stands in the shoes of the assignor'').

[28] *See Olvera,* 413 F.3d at 288–89.

[29] *See id.* at 286, 289.

[30] *See* 29 Williston on Contracts section 74:10.

[31] *Astoria Fed. Sav. & Loan Ass'n* v. *Solimino,* 501 U.S. 104, 108 (1991).

[32] *See Marquette Nat. Bank of Minneapolis* v. *First of Omaha Serv. Corp.,* 439 U.S. 299, 315–18 (1978) (concluding that Congress was aware of, and intended to facilitate, interstate lending when it enacted section 85); *Easton* v. *Iowa,* 188 U.S. 220, 229 (1903) (''[The NBA] has in view the erection of a system extending throughout the country, and independent, so far as powers conferred are concerned, of state legislation which, if permitted to be applicable, might impose limitations and restrictions as various and as numerous as the states.''); *Tiffany* v. *Nat'l Bank of Mo.,* 85 U.S. 409, 413 (1873) (''National banks have been National favorites . . . It could not have been intended, therefore, to expose them to the hazard of unfriendly legislation by the States . . . .'').

[33] *See* 12 U.S.C. 1463(g), 1785, and 1831d.

[34] 12 U.S.C. 25b(f).

[35] *See Marquette,* 439 U.S. at 312 (declining to interpret section 85 in a manner that would ''throw into confusion the complex system of modern interstate banking'').

[36] *Planters' Bank,* 47 U.S. 301.

unusual amount of deposits withdrawn, or pay large debts for a banking-house.'' [37] Although the banking system has evolved significantly in the 150 years since *Planters' Bank,* national banks of all sizes continue to routinely rely on loan transfers to access alternative funding sources, manage concentrations, improve financial performance ratios, and more efficiently meet customer needs.[38] While the *Madden* decision's effect on a particular national bank necessarily varies depending on the bank's business model, the resulting legal uncertainty impairs many national banks' ability to rely on this risk management tool, which is particularly worrisome in times of economic stress when funding and liquidity challenges may be acute.[39] The OCC, therefore, concludes that its interpretation promotes safety and soundness.

The OCC also received comments arguing that the OCC's rulemaking is foreclosed by *Madden.* The OCC disagrees; the Second Circuit made no finding that section 85's language unambiguously forecloses the OCC's interpretation, nor did it rely on section 85 in arriving at its holding.[40] Therefore, the *Madden* decision does not limit the OCC's ability to issue this rulemaking.

With respect to the comments arguing that neither section 24(Third) nor section 24(Seventh) provides the OCC with authority to preempt state usury law, the OCC does not cite these statutes for this purpose. As this authority section makes clear, these statutes describe the scope of national bank authorities, highlight the silence in section 85, and inform the OCC's efforts to resolve this silence.[41]

Although the foregoing discussion specifically addresses national banks, it applies equally to savings associations. In 12 U.S.C. 1463(g), Congress provided savings associations with authority similar to section 85 to charge interest as permitted by the laws of the state in which the savings association is located. Congress modeled section 1463(g) on section 85 to place savings associations on equal footing with their national bank competitors, and thus, these provisions are interpreted *in pari materia.*[42] Therefore, the OCC concludes that section 1463(g) should be interpreted coextensively with section 85 in this regard, which will help ensure that savings associations and national banks have equal authority to transfer their loans without affecting the permissibility of the interest term.

Based on the foregoing, the OCC concludes that, as a matter of Federal law, banks may transfer their loans without impacting the permissibility or enforceability of the interest term.

12 U.S.C. 25b

Several commenters argued that the OCC's rule is subject to the substantive and procedural requirements set forth in section 25b and that the OCC has not complied with these requirements. The OCC disagrees and continues to conclude that the requirements of section 25b are inapplicable to this rulemaking.

Section 25b applies when the Comptroller determines, on a case-by-case basis, that a state consumer financial law is preempted pursuant to the standard for conflict preemption established by the Supreme Court in *Barnett Bank of Marion County, N. A.* v. *Nelson, Florida Insurance Commissioner,*[43] *i.e.,* when the Comptroller makes a ''preemption determination.'' [44] Interpretations about the substantive scope of section 85 are not preemption determinations. For example, the two most recent substantive Supreme Court opinions on section 85 primarily analyze what the statute authorizes as a matter of Federal law, rather than focus on preemption.[45] In fact, the Court specifically recognized this difference in *Smiley,* noting that ''the question of the substantive (as opposed to pre-emptive) *meaning* of a statute'' is distinct from ''the question of *whether* a statute is pre-emptive.'' [46] This rulemaking addresses the former question, *i.e.,* the meaning of section 85. The proposal simply articulated the OCC's view about the substantive scope of authority granted to banks. The final rule adopts the same approach and thus is not a preemption determination under section 25b.[47]

The OCC also concludes that this rulemaking is outside the scope of section 25b because of section 25b(f), which provides that ''[n]o provision of title 62 of the Revised Statutes shall be construed as altering or otherwise affecting the authority conferred by section 85.'' Section 25b is in title 62 of the Revised Statutes, and therefore, its requirements also do not alter or affect the authority conferred under section 85, including as interpreted in this rulemaking.[48] For these reasons, the OCC disagrees with the commenters who argued that section 25b(f) does not exempt rules interpreting section 85.[49]

The OCC thus concludes that this rulemaking is not subject to the requirements of section 25b.[50] Because the OCC concludes that these requirements are inapplicable, the OCC declines to address comments regarding how to comply with these requirements.

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[37] *Id.* at 323.

[38] *Comptroller's Handbook, Safety and Soundness,* ''Liquidity,'' at 5, June 2012.

[39] *See Strike* v. *Trans-W. Disc. Corp.,* 92 Cal. App. 3d 735, 745 (Cal. Ct. App. 1979) (concluding that the assignee of a bank note could continue to receive the rate the assigning bank could, because to conclude otherwise would ''prohibit-make uneconomic-the assignment or sale by banks of their commercial property to a secondary market[, which] would be disastrous in terms of bank operations and not conformable to the public policy exempting banks in the first instance''); *see also LFG Nat'l Capital, LLC* v. *Gary, Williams, Finney, Lewis, Watson & Sperando P.L.,* 874 F. Supp. 2d 108, 125 (N.D.N.Y. 2012) (stating the same).

[40] *See Brand X,* 545 U.S. at 982–83 (requiring that ''judicial precedent *hold*[ ] that the statute *unambiguously forecloses* the agency's interpretation'' (emphasis added)); *see also Mhany Mgmt., Inc.* v. *Cty. of Nassau,* 819 F.3d 581, 618–19 (2d Cir. 2016) (applying *Brand X* to adopt a more recent agency interpretation rather than two prior Second Circuit interpretations where the court ''did not hold that the statute was unambiguous'').

[41] *See King* v. *Burwell,* 135 S. Ct. 2480, 2489 (2015) (''[W]hen deciding whether the language is plain, we must read the words 'in their context and with a view to their place in the overall statutory scheme.' '' (quoting *FDA* v. *Brown & Williamson Tobacco Corp.,* 529 U.S. 120, 133 (2000)).

[42] *See Gavey Props./762* v. *First Fin. Sav. & Loan Ass'n,* 845 F.2d 519, 521 (5th Cir. 1988) (''Given the similarity of language, the conclusion is virtually compelled that Congress sought to provide federally insured credit institutions with the same 'most-favored lender' status enjoyed by national banks.''); 61 FR 50951, 50968 (Sept. 30, 1996) (''OTS and its predecessor, the FHLBB, have long looked to the OCC regulation and other precedent interpreting the national bank most favored lender provision for guidance in interpreting [12 U.S.C. 1463(g)] and OTS's implementing regulation.''); OTS letter from Harris Weinstein, December 24, 1992, 1992 WL 12005275.

[43] 517 U.S. 25 (1996).

[44] *See* 12 U.S.C. 25b(b)(1)(B).

[45] *See Smiley,* 517 U.S. 735; *Marquette,* 439 U.S. 299.

[46] *Smiley,* 517 U.S. at 744 (emphasis in original).

[47] For these same reasons, the OCC is not persuaded by commenters who argued that sections 25b(b)(2), (e), and (h)(2) preclude the agency from issuing this rule.

[48] Section 25b(f) also supports the OCC conclusion that sections 25b(b)(2), (e), and (h)(2) do not preclude the agency from issuing this rule.

[49] This conclusion is supported by consideration of the parallel authority conferred under 12 U.S.C. 1831d, which is construed *in pari materia* with section 85. *See, e.g., Greenwood Tr. Co.* v. *Massachusetts,* 971 F.2d 818, 827 (1st Cir. 1992); FDIC General Counsel's Opinion No. 11, Interest Charges by Interstate State Banks, 63 FR 27282 (May 18, 1998). Congress did not subject Federal Deposit Insurance Corporation (FDIC) interpretations of section 1831d to section 25b or equivalent requirements. Given that sections 1831d and 85 are construed *in pari materia,* it would be incongruous to conclude that an OCC rule interpreting section 85 would be subject to the requirements of section 25b while a substantively identical FDIC rule issued pursuant to parallel statutory authority would not. The same argument can be made regarding section 1463(g).

[50] Some commenters also argued that section 25b applies to this rulemaking because the OCC cited sections 24(Third) and 24(Seventh) in its proposal. As explained above, the OCC does not cite these statutes as direct authority for this rule or for their preemptive effect.

Administrative Procedure Act

Several commenters argued that the OCC's actions violate the APA. First, commenters argued that the OCC is acting ''in excess of statutory jurisdiction, authority, or limitations,'' [51] because it lacks authority to issue the rule. As described in detail above, the OCC disagrees and concludes that it has the authority to issue this rule under sections 85 and 1463(g).

Second, several commenters argued that the OCC is acting ''without observance of procedure required by law''[52] in violation of the APA because it did not comply with the procedural requirements in section 25b. As explained above, the OCC concludes that these provisions do not apply.

Finally, commenters argued that the OCC's proposal is arbitrary and capricious, including because it did not provide evidence of the problem it seeks to remedy. The OCC disagrees. The APA's arbitrary and capricious standard requires an agency to make rational and informed decisions based on the information before it.[53] The primary problem the OCC seeks to address is the legal uncertainty resulting from the *Madden* decision, and the OCC has observed considerable evidence of this uncertainty.[54] The OCC understands that its rule may not resolve all legal uncertainty for every loan transfer, as at least one opposing commenter noted. However, resolving every potential uncertainty is not a prerequisite for the OCC to take this narrowly tailored action to address a discrete source of uncertainty.[55]

Relying on this clear evidence of current legal uncertainty, the OCC has made a rational and informed decision to issue this rule.

Furthermore, the OCC is not required to develop or adduce empirical or other data to support its conclusions about the importance of issuing this rule, nor must the OCC wait for the additional problems to materialize before taking action.[56] Instead, the OCC may rely on its supervisory expertise to anticipate and address the problems that may arise from *Madden* and the legal uncertainty it has created.[57] As described above, the OCC believes that its interpretation promotes safety and soundness and may facilitate responsible lending and efficient and effective bank operations.

Commenters also argued that the rule is arbitrary and capricious because it failed to consider the potential negative consequences that would, they argued, result from the rule, including the facilitation of predatory lending through ''rent-a-charter relationships.'' The OCC disagrees. The agency takes the risks created by predatory lending, including through third-party relationships, very seriously but, for the reasons discussed below, does not believe that that this rule will facilitate predatory lending through these relationships.

Predatory Lending

Some commenters argued that the proposal would facilitate predatory lending by promoting rent-a-charter relationships that allow nonbanks to evade state law and that it would reverse the OCC's historical opposition to these relationships. These commenters asserted that the proposal would undermine or eliminate state interest caps, a vital tool that states use to protect residents against predatory lending.

The OCC disagrees with these commenters' criticisms of this rulemaking. As made clear above, the OCC is issuing the rule to clarify its position with regard to the proper interpretation of sections 85 and 1463(g)(1), which relates to a core element of banks' ability to engage in safe and sound banking: The ability to transfer loans. However, the OCC also notes, as many commenters did, that the agency has consistently opposed predatory lending, including through relationships between banks and third parties. Nothing in this rulemaking in any way alters the OCC's strong position on this issue, nor does it rescind or amend any related OCC issuances.

The OCC also understands that appropriate third-party relationships play an important role in banks' operations and the economy, and the OCC has issued guidance on how banks can appropriately manage the risks associated with these relationships.[58]

Because commenters are concerned that the rule would undermine state interest caps, it is also important to emphasize that sections 85 and 1463(g) incorporate, rather than eliminate, these state caps. As noted above, these statutes require that a bank refer to, and comply with, the interest cap established by the laws of the state where the bank is located. Thus, disparities between the interest caps applicable to particular bank loans result primarily from differences in the state laws that impose these caps. This rule does not change that.

IV. Regulatory Text

The OCC proposed to amend 12 CFR 7.4001 and 12 CFR 160.110 by adding a new paragraph, which would provide that interest on a loan that is permissible under sections 85 and 1463(g)(1), respectively, shall not be affected by the sale, assignment, or other transfer of the loan. As the proposal explained, this rule would expressly codify what the OCC and the banking industry have always believed and address the legal confusion about the impact of a transfer on the permissible interest. The proposal also noted that this rule would not address which entity is the true lender when a bank transfers a loan to a third party.

The OCC received several comments on its proposed regulatory text. Commenters requested several clarifying changes, including recommendations to (1) specifically reference non-bank third

[51] 5 U.S.C. 706(2)(C).

[52] *Id.* at 706(2)(D).

[53] *Ass'n of Private Colls. & Univs.* v. *Duncan,* 870 F. Supp. 2d 133, 154 (D.D.C. 2012); *see Motor Vehicle Mfrs. Ass'n of U.S., Inc.* v. *State Farm Mut. Auto. Ins. Co.,* 463 U.S. 29, 52 (1983) (''The agency must explain the evidence which is available, and must offer a 'rational connection between the facts found and the choice made.''' (quoting *Burlington Truck Lines, Inc.* v. *United States,* 371 U.S. 156, 168 (1962))).

[54] For example, there are ongoing cases challenging the interest charged on securitized credit card receivables, with competing arguments regarding whether *Madden* applies in that circumstance. Similarly, the application of *Madden* to inter-bank loan transfers remains unresolved. Comments on the NPR from industry representatives also evidence the existence of legal uncertainty post-*Madden.*

[55] *See Taylor* v. *Fed. Aviation Admin.,* 895 F.3d 56, 68 (2018); *cf. Smiley,* 517 U.S. at 743 (stating ''that there was good reason for the Comptroller to promulgate the new regulation, in order to eliminate uncertainty and confusion'').

[56] *Stilwell* v. *Office of Thrift Supervision,* 569 F.3d 514, 519 (D.C. Cir. 2009) (''The APA imposes no general obligation on agencies to produce empirical evidence. . . . Moreover, agencies can, of course, adopt prophylactic rules to prevent potential problems before they arise. . . . OTS based its proposed rule on its long experience of supervising mutual savings associations; its view found support in various comments submitted in response to the proposed rule.''); *Chamber of Commerce of U.S.* v. *SEC,* 412 F.3d 133, 142 (D.C. Cir. 2005) (holding that the SEC did not have to conduct an empirical study in support of its rulemaking where it based its decision on ''its own and its staff's experience, the many comments received, and other evidence, in addition to the limited and conflicting empirical evidence'').

[57] *FCC* v. *WNCN Listeners Guild,* 450 U.S. 582, 595–96 (1981) (granting deference to the agency's ''forecast of the direction in which future public interest lies''); *U.S. Telecom Ass'n* v. *FCC,* 825 F.3d 674, 732 (D.C. Cir. 2016) (''[A]n agency's predictive judgments about areas that are within the agency's field of discretion and expertise are entitled to *particularly deferential* review, as long as they are reasonable.'' (emphasis in original) (quoting *EarthLink, Inc.* v. *FCC,* 462 F.3d 1, 12 (D.C. Cir. 2006)).

[58] *See* OCC Bulletin 2014–37, *Consumer Debt Sales: Risk Management Guidance* (Aug. 4, 2014); OCC Bulletin 2013–29, *Third-Party Relationships: Risk Management Guidance* (Oct. 30, 2013); OCC Bulletin 2020–10, *Third-Party Relationships: Frequently Asked Questions to Supplement OCC Bulletin 2013–29* (Mar. 5, 2020).

parties in the regulatory text; (2) ensure that the rule applies to transfers of partial interests in loans; and (3) clarify that the rule does not affect the applicability of other state law requirements, including licensing requirements. The OCC does not believe any changes to the regulatory text are necessary to address these recommendations because the OCC reads the regulatory text to be consistent with these recommendations.

In addition, a commenter requested that the OCC clarify that the rule applies to all price terms of a loan. The OCC's rule applies to ''interest,'' as that term is defined in 12 CFR 7.4001(a) and 12 CFR 160.110(a).

Several commenters also requested that the OCC address who is the true lender in its regulatory text. One commenter requested that the OCC specifically include regulatory text providing that the rule does not affect the determination of which entity is the true lender. The OCC reiterates that this rule does not address which entity is the true lender but does not believe it is necessary to specifically include a statement to this effect in the regulatory text. Another commenter requested that the OCC include a *proviso* providing that the rule only applies when the bank is the true lender, as determined by the law of the state where the borrower resides. Because the rule only applies to bank loans that are permissible under section 85 or 1463(g), the OCC does not believe that adding this *proviso* is necessary. Other commenters requested that the OCC establish a test for determining when the bank is the true lender. This would raise issues distinct from, and outside the scope of, this narrowly tailored rulemaking.

Finally, several commenters argued that the OCC and the FDIC should coordinate and harmonize their respective regulatory texts, which will help minimize any differences in court decisions.[59] The OCC's proposed regulatory text was narrowly tailored to address the specific legal uncertainty created by *Madden,* and the OCC believes this regulatory text best implements its interpretation of the statutory language in sections 85 and 1463(g)(1). Accordingly, the OCC adopts the rule as proposed. However, the OCC notes that it intends that its rule will function in the same way as the FDIC's proposed regulatory text would, which is consistent with interpreting sections 85 and 1831d *in pari materia.*[60]

V. Regulatory Analyses

Paperwork Reduction Act

In accordance with the requirements of the Paperwork Reduction Act of 1995 (PRA), 44 U.S.C. 3501 *et seq.,* the OCC may not conduct or sponsor, and respondents are not required to respond to, an information collection unless it displays a currently valid Office of Management and Budget (OMB) control number. The OCC has reviewed the final rule and determined that it would not introduce any new or revise any existing collection of information pursuant to the PRA. Therefore, no PRA submission will be made to OMB.

Regulatory Flexibility Act

The Regulatory Flexibility Act (RFA), 5 U.S.C. 601 *et seq.,* requires an agency, in connection with a final rule, to prepare a Final Regulatory Flexibility Analysis describing the impact of the rule on small entities (defined by the Small Business Administration (SBA) for purposes of the RFA to include commercial banks and savings institutions with total assets of $600 million or less and trust companies with total assets of $41.5 million or less) or to certify that the final rule would not have a significant economic impact on a substantial number of small entities. The OCC currently supervises approximately 745 small entities.[61] The ability to transfer a loan is important to all banks, so the OCC expects that all of these small entities would be impacted by this rule. However, the rule does not contain any new recordkeeping, reporting, or significant compliance requirements. Therefore, the OCC anticipates that costs, if any, will be *de minimis* and certifies that this rule will not have a significant economic impact on a substantial number of small entities. Accordingly, a Final Regulatory Flexibility Analysis is not required.

Unfunded Mandates Reform Act

Pursuant to the Unfunded Mandates Reform Act of 1995, 2 U.S.C. 1532, the OCC considers whether a final rule includes a Federal mandate that may result in the expenditure by State, local, and tribal governments, in the aggregate, or by the private sector, of $100 million or more in any one year (adjusted for inflation). The final rule does not impose new mandates. Therefore, the OCC concludes that implementation of the final rule would not result in an expenditure of $100 million (adjusted for inflation) or more annually by State, local, and tribal governments, or by the private sector.

Riegle Community Development and Regulatory Improvement Act

Pursuant to section 302(a) of the Riegle Community Development and Regulatory Improvement Act of 1994 (RCDRIA), 12 U.S.C. 4802(a), in determining the effective date and administrative compliance requirements for new regulations that impose additional reporting, disclosure, or other requirements on insured depository institutions, the OCC must consider, consistent with principles of safety and soundness and the public interest, any administrative burdens that such regulations would place on depository institutions, including small depository institutions, and customers of depository institutions, as well as the benefits of such regulations. In addition, section 302(b) of RCDRIA, 12 U.S.C. 4802(b), requires new regulations and amendments to regulations that impose additional reporting, disclosures, or other new requirements on insured depository institutions generally to take effect on the first day of a calendar quarter that begins on or after the date on which the regulations are published in final form. This rule imposes no additional reporting, disclosure, or other requirements on insured depository institutions, and therefore, neither section 302(a) or 302(b) is applicable to this rule.

Congressional Review Act

For purposes of Congressional Review Act (CRA), 5 U.S.C. 801 *et seq.,* the Office of Information and Regulatory Affairs (OIRA) of the OMB determines whether a final rule is a ''major rule,'' as that term is defined at 5 U.S.C. 804(2). OIRA has determined that this rule is not a ''major rule.''

[59] On December 6, 2019, the FDIC proposed a similar rule based on section 1831d. Federal Interest Rate Authority, 84 FR 66845.

[60] This discussion refers specifically to 12 CFR 331.4(e) of the FDIC's proposed rule, which would address the impact a loan transfer has on permissible interest. The FDIC's proposed regulatory text also would address additional subsequent events, including changes in state law and changes in the relevant commercial paper rate. Although the OCC's rule does not address these circumstances, the OCC believes that the result would generally be the same for loans made by OCC-regulated banks.

[61] The OCC bases its estimate of the number of small entities on the SBA's size thresholds for commercial banks and savings institutions, and trust companies, which are $600 million and $41.5 million, respectively. Consistent with the General Principles of Affiliation, 13 CFR 121.103(a), the OCC counts the assets of affiliated financial institutions when determining if the OCC should classify an OCC-supervised institution as a small entity. The OCC uses December 31, 2019, to determine size because a ''financial institution's assets are determined by averaging the assets reported on its four quarterly financial statements for the preceding year.'' *See* footnote 8 of the SBA's *Table of Size Standards.*

As required by the CRA, the OCC will submit the final rule and other appropriate reports to Congress and the Government Accountability Office for review.

Administrative Procedure Act

The APA, 5 U.S.C. 551 *et seq.,* generally requires that a final rule be published in the **Federal Register** not less than 30 days before its effective date. This final rule will be effective 60 days after publication in the **Federal Register**, which meets the APA's effective date requirement.

List of Subjects

12 CFR Part 7

National banks, Interest, Usury.

12 CFR Part 160

Savings associations, Interest, Usury.

Office of the Comptroller of the Currency

For the reasons set out in the preamble, the OCC amends 12 CFR parts 7 and 160 as follows.

PART 7—ACTIVITIES AND OPERATIONS

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

Authority: 12 U.S.C. 1 *et seq.,* 25b, 29, 71, 71a, 92, 92a, 93, 93a, 95(b)(1), 371, 371d, 481, 484, 1463, 1464, 1465, 1818, 1828(m) and 5412(b)(2)(B).

Subpart D—Preemption

■ 2. Section 7.4001 is amended by adding paragraph (e) to read as follows:

§ 7.4001 Charging interest by national banks at rates permitted competing institutions; charging interest to corporate borrowers.

* * * * *

(e) *Transferred loans.* Interest on a loan that is permissible under 12 U.S.C. 85 shall not be affected by the sale, assignment, or other transfer of the loan.

PART 160—LENDING AND INVESTMENT

■ 3. The authority citation for part 160 continues to read as follows:

Authority: 12 U.S.C. 1462a, 1463, 1464, 1467a, 1701j–3, 1828, 3803, 3806, 5412(b)(2)(B); 42 U.S.C. 4106.

■ 4. Section 160.110 is amended by adding paragraph (d) to read as follows:

§ 160.110 Most favored lender usury preemption for all savings associations.

* * * * *

(d) *Transferred loans.* Interest on a loan that is permissible under 12 U.S.C. 1463(g)(1) shall not be affected by the sale, assignment, or other transfer of the loan.

Brian P. Brooks,

Acting Comptroller of the Currency.

[FR Doc. 2020–11963 Filed 6–1–20; 8:45 am]

BILLING CODE 4810–33–P

DEPARTMENT OF TRANSPORTATION

Federal Aviation Administration

14 CFR Part 71

[Docket No. FAA–2020–0085; Airspace Docket No. 20–ASO–2]

RIN 2120–AA66

Amendment of Class D Airspace, Jacksonville NAS, FL; and, Amendment of Class D and Class E Airspace, Mayport, FL

AGENCY: Federal Aviation Administration (FAA), DOT.

ACTION: Final rule.

SUMMARY: This action amends Class D airspace for Jacksonville NAS, FL, by updating the name and geographical coordinates of Jacksonville NAS (Towers Field) (previously Jacksonville NAS) and Herlong Recreational Airport (previously Herlong Airport). This action would also amend Class D airspace and Class E airspace designated as an extension to Class D or E surface area by updating the name and geographic coordinates of Mayport Naval Station (ADM David L McDonald Field), (previously Mayport Naval Air Station), and the name and geographic coordinates of Jacksonville Executive Airport at Craig, (previously Craig Municipal Airport). Controlled airspace is necessary for the safety and management of instrument flight rules (IFR) operations in the area. This action also would make an editorial change replacing the term Airport/Facility Directory with the term Chart Supplement in the legal descriptions of associated Class D and E airspace.

DATES: Effective 0901 UTC, July 16, 2020. 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 7400.11D, Airspace Designations and Reporting Points, and subsequent amendments can be viewed on line 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 FAA Order 7400.11D at NARA, email *fedreg.legal@nara.gov* or go to *https://www.archives.gov/federal-register/cfr/ibr-locations.html.*

FOR FURTHER INFORMATION CONTACT: John Fornito, Operations Support Group, Eastern Service Center, Federal Aviation Administration, 1701 Columbia Avenue, College Park, GA 30337; telephone (404) 305–6364.

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 amends Class D and E airspace in Jacksonville NAS, FL, and Mayport, FL, to support IFR operations in the area.

History

The FAA published a notice of proposed rulemaking in the **Federal Register** (85 FR 8212, February 13, 2020) for Docket No. FAA–2020–0085, to amend Class D airspace for Jacksonville NAS, FL by updating the name and geographical coordinates of the airport, and the name of Herlong Recreational Airport. The FAA also proposed to update the geographic coordinates of Mayport NS (ADM David L McDonald Field), Mayport, FL, under Class D airspace and Class E surface airspace designated as an extension to a Class D surface area, as well as the name and geographic coordinates of Jacksonville Executive Airport at Craig. In addition, the FAA proposed to replace the outdated term Airport/Facility Directory with the term Chart Supplement in the associated Class D airspace and Class E surface airspace designated as an extension to a Class D surface area in the legal descriptions for

Mayport NS (ADM David L McDonald Field), Mayport, FL.

Interested parties were invited to participate in this rulemaking effort by submitting written comments on the proposal to the FAA. No comments were received.

Class D and Class E airspace designations are published in Paragraphs 5000 and 6004, respectively, of FAA Order 7400.11D, dated August 8, 2019, and effective September 15, 2019, which is incorporated by reference in 14 CFR part 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 7400.11D, Airspace Designations and Reporting Points, dated August 8, 2019, and effective September 15, 2019. FAA Order 7400.11D is publicly available as listed in the **ADDRESSES** section of this document. FAA Order 7400.11D lists Class A, B, C, D, and E airspace areas, air traffic service routes, and reporting points.

The Rule

The amendment to Title 14 Code of Federal Regulations (14 CFR) part 71 amends Class D airspace at Jacksonville NAS (Towers Field), Jacksonville NAS, FL, by updating the name and geographical coordinates of the airport, and the name of Herlong Recreational Airport. Also, the name and geographic coordinates of Mayport NS (ADM David L McDonald Field), Mayport, FL, are updated under Class D airspace and Class E surface airspace designated as an extension to a Class D surface area, as well as the name and geographic coordinates of Jacksonville Executive Airport at Craig to coincide with the FAA's aeronautical database. In addition, the FAA replaces the outdated term Airport/Facility Directory with the term Chart Supplement in the associated Class D airspace and Class E surface airspace designated as an extension to a Class D surface area in the legal descriptions for Mayport NS (ADM David L McDonald Field), Mayport, FL.

These changes are necessary for continued safety and management of IFR operations at these airports.

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

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. It, therefore: (1) Is not a ''significant regulatory action'' under Executive Order 12866; (2) is not a ''significant rule'' under DOT Regulatory Policies and Procedures (44 FR 11034; February 26, 1979); and (3) does not warrant preparation of a regulatory evaluation as the anticipated impact is so minimal. Since this is a routine matter that only affects air traffic procedures and air navigation, it is certified that this rule, when promulgated, does not have a significant economic impact on a substantial number of small entities under the criteria of the Regulatory Flexibility Act.

Environmental Review

The FAA has determined that this action qualifies for categorical exclusion under the National Environmental Policy Act in accordance with FAA Order 1050.1F, ''Environmental Impacts: Policies and Procedures,'' paragraph 5–6.5a. 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 7400.11D, Airspace Designations and Reporting Points, dated August 8, 2019, effective September 15, 2019, is amended as follows:

Paragraph 5000 Class D Airspace.

* * * * *

ASO FL D Jacksonville NAS, FL [Amended]

Jacksonville NAS (Towers Field), FL
(Lat. 30°14′01″ N, long. 81°40′34″ W)
Jacksonville TACAN
(Lat. 30°14′05″ N, long. 81°40′30″ W)
Herlong Recreational Airport, FL
(Lat. 30°16′40″ N, long. 81°48′21″ W)

That airspace extending upward from the surface of the Earth, to and including 2,600 feet MSL, within a 5.3-mile radius of Jacksonville NAS (Towers Field) and within 1 mile north and 2.5 miles south of the Jacksonville TACAN 270 radial, extending from the 5.3-mile radius to 6.5 miles west of the TACAN; excluding that airspace within a 1.8-mile radius of the Herlong Recreational Airport.

ASO FL D Mayport, FL [Amended]

Mayport NS (ADM David L McDonald Field), FL
(Lat. 30°23′29″ N, long. 81°25′28″ W)
Jax Executive Airport at Craig
(Lat. 30°20′11″ N, long. 81°30′52″ W)

That airspace extending upward from the surface to and including 2,500 feet MSL within a 4.2-mile radius of Mayport NS (ADM David L McDonald Field), excluding the portion southwest of a line connecting the two points of intersection with a 4.2-mile radius circle centered on Jacksonville Executive Airport at Craig. 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 6004 Class E Airspace Designated as an Extension to Class D or E Surface Area.

* * * * *

ASO FL E4 Mayport, FL [Amended]

Mayport NS (ADM David L McDonald Field), FL
(Lat. 30°23′29″ N, long. 81°25′28″ W)
Mayport (Navy) TACAN
(Lat. 30°23′19″ N, long. 81°25′23″ W)

That airspace extending upward from the surface within 3.2-miles each side of the Mayport (Navy) TACAN 035° radial extending from the 4.2-mile radius of Mayport NS (ADM David L McDonald Field) to 5 miles northeast of the TACAN. This Class E airspace is effective during the 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.

Issued in College Park, Georgia, on May 22, 2020.

Andreese C. Davis,

Manager, Airspace & Procedures Team South, Eastern Service Center, Air Traffic Organization.

[FR Doc. 2020–11522 Filed 6–1–20; 8:45 am]

BILLING CODE 4910–13–P

DEPARTMENT OF HEALTH AND HUMAN SERVICES

Food and Drug Administration

21 CFR Part 573

[Docket No. FDA–2019–F–3911]

Food Additives Permitted in Feed and Drinking Water of Animals; Silicon Dioxide

AGENCY: Food and Drug Administration, HHS.

ACTION: Final rule.

SUMMARY: The Food and Drug Administration (FDA, we, or the Agency) is amending the regulations for food additives permitted in feed and drinking water of animals to provide for the safe use of silicon dioxide as an anticaking agent, grinding aid, antifoaming agent, or carrier in animal feed components (ingredients, intermediate premixes, premixes, supplements, or concentrates). This action is in response to a food additive petition filed by Evonik Corp.

DATES: This rule is effective June 2, 2020. See section V of this document for further information on the filing of objections. Submit either electronic or written objections and requests for a hearing on the final rule by July 2, 2020.

ADDRESSES: You may submit objections and requests for a hearing as follows. Please note that late, untimely filed objections will not be considered. Electronic objections must be submitted on or before July 2, 2020. The *https://www.regulations.gov* electronic filing system will accept comments until 11:59 p.m. Eastern Time at the end of July 2, 2020. Objections received by mail/hand delivery/courier (for written/paper submissions) will be considered timely if they are postmarked or the delivery service acceptance receipt is on or before that date.

Electronic Submissions

Submit electronic objections in the following way:

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

Written/Paper Submissions

Submit written/paper submissions as follows:

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

Instructions: All submissions received must include the Docket No. FDA–2019–F–3911 for ''Food Additives Permitted in Feed and Drinking Water of Animals; Silicon Dioxide.'' Received objections, those filed in a timely manner (see **ADDRESSES**), will be placed in the docket and, except for those submitted as ''Confidential Submissions,'' publicly viewable at *https://www.regulations.gov* or at the Dockets Management Staff between 9 a.m. and 4 p.m., Monday through Friday.

- Confidential Submissions—To submit an objection with confidential information that you do not wish to be made publicly available, submit your objections only as a written/paper submission. You should submit two copies in 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 objections. 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 objections 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.govinfo.gov/content/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 objections 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: Chelsea Cerrito, Center for Veterinary Medicine, Food and Drug Administration, 7519 Standish Pl. (HFV–224), Rockville, MD 20855, 240–402–6729, *Chelsea.Cerrito@fda.hhs.gov.*

SUPPLEMENTARY INFORMATION:

I. Background

In a document published in the **Federal Register** of October 1, 2019 (84 FR 52055), FDA announced that we had filed a food additive petition (animal use) (FAP 2308) submitted by Evonik Corp., 1707 Barrett Lakes Blvd. NW, Suite 340, Kennesaw, GA 30144. The petition proposed that the regulations for food additives permitted in feed and drinking water of animals be amended to provide for the safe use of silicon dioxide as an anticaking agent, grinding aid, antifoaming agent, or carrier in animal feed components (ingredients, intermediate premixes, premixes, supplements, or concentrates). This amendment to the regulation approves the use of the food additive for these technical uses across food substances.

II. Conclusion

FDA concludes that the data establish the safety and utility of silicon dioxide as an anticaking agent, grinding aid, antifoaming agent, or carrier in animal feed components (ingredients, intermediate premixes, premixes, supplements, or concentrates) and that the food additive regulations should be amended as set forth in this document.

III. Public Disclosure

In accordance with § 571.1(h) (21 CFR 571.1(h)), the petition and documents we considered and relied upon in reaching our decision to approve the petition will be made available for public disclosure (see **FOR FURTHER**

INFORMATION CONTACT). As provided in § 571.1(h), we will delete from the documents any materials that are not available for public disclosure.

IV. Analysis of Environmental Impact

We have determined under 21 CFR 25.32(r) that this action is of a type that does not individually or cumulatively have a significant effect on the human environment. Therefore, neither an environmental assessment nor an environmental impact statement is required.

V. Objections and Hearing Requests

Any person who will be adversely affected by this regulation may file with the Dockets Management Staff (see **ADDRESSES**) either electronic or written objections. Each objection shall be separately numbered, and each numbered objection shall specify with particularity the provision of the regulation to which objection is made and the grounds for the objection. Each numbered objection on which a hearing is requested shall specifically so state. Failure to request a hearing for any particular objection shall constitute a waiver of the right to a hearing on that objection. Each numbered objection for which a hearing is requested shall include a detailed description and analysis of the specific factual information intended to be presented in support of the objection in the event that a hearing is held. Failure to include such a description and analysis for any particular objection shall constitute a waiver of the right to a hearing on the objection.

List of Subjects in 21 CFR Part 573

Animal feeds, Food additives.

Therefore, under the Federal Food, Drug, and Cosmetic Act and under authority delegated to the Commissioner of Food and Drugs, 21 CFR part 573 is amended as follows:

PART 573—FOOD ADDITIVES PERMITTED IN FEED AND DRINKING WATER OF ANIMALS

■ 1. The authority citation for part 573 continues to read as follows:

Authority: 21 U.S.C. 321, 342, 348.

■ 2. In § 573.940, revise paragraphs (b) through (e) to read as follows:

§ 573.940 Silicon dioxide.

* * * * *

(b) It is used or intended for use as an anticaking agent, antifoaming agent, carrier, and/or grinding aid in animal feed, including ingredients, intermediate premixes, premixes, supplements, concentrates, and complete feed.

(c) To ensure safe use of the additive, silicon dioxide is to be used in an amount not to exceed that reasonably required to accomplish its intended effect, and silicon dioxide from all sources cannot exceed 2 percent by weight of the complete feed.

(d) To ensure safe use of the additive, the label and labeling of the additive and ingredients, intermediate premixes, premixes, supplements, concentrates, and complete feed containing the additive shall meet the requirements of the Federal Food, Drug, and Cosmetic Act, including part 501 of this chapter.

(e) To ensure safe use of the additive, in addition to the other information required by the Federal Food, Drug, and Cosmetic Act, the label and labeling of the additive and ingredients, intermediate premixes, premixes, supplements, and concentrates containing the additive shall have:

(1) A statement of the concentration of the additive.

(2) A statement that silicon dioxide from all sources cannot exceed 2 percent by weight of the complete feed.

Dated: May 6, 2020.

Lowell J. Schiller,

Principal Associate Commissioner for Policy.

[FR Doc. 2020–10033 Filed 6–1–20; 8:45 am]

BILLING CODE 4164–01–P

DEPARTMENT OF THE TREASURY

Alcohol and Tobacco Tax and Trade Bureau

27 CFR Parts 18, 19, 24, 25, 26, 27, 28, 30, and 70

[Docket No. TTB–2016–0013; T.D. TTB–159; Re: T.D. TTB–146; Notice No. 167]

RIN 1513–AC30

Changes to Certain Alcohol-Related Regulations Governing Bond Requirements and Tax Return Filing Periods

AGENCY: Alcohol and Tobacco Tax and Trade Bureau, Treasury.

ACTION: Final rule; Treasury decision.

SUMMARY: The Alcohol and Tobacco Tax and Trade Bureau is adopting as final, with minor technical corrections, temporary regulations relating to excise taxes imposed on distilled spirits, wines, and beer that were published in the **Federal Register** on January 4, 2017. These regulatory amendments implement certain changes made to the Internal Revenue Code of 1986 (IRC) by the Protecting Americans from Tax Hikes Act of 2015, which amended the IRC to remove bond requirements and change tax return due dates for certain eligible excise taxpayers.

DATES: This final rule is effective June 2, 2020. As of June 2, 2020, the temporary regulations published in the **Federal Register** as T.D. TTB–146 at 82 FR 1108 on January 4, 2017, at 82 FR 1108, are adopted as final.

FOR FURTHER INFORMATION CONTACT: Karen A. Thornton, Regulations and Rulings Division, Alcohol and Tobacco Tax and Trade Bureau, 1310 G Street, NW, Box 12, Washington, DC 20005; telephone 202–453–2265, ext. 175.

SUPPLEMENTARY INFORMATION:

Background

TTB Authority

The Alcohol and Tobacco Tax and Trade Bureau (TTB) administers provisions in chapter 51 of the IRC pertaining to the taxation of distilled spirits, wines, and beer (see title 26 of the United States Code (U.S.C.), chapter 51 (26 U.S.C. chapter 51)). The IRC also contains provisions requiring certain persons who are liable for taxes imposed with respect to distilled spirits, wines, and beer to furnish bonds, which are formal guarantees to pay tax obligations under the IRC (see, *e.g.,* 26 U.S.C. 5173, 5354, and 5401(b)). TTB administers the provisions of the IRC, and their implementing regulations, pursuant to section 1111(d) of the Homeland Security Act of 2002, codified at 6 U.S.C. 531(d). The Secretary has delegated various authorities through Treasury Department Order 120–01, dated December 10, 2013 (superseding Treasury Department Order 120–01, dated January 24, 2003), to the TTB Administrator to perform the functions and duties in administration and enforcement of these provisions of law.

The PATH Act

On December 18, 2015, the President signed into law the Consolidated Appropriations Act, 2016 (Pub. L. 114–113). Division Q of this Act is titled the Protecting Americans from Tax Hikes Act of 2015 (PATH Act). Section 332 of the PATH Act amends the IRC to change tax return due dates and remove bond requirements for certain eligible taxpayers beginning January 1, 2017. These PATH Act amendments apply to certain taxpayers who reasonably expect to be liable for not more than $50,000 in taxes imposed with respect to distilled spirits, wines, and beer for the calendar year and who were not liable for more than $50,000 in such taxes in the preceding calendar year.

With respect to tax return dates, section 332 amends section 5061(d) of the IRC to authorize a new annual return period for deferred payment of tax, in addition to the preexisting semimonthly or quarterly periods for the deferred payment of taxes authorized under that section. ''Deferred payment'' refers to payment of tax by the proprietor of a distilled spirits plant, wine premises, or brewery after the product is removed from the facility, rather than payment immediately before or at the time the product is removed from the facility. To be eligible to use the new annual deferred payment period, the taxpayer must reasonably expect to be liable for not more than $1,000 in excise tax imposed with respect to distilled spirits, wines, and beer for the calendar year and must be liable for not more than $1,000 in such taxes in the preceding calendar year. To be eligible to use quarterly deferred payment periods, the taxpayer must reasonably expect to be liable for not more than $50,000 in such taxes imposed for the calendar year and must be liable for not more than $50,000 in such taxes in the preceding calendar year.

Section 332 of the PATH Act also amends several provisions of the IRC to remove bond requirements for certain eligible taxpayers. To be exempt from bond requirements, taxpayers must be eligible to use quarterly or annual return periods and must pay such taxes on a deferred basis. Even if taxpayers choose to pay taxes semimonthly, they still qualify for the bond exemption if they meet the criteria to pay taxes quarterly or annually. In addition, taxpayers are exempt from bond requirements with respect to distilled spirits and wine only to the extent those products are for nonindustrial use.

For a more detailed discussion of the provisions of section 332 of the PATH Act, see T.D. TTB–146.

Publication of Temporary Regulations and Notice of Proposed Rulemaking

On January 4, 2017, TTB published in the **Federal Register** at 82 FR 1108, T.D. TTB–146, amending the regulations in parts 18, 19, 24, 25, 26, 27, 28, and 30. The temporary rule was effective January 4, 2017, and would have expired on January 4, 2020, if not finalized prior to that date. The temporary rule amended the regulations in 27 CFR parts 19, 24, 25, and 26 to incorporate the new annual tax return period provisions for eligible taxpayers, and it also amended parts 19, 24, 25, 26, and 28 to remove the bond requirements for taxpayers who are eligible for the bond exemption. In conjunction with removing bond requirements, TTB made other amendments to implement the bond exemption, including new procedures for eligible proprietors to terminate existing bonds and identify themselves as eligible for the bond exemption.

In addition, the temporary rule included amendments to parts 19, 24, 25, 26, and 28 to conform other regulatory language to the new tax return periods and bond exemptions, to remove provisions made obsolete by the provisions of section 332 of the PATH Act, to make technical corrections, and to update the information that the regulations prescribe for forms relating to tax payments and bonds.

For a detailed discussion of the specific amendments included in the temporary final rule, see T.D. TTB–146.

TTB solicited comments on the amendments adopted in the temporary rule through a notice of proposed rulemaking published in the **Federal Register** (Notice No. 167, 82 FR 780). TTB did not receive comments on the temporary regulations. Accordingly, TTB is adopting the regulations in the temporary rule as final. In conjunction with finalizing the regulations, TTB is making technical amendments and corrections to these regulations as discussed later in this document.

Notice of Proposed Rulemaking Pertaining to Reporting Requirements

In Notice No. 167, TTB also proposed to amend the regulations governing reporting requirements for distilled spirits plants (DSPs) and brewers generally to align the frequency of submitting reports with the new tax filing periods. That is, an industry member who was eligible to pay tax annually or quarterly and did so, would also file reports either annually or quarterly, as applicable. This new requirement was intended to reduce regulatory burden. TTB also solicited comments on whether to make any amendments to current reporting requirements for bonded wine cellars (including bonded wineries), although current regulations for bonded wine cellars include reduced reporting requirements for certain proprietors who pay taxes using annual or quarterly return periods. TTB sought comment in Notice No. 167 on these new reporting requirements for proprietors who pay taxes less frequently under Section 332 of the PATH Act, but the PATH Act amendments did not require any changes to TTB's reporting regulations for DSPs, bonded wine cellars, or brewers.

TTB did not receive comments in response to Notice No. 167 regarding the proposed reporting requirements for DSPs and brewers or regarding whether it should amend current reporting requirements for bonded wine cellars. Because no changes to TTB's reporting regulations are required under the PATH Act amendments, TTB has decided not to move forward with new reporting regulations in this final rule, even those that might require less frequent reporting, but also less flexibility in instances in which an industry member may not want to change its reporting frequency. Instead, TTB is reviewing its current reporting requirements to identify any reductions it can make in the information collected and the frequency in reporting, and intends to address such changes in the future.

Miscellaneous Technical Amendments and Corrections

In addition to the temporary regulations TTB is adopting through this final rule, TTB is also making several technical amendments and corrections, as follows:

- In §§ 26.200(e), 26.300, 27.48(b), 27.171(b) and (c), and the heading of subpart L of part 27, TTB is removing or modifying certain references to bonds to clarify that the regulations apply to facilities that are required to have a bond, as well as to facilities that are exempt from bond requirements under section 332 of the PATH Act. See section 5551(d)(2) of the IRC, which provides that taxpayers exempt from bond requirements under section 5551(d)(1) ''shall be treated as if sufficient bond has been furnished for purposes of covering operation and withdrawals of distilled spirits or wines for nonindustrial use or of beer for purposes of any requirements relating to bonds under [chapter 51 of the IRC].'' These conforming amendments were inadvertently omitted from the temporary final rule (T.D. TTB–146).
- The last two sentences of paragraph (k) of § 24.109 are redesignated as a new paragraph (m) in order to clarify that all applicants shall furnish additional information upon request by the appropriate TTB officer and shall notify the appropriate TTB officer if any submitted information changes during the pending application. The addition of a new paragraph (l) to this section by T.D. TTB–146 had the unintended effect of making it appear as though the requirements in paragraph (k) to respond to requests for additional information and to inform TTB of information changes only applied to applicants who conduct other operations not specifically authorized by 27 CFR part 24 on wine premises.

• TTB is removing references to ''the bonded premises of a distilled spirits plant'' in § 27.171(b) and (c) that were added due to an inadvertent error in an amendatory instruction of T.D. TTB–146, and is replacing those references with the words ''cellar'' and ''brewery,'' respectively.

• TTB is amending several regulations in 27 CFR part 70 to reflect current requirements pertaining to tax returns and bond requirements. In 27 CFR 70.411(c)(26), TTB is replacing the words ''internal revenue bond'' with the words ''distilled spirits plants'' because the term ''distilled spirits plant'' refers to those plants that are required to have a bond, as well as those that are exempt from bond requirements under section 332 of the PATH Act. This change is in a cross-reference to part 26, and is intended to accurately describe the regulations in part 26. TTB is also amending 27 CFR 70.412(a) to add references to annual return periods. Finally, TTB is removing the word ''bonded'' from 27 CFR 70.414(b) to reflect the fact that 27 CFR part 20 does not currently require dealers and users of specially denatured spirits to hold bonds.

Regulatory Analyses and Notices

Regulatory Flexibility Act

In accordance with the Regulatory Flexibility Act (5 U.S.C. 601 *et seq.*), TTB certifies that this final rule will not have a significant economic impact on a substantial number of small entities. The final rule will not impose, or otherwise cause, a significant increase in reporting, recordkeeping, or other compliance burdens on a substantial number of small entities. The final rule implements certain changes made to the Internal Revenue Code of 1986 by the Protecting Americans from Tax Hikes Act of 2015 (see Pub. L. 114–113, Division Q, section 332). These statutory changes eliminate bond requirements and reduce tax return filing frequency for certain eligible taxpayers. The regulatory amendments provide for taxpayers to use TTB's existing qualification procedures to establish that they are exempt from bond requirements, and any minor increased burden associated with conveying to TTB an industry member's eligibility for the exemption flows directly from the statutory changes that prescribe the criteria for eligibility for the exemption. Pursuant to section 7805(f) of the IRC (26 U.S.C. 7805(f)), TTB submitted the temporary regulations to the Chief Counsel for Advocacy of the Small Business Administration for comment on the impact of the temporary regulations on small businesses; TTB received no comment in reply.

Executive Order 12866

This regulation is not subject to review under section 6(b) of Executive Order 12866 pursuant to the Memorandum of Agreement (April 11, 2018) between the Department of the Treasury and the Office of Management and Budget regarding review of tax regulations.

Paperwork Reduction Act

Regulations addressed in this final rule contain current collections of information that have been previously reviewed and approved by the Office of Management and Budget (OMB) in accordance with the Paperwork Reduction Act of 1995 (PRA) (44 U.S.C. 3507). 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 OMB.

The collections of information associated with the regulations adopted in T.D. TTB–146 are assigned control numbers 1513–0005, 1513–0009, 1513–0015, 1513–0031, 1513–0037, 1513–0038, 1513–0048, 1513–0050, 1513–0083, 1513–0123, 1513–0125, and 1513–0135. Revisions to these collections and their connections to the regulatory amendments in T.D. TTB–146 are described in detail in that document, which also solicited comment regarding the revisions. TTB received no comments on the revisions. In cases where TTB revised the collections, these revisions were submitted to and approved by OMB.

Inapplicability of Prior Notice and Public Comment and Delayed Effective Date Procedures

TTB is finalizing the temporary regulations set forth in T.D TTB–146 in this final rule without a delayed effective date, pursuant to the provisions of 5 U.S.C. 553(d)(1) and (d)(3). As provided for in section 553(d)(1), the temporary regulations being finalized in this final rule recognize a statutory exemption from bond requirements and authorize a new voluntary annual tax return period. TTB has also determined that good cause exists under section 553(d)(3) to provide industry members with guidance on procedures to apply for and obtain the bond exemption authorized under provisions of a law that are already in effect.

The technical corrections in this final rule address typographical errors, and are meant to clarify the uniformity of the regulations, rather than change the Bureau's interpretation. Therefore, TTB has determined that no notice of proposed rulemaking and public comment period are required under section 553(b) for the technical corrections set out in this final rule. For these same reasons, TTB has determined that the technical corrections in this final rule are exempt from the delayed effective date procedure under section 553(d)(3).

Drafting Information

Karen A. Thornton of the Regulations and Rulings Division drafted this document with the assistance of other Alcohol and Tobacco Tax and Trade Bureau personnel.

List of Subjects

27 CFR Part 18

Alcohol and alcoholic beverages, Fruits, Reporting and recordkeeping requirements, Spices and flavorings.

27 CFR Part 19

Administrative practice and procedure, Alcohol and alcoholic beverages, Authority delegations (Government agencies), Caribbean Basin initiative, Chemicals, Claims, Customs duties and inspection, Electronic funds transfers, Excise taxes, Exports, Gasohol, Imports, Labeling, Liquors, Packaging and containers, Puerto Rico, Reporting and recordkeeping requirements, Research, Security measures, Spices and flavorings, Stills, Surety bonds, Transportation, Vinegar, Virgin Islands, Warehouses, Wine.

27 CFR Part 24

Administrative practice and procedure, Claims, Electronic funds transfers, Excise taxes, Exports, Food additives, Fruit juices, Labeling, Liquors, Packaging and containers, Reporting and recordkeeping requirements, Research, Scientific equipment, Spices and flavorings, Surety bonds, Vinegar, Warehouses, Wine.

27 CFR Part 25

Beer, Claims, Electronic funds transfers, Excise taxes, Exports, Labeling, Packaging and containers, Reporting and recordkeeping requirements, Research, Surety bonds.

27 CFR Part 26

Alcohol and alcoholic beverages, Caribbean Basin initiative, Claims, Customs duties and inspection, Electronic funds transfers, Excise taxes, Packaging and containers, Puerto Rico, Reporting and recordkeeping requirements, Surety bonds, Virgin Islands, Warehouses.

27 CFR Part 27

Alcohol and alcoholic beverages, Beer, Cosmetics, Customs duties and inspection, Electronic funds transfers, Excise taxes, Imports, Labeling, Liquors, Packaging and containers, Reporting and recordkeeping requirements, Wine.

27 CFR Part 28

Aircraft, Alcohol and alcoholic beverages, Armed forces, Beer, Claims, Excise taxes, Exports, Foreign trade zones, Labeling, Liquors, Packaging and containers, Reporting and recordkeeping requirements, Surety bonds, Vessels, Warehouses, Wine.

27 CFR Part 30

Liquors, Scientific equipment.

27 CFR Part 70

Administrative practice and procedure, Claims, Excise taxes, Freedom of information, Law enforcement, Penalties, Reporting and recordkeeping requirements, Surety bonds.

Amendments to the Regulations

The temporary rule that amended 27 CFR parts 18, 19, 24, 25, 26, 27, 28, and 30, and published as T.D. TTB–146 at 82 FR 1108, January 4, 2017, is adopted as a final rule without change.

Further, as discussed in the preamble, TTB is making technical amendments and corrections to 27 CFR, chapter I, parts 24, 26, 27, and 70, as set forth below.

PART 24—WINE

■ 1. The authority citation for part 24 continues to read as follows:

Authority: 5 U.S.C. 552(a); 26 U.S.C. 5001, 5008, 5041, 5042, 5044, 5061, 5062, 5121, 5122–5124, 5173, 5206, 5214, 5215, 5351, 5353, 5354, 5356, 5357, 5361, 5362, 5364–5373, 5381–5388, 5391, 5392, 5511, 5551, 5552, 5661, 5662, 5684, 6065, 6091, 6109, 6301, 6302, 6311, 6651, 6676, 7302, 7342, 7502, 7503, 7606, 7805, 7851; 31 U.S.C. 9301, 9303, 9304, 9306.

■ 2. Section 24.109 is amended:
■ a. By removing the last two sentences of paragraph (k);
■ b. By removing the period at the end of paragraph (l) and adding in its place ''; and'';
■ c. By adding paragraph (m); and
■ d. By revising the Office of Management and Budget control number reference at the end of the section.

The addition and revision read as follows:

§ 24.109 Data for application.

* * * * *

(m) The applicant shall, when required by the appropriate TTB officer, furnish as part of the application, additional information as may be necessary to determine whether the application should be approved. If any of the submitted information changes during the pending application, the applicant shall immediately notify the appropriate TTB officer of the revised information.

(Approved by the Office of Management and Budget under control number 1513–0009)

PART 26—LIQUORS AND ARTICLES FROM PUERTO RICO AND THE VIRGIN ISLANDS

■ 3. The authority citation for part 26 continues to read as follows:

Authority: 19 U.S.C. 81c; 26 U.S.C. 5001, 5007, 5008, 5010, 5041, 5051, 5061, 5111–5114, 5121, 5122–5124, 5131–5132, 5207, 5232, 5271, 5275, 5301, 5314, 5555, 6001, 6109, 6301, 6302, 6804, 7101, 7102, 7651, 7652, 7805; 27 U.S.C. 203, 205; 31 U.S.C. 9301, 9303, 9304, 9306.

§ 26.200 [Amended]

■ 4. Section 26.200 is amended in paragraph (e) by removing the words ''from internal revenue bonded premises'' and adding in their place the words ''from, respectively, a distilled spirits plant, bonded wine cellar, or brewery''.

§ 26.300 [Amended]

■ 5. Section 26.300 is amended:
■ a. In paragraph (a), by removing the words ''internal revenue bond'' and adding in their place the words ''a distilled spirits plant'';
■ b. In paragraph (b), by removing the words ''cellar's internal revenue bond'' and adding in their place the word ''cellar'';
■ c. In paragraph (c), by removing the word ''bonded'' each place it appears; and
■ d. In paragraph (c), by removing the words ''brewery's internal revenue bond'' and adding in their place the word ''brewery''.

PART 27—IMPORTATION OF DISTILLED SPIRITS, WINES, AND BEER

■ 6. The authority citation for part 27 continues to read as follows:

Authority: 5 U.S.C. 552(a), 19 U.S.C. 81c, 1202; 26 U.S.C. 5001, 5007, 5008, 5010, 5041, 5051, 5054, 5061, 5121, 5122–5124, 5201, 5205, 5207, 5232, 5273, 5301, 5313, 5555, 6109, 6302, 7805.

■ 7. Section 27.48 is amended by revising the paragraph (b) subject heading to read as follows:

§ 27.48 Imported distilled spirits, wines, and beer.

* * * * *

(b) *Distilled spirits, natural wines, and beer transferred without payment of tax to distilled spirits plants, bonded wine cellars, and breweries.* * * *

* * * * *

Subpart L—Transfer of Distilled Spirits, Natural Wines, and Beer Without Payment of Tax, From Customs Custody to Distilled Spirits Plants, Bonded Wine Cellars, and Breweries

■ 8. The heading of subpart L is revised to read as set forth above.

§ 27.171 [Amended]

■ 9. Section 27.171 is amended:
■ a. In paragraph (b), by removing the words ''cellar's the bonded premises of a distilled spirits plant'' and adding in their place the word ''cellar'';
■ b. In paragraph (c), by removing the words ''brewery's the bonded premises of a distilled spirits plant'' and adding in their place the word ''brewery'';
■ c. In paragraph (c), by removing the word ''bonded'' in every other place it appears; and
■ d. In paragraph (c), by removing the phrase ''by the proprietor of'' and adding in its place the phrase ''by the proprietor of a''.

PART 70—PROCEDURE AND ADMINISTRATION

■ 10. The authority citation for part 70 continues to read as follows:

Authority: 5 U.S.C. 301 and 552; 26 U.S.C. 4181, 4182, 5123, 5203, 5207, 5275, 5367, 5415, 5504, 5555, 5684(a), 5741, 5761(b), 5802, 6020, 6021, 6064, 6102, 6155, 6159, 6201, 6203, 6204, 6301, 6303, 6311, 6313, 6314, 6321, 6323, 6325, 6326, 6331–6343, 6401–6404, 6407, 6416, 6423, 6501–6503, 6511, 6513, 6514, 6532, 6601, 6602, 6611, 6621, 6622, 6651, 6653, 6656–6658, 6665, 6671, 6672, 6701, 6723, 6801, 6862, 6863, 6901, 7011, 7101, 7102, 7121, 7122, 7207, 7209, 7214, 7304, 7401, 7403, 7406, 7423, 7424, 7425, 7426, 7429, 7430, 7432, 7502, 7503, 7505, 7506, 7513, 7601–7606, 7608–7610, 7622, 7623, 7653, 7805.

§ 70.411 [Amended]

■ 11. Section 70.411 is amended in paragraph (c)(26) by removing the words ''internal revenue bond'' and adding in their place the words ''distilled spirits plants''.

■ 12. In § 70.412, the second sentence of paragraph (a) is revised to read as follows:

§ 70.412 Excise taxes.

(a) * * * Depending on the circumstances, the person responsible

for paying the taxes may be eligible to file semimonthly, quarterly, or annual returns, with proper remittances, to cover the taxes incurred on distilled spirits, wines, and beer during the semimonthly, quarterly, or annual period. * * *

* * * * *

§ 70.414 [Amended]

■ 13. Section 70.414 is amended in paragraph (b) by removing the word ''bonded''.

Signed: December 13, 2019.

Mary G. Ryan,

Acting Administrator.

Approved: May 7, 2020.

Timothy E. Skud,

Deputy Assistant Secretary (Tax, Trade and Tariff Policy).

[FR Doc. 2020–10709 Filed 6–1–20; 8:45 am]

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DEPARTMENT OF HOMELAND SECURITY

Coast Guard

33 CFR Part 100

[Docket Number USCG–2019–0691]

RIN 1625–AA08

Special Local Regulations; Recurring Marine Events, Sector Charleston

AGENCY: Coast Guard, DHS.

ACTION: Final rule.

SUMMARY: The Coast Guard is revising existing regulations and consolidating into one table the special local regulations for recurring marine events at various locations within the geographic boundaries of the Seventh Coast Guard District Captain of the Port (COTP) Charleston Zone. Consolidating marine events into one table simplifies Coast Guard oversight and public notification of special local regulations within COTP Charleston Zone.

DATES: This rule is effective July 2, 2020.

ADDRESSES: To view documents mentioned in this preamble as being available in the docket, go to *http://www.regulations.gov,* type USCG–2019–0691 in the ''SEACH'' box and click ''SEARCH''. Click on Open Docket Folder on the line associated with this rule.

FOR FURTHER INFORMATION CONTACT: If you have questions on this rule, call or email LT Chad Ray, Sector Charleston Waterways Management Division, U.S. Coast Guard; telephone 843–740–3184, email *Chad.L.Ray@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

Recurring race, swim, and other marine events within the Seventh Coast Guard District are currently listed in 33 CFR 100.701, Table 1 to § 100.701. The process for amending the table (*e.g.* adding or removing marine events) is lengthy and inefficient since it includes recurring marine events for seven different COTP zones within the Seventh District. To expedite and simplify the rulemaking process for new marine events/special local regulations, COTP's resorted to creating individual rules rather than amending the Table 1 to § 100.701.

This rule serves two purposes: (1) Create a table of recurring marine events/special local regulations occurring solely within the COTP Charleston Zone, and (2) consolidate into that table marine events/special local regulations previously established outside of Table 1 to § 100.701. The new table facilitates management of and public access to information about marine events within the COTP Charleston Zone.

The Coast Guard published a notice of proposed rulemaking (NPRM) titled ''Special Local Regulations; Recurring Marine Events, Sector Charleston'' (85 FR 5177). There we stated why we issued the NPRM, and invited comments on our proposed regulatory action. During the comment period that ended February 28, 2020, we received no comments.

III. Legal Authority and Need for Rule

The Coast Guard is issuing this rule under authority in 46 U.S.C. 70034 (previously 33 U.S.C. 1231). This rule makes the following changes:

1. Revise the contact information in § 100.701(d)(1) to read ''Captain of the Port Charleston, South Carolina: (843) 740–7050.'';
2. Delete the existing special local regulation for the ''Head of South'' event listed in existing Table 1 to § 100.701(f)(5) because it is no longer held;
3. Establish § 100.704 for Special Local Regulations; Marine Events Within COTP Zone Charleston;
4. Move the remaining list of existing marine events/special local regulations listed in Table 1 to § 100.701(f) under COTP Zone Charleston; Special Local Regulations to new § 100.704, Table 1 to § 100.704;
5. Add new event, ''Cooper River Bridge Run'' to new Table 1 to § 100.704, Line 1;
6. Add new event, ''Myrtle Beach Triathlon'' to new Table 1 § 100.704, Line 3;
7. Add new event, ''North Charleston Fireworks'' to new Table 1 § 100.704, Line 5;
8. Add new event, ''Patriots Point Fireworks'' to new Table 1 § 100.704, Line 6;
9. Add new event, ''Beaufort Water Festival Air Show'' to new Table 1 § 100.704, Line 8;
10. Revise the dates for the existing event, ''Charleston Race Week'' listed in new § 100.704, Line 2 to one week (Monday through Sunday) in April;
11. Revise the dates for the existing event, ''Low Country Splash'' listed in new Table 1 to § 100.704, Line 4 to one Saturday or Sunday during the last two weeks of May or the first two weeks of June;
12. Revise the dates for the existing event, ''Beaufort Water Festival'' listed in new Table 1 to § 100.704, Line 7 to ten consecutive days (Friday through Sunday) in July;
13. Revise the dates for the existing event, ''Swim Around Charleston'' listed in new Table 1 to § 100.704, Line 9 to one weekend day (Saturday or Sunday) during the last two weeks of September through the first two weeks of October;
14. Revise the dates for the existing event, ''Charleston Parade of Boats'' in new Table 1 to to § 100.704, Line 10 to one weekend day (Friday, Saturday, or Sunday) in December; and
15. Delete existing § 100.713, which contains a special local regulation for the Annual Harborwalk Boat Race; Sampit River, Georgetown, SC because it is no longer held.

The marine events listed in the new Table 1 to § 100.704 are scheduled to occur over a particular weekend and month each year. Exact dates are intentionally omitted since calendar dates for a specific weekend change from year to year. Once dates for a marine event are known, the Coast Guard will notify the public of its intent to enforce the special local regulation through various means including a Notice of Enforcement published in the **Federal Register**, Local Notice to Mariners, and Broadcast Notice to Mariners.

IV. Discussion of Comments, Changes, and the Rule

As noted above, we received no comments on our NPRM published January 29, 2020. There are no changes in the regulatory text of this rule from the proposed rule in the NPRM.

This rule revises existing regulations and consolidates the special local regulations into one table for recurring marine events at various locations within the geographic boundaries of the Seventh Coast Guard District Captain of the Port (COTP) Charleston Zone.

V. Regulatory Analyses

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

A. Regulatory Planning and Review

Executive Orders 12866 and 13563 direct agencies to assess the costs and benefits of available regulatory alternatives and, if regulation is necessary, to select regulatory approaches that maximize net benefits. Executive Order 13771 directs agencies to control regulatory costs through a budgeting process. This rule has not been designated a ''significant regulatory action,'' under Executive Order 12866. Accordingly, the rule has not been reviewed by the Office of Management and Budget (OMB), and pursuant to OMB guidance it is exempt from the requirements of Executive Order 13771.

This regulatory action determination is based on the size, location, and duration of the special local regulations. These areas are limited in size and duration, and usually do not affect high vessel traffic areas. Moreover, the Coast Guard would provide advance notice of the regulated areas to the local maritime community Local Notice to Mariners, Broadcast to Mariners via VHF–FM marine channel 16, and the rule would allow vessels to seek permission to enter the regulated area.

B. Impact on Small Entities

The Regulatory Flexibility Act of 1980, 5 U.S.C. 601–612, as amended, requires Federal agencies to consider the potential impact of regulations on small entities during rulemaking. The term ''small entities'' comprises small businesses, not-for-profit organizations that are independently owned and operated and are not dominant in their fields, and governmental jurisdictions with populations of less than 50,000. The Coast Guard received no comments from the Small Business Administration on this rulemaking. The Coast Guard certifies under 5 U.S.C. 605(b) that this rule will not have a significant economic impact on a substantial number of small entities.

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

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

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

C. Collection of Information

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

D. Federalism and Indian Tribal Governments

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

Also, this rule does not have tribal implications under Executive Order 13175, Consultation and Coordination with Indian Tribal Governments, because it 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.

E. Unfunded Mandates Reform Act

The Unfunded Mandates Reform Act of 1995 (2 U.S.C. 1531–1538) requires Federal agencies to assess the effects of their discretionary regulatory actions. In particular, the Act addresses actions that may result in the expenditure by a State, local, or tribal government, in the aggregate, or by the private sector of $100,000,000 (adjusted for inflation) or more in any one year. Though this rule 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 rule under Department of Homeland Security Directive 023–01, Rev. 1, associated implementing instructions, and Environmental Planning COMDTINST 5090.1 (series), which guide the Coast Guard in complying with the National Environmental Policy Act of 1969 (42 U.S.C. 4321–4370f), and have 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 rule involves the establishment of special local regulations for recurring marine events within the COTP Charleston Zone. Normally such actions are categorically excluded from further review under paragraphs L61 of Appendix A, Table 1 of DHS Instruction Manual 023–01–001–01, Rev. 1. A preliminary Record of Environmental Consideration supporting this determination is available in the docket. For instructions on locating the docket, see the **ADDRESSES** section of this preamble.

G. Protest Activities

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

List of Subjects in 33 CFR Part 100

Harbors, Marine Safety, Navigation (water), Reporting and Record keeping requirements, Security measures, Waterways.

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

PART 100—SAFETY OF LIFE ON NAVIGABLE WATERS

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

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

■ 2. In § 100.701:
■ a. Revise paragraph (d)(1); and
■ b. Remove section (e) from table 1 to the section.

The revision reads as follows:

§ 100.701 Special Local Regulations; Marine Events in the Seventh Coast Guard District.

* * * * *

(d) * * *

(1) Captain of the Port Charleston, South Carolina: (843) 740–7050.

* * * * *

■ 3. Add § 100.704 to read as follows:

§ 100.704 Special Local Regulations; Marine Events within the Captain of the Port Charleston.

The regulations in this section apply to the marine events listed in Table 1 of this section. The regulations in this section will be effective annually for the duration listed in Table 1 of this section. The Coast Guard will notify the maritime community of exact dates and times each regulation will be in effect and the nature of each event (*e.g.* location, number of participants, type of vessels involved, etc.) through a Notice of Enforcement published in the **Federal Register**, Local Notice to Mariners, and Broadcast Notice to Mariners.

(a) *Definitions.* The following definitions apply to this section:

(1) *Designated representative.* The term ''designated representative'' means Coast Guard Patrol Commanders, including Coast Guard coxswains, petty officers, others operating Coast Guard vessels, and Federal, state, and local officers designated by or assisting the Captain of the Port (COTP) Charleston in the enforcement of the regulated areas.

(2) *Spectators.* All persons and vessels not registered with the event sponsor as participants.

(b) *Event patrol.* The Coast Guard may assign an event patrol, as described in § 100.40, to each regulated event listed in Table 1 of this section. Additionally, a Patrol Commander may be assigned to oversee the patrol. The event patrol and Patrol Commander may be contacted on VHF Channel 16.

(c) *Special local regulations.* (1) The COTP Charleston or designated representative may control the movement of all vessels in the regulated area. When hailed or signaled by an official patrol vessel, a vessel in these areas shall immediately comply with the directions given. Failure to do so may result in removal from the area, citation for failure to comply, or both.

(2) The COTP Charleston or designated representative may terminate the event, or the operation of any vessel participating in the event, at any time it is deemed necessary for the protection of life or property.

(3) Only event sponsor designated participants and official patrol vessels are allowed to enter the regulated area, unless otherwise authorized by the COTP Charleston or designated representative.

(4) Spectators may request permission from the COTP Charleston or designated representative to enter, transit, remain within, or anchor in the regulated area. If permission is granted, spectators must abide by the directions of the COTP Charleston or a designated representative.

(d) *Event delays or termination.* The COTP Charleston or designated representative may delay or terminate any event in this section at any time to ensure safety of life or property. Such action may be justified as a result of weather, traffic density, spectator operation, or participant behavior.

TABLE 1 TO § 100.704—SPECIAL LOCAL REGULATIONS; MARINE EVENTS WITHIN THE CAPTAIN OF THE PORT CHARLESTON

[Datum NAD 1983]

Date/time	Event/sponsor	Location	Regulated area
1. The First Saturday in April:			
Time (Approximate): 7 a.m. to 10 a.m.	Cooper River Bridge Run .. Sponsor: The Cooper River Bridge Run Executive Committee.	Charleston, SC and Mt. Pleasant, SC.	Location: The following is a safety or security zone. All waters of the Cooper River, and Town Creek Reaches encompassed within the following points: Beginning at 32°48′32″ N, 079°56′08″ W, thence east to 32°48′20″ N, 079°54′20″ W, thence south to 32°47′20″ N, 079°54′29″ W, thence west to 32°47′20″ N, 079°55′28″ W, thence north to origin.
2. One week (Monday through Sunday) in April:			
Time (Approximate): 8 a.m. to 5 p.m. each day.	Charleston Race Week ..... Sponsor: Charleston Race Week LLC.	Charleston, SC	Location: There are five race areas: (i) Race Area #1. All waters of the Charleston Harbor encompassed within a 700 yard radius of position 32°46′10″ N, 079°55′15″ W. (ii) Race Area #2. All waters of the Charleston Harbor encompassed within a 700 yard radius of position 32°46′02″ N, 079°54′15″ W. (iii) Race Area #3. All waters of the Charleston Harbor encompassed within a 700 yard radius of position 32°45′55″ N, 079°53′39″ W. (iv) Race Area #4. All waters of the Charleston Harbor encompassed within a 600 yard radius of position 32°47′40″ N, 079°55′10″ W. (v) Race Area #5. All waters of the Charleston Harbor and Entrance Channel encompassed within a 500 yard radius of position 32°45′34″ N, 79°52′09″ W continuing to Charleston Entrance Channel Buoys Green 11 (LLN 2395.5) and Red 12 (LLN 2400).
3. One Saturday or Sunday in April:			

TABLE 1 TO § 100.704—SPECIAL LOCAL REGULATIONS; MARINE EVENTS WITHIN THE CAPTAIN OF THE PORT CHARLESTON—Continued

[Datum NAD 1983]

Date/time	Event/sponsor	Location	Regulated area
Time (Approximate): 7:30 a.m. to 9:30 a.m.	Myrtle Beach Triathlon ..... Sponsor: GO Race Productions.	Myrtle Beach, SC	Location: The following is a safety zone: Certain waters of the Atlantic Intracoastal Waterway within the following two points of position and the North shore: 33°45′03″ N, 78°50′47″ W to 33°45′18″ N, 78°50′14″ W, located in Myrtle Beach, South Carolina.
4. One Saturday or Sunday during the last two weeks of May or the first two weeks of June:			
Time (Approximate): 6 a.m. to 11 a.m.	Low Country Splash ..... Sponsor: Logan Rutledge Children's Foundation.	Charleston, SC and Mt. Pleasant, SC.	Location: All waters within a moving safety zone, beginning at Daniel Island Pier in approximate position 32°51′20″ N, 079°54′06″ W, south along the coast of Daniel Island, across the Wando River to Hobcaw Yacht Club, in approximate position 32°49′20″ N, 079°53′49″ W, south along the coast of Mt. Pleasant, S.C., to Charleston Harbor Resort Marina, in approximate position 32°47′20″ N, 079°54′39″ W.
5. One night during the first week of July:			
Time (Approximate): 8 p.m. to 10 p.m.	North Charleston Fireworks Sponsor: City of North Charleston.	North Charleston, SC	Location: The following is a safety zone. All waters within a 500-yard radius of the barge, from which fireworks will be launched on the bank of the Cooper River at River Front Park in North Charleston, South Carolina.
6. One night during the first week of July:			
Time (Approximate): 8 p.m. to 10 p.m.	Patriots Point Fireworks .... Sponsor: USS Yorktown Foundation Patriot's Naval Museum.	Mt. Pleasant, SC	Location: The following is a safety zone: All waters within a 500-yard radius of the barge, from which fireworks will be launched on the bank of the Cooper River at Patriots Point in Charleston, SC.
7. Ten consecutive days (Friday through the next Sunday) in July:			
Time (Approximate): 8 a.m. to 5 p.m. each day.	Beaufort Water Festival ..... Sponsor: Beaufort Water Festival.	Beaufort, SC	Location: All waters 200 yards from seawall at Waterfront Park extending from Lady's Island Bridge to Spanish Point in Beaufort, SC.
8. One Saturday or Sunday in July:			
Time (Approximate): 12 p.m. to 5 p.m.	Beaufort Water Festival Air Show. Sponsor: Beaufort Water Festival.	Beaufort, SC	Location: The following is a safety zone: A portion Beaufort River near Riverfront Park in Beaufort, SC. The zone is 700 feet wide by 2600 feet in length on waters of the Beaufort River encompassed within the following points: (1) 32°25′47″ N/080°40′44″ W, (2) 32°25′41″ N/080°40′14″ W, (3) 32°25′35″ N/080°40′16″ W, (4) 32°25′40″ N/080°40′46″ W.
9. One Saturday or Sunday during the last two weeks of September or the first two weeks of October:			
Time (Approximate): 7:30 a.m. to 2 p.m.	Swim Around Charleston .. Sponsor: Kathleen Wilson	Charleston, SC	Location: The following is a moving safety zone. All waters 50 yards in front of the lead safety vessel preceding the first race participants, 50 yards behind the safety vessel trailing the last race participants, and at all times extends 100 yards on either side of safety vessels. The Swim Around Charleston swimming race consists of a 12 mile course that starts at Remley's Point on the Wando River in approximate position 32°48′49″ N, 79°54′27″ W, crosses the main shipping channel under the main span of the Ravenel Bridge, and finishes at the I–526 bridge and boat landing on the Ashley River in approximate position 32°50′14″ N, 80°01′23″ W.
10. One Friday, Saturday or Sunday in December:			

TABLE 1 TO § 100.704—SPECIAL LOCAL REGULATIONS; MARINE EVENTS WITHIN THE CAPTAIN OF THE PORT CHARLESTON—Continued

[Datum NAD 1983]

Date/time	Event/sponsor	Location	Regulated area
Time (Approximate): 4 p.m. to 9 p.m.	Charleston Parade of Boats. Sponsor: City of Charleston, SC Office of Cultural Affairs.	Charleston, SC	Location: Charleston harbor, South Carolina, from Anchorage A through Shutes Folly, Horse Reach, Hog Island Reach, Town Creek Lower Reach, Ashley River, and finishing at City Marina.

§ 100.713 [Removed]

■ 4. Remove § 100.713.

Dated: April 17, 2020.

J.W. Reed,

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

[FR Doc. 2020–08709 Filed 6–1–20; 8:45 am]

BILLING CODE 9110–04–P

DEPARTMENT OF HOMELAND SECURITY

Coast Guard

33 CFR Part 100

[Docket Number USCG–2020–0124]

RIN 1625–AA08

Special Local Regulations; Recurring Marine Events in the Lake Michigan Captain of the Port Zone

AGENCY: Coast Guard, DHS.

ACTION: Final rule.

SUMMARY: The Coast Guard is updating its recurring special local regulations for marine events located within the Captain of the Port Lake Michigan zone. This rule reorganizes five separate regulations of a similar nature currently listed in the Code of Federal Regulations into a single regulation, makes minor formatting changes for consistency, moves six existing events into this regulation, updates the dates listed for events, and lists these regulations in table form.

DATES: This rule is effective July 2, 2020.

ADDRESSES: To view documents mentioned in this preamble as being available in the docket, go to *https://www.regulations.gov,* type USCG–2020–0124 in the ''SEARCH'' box and click ''SEARCH.'' Click on Open Docket Folder on the line associated with this rule.

FOR FURTHER INFORMATION CONTACT: If you have questions on this rule, call or email Chief Petty Officer Kyle Weitzell, Waterways Management Division, Sector Lake Michigan, U.S. Coast Guard; telephone 414–747–7148, email *Kyle.W.Weitzell@uscg.mil.*

SUPPLEMENTARY INFORMATION:

I. Table of Abbreviations

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

II. Background Information and Regulatory History

On March 19, 2020, the Coast Guard published a notice of proposed rulemaking (NPRM) titled ''Special Local Regulations; Recurring Marine Events in the Lake Michigan Captain of the Port Zone'' (85 FR 15745). There we stated why we issued the NPRM, and invited comments on our proposed regulatory action to revise special local regulations regarding recurring marine events within the Captain of the Port Lake Michigan (COTP) zone. During the comment period that ended April 20, 2020, we received no comments.

III. Legal Authority and Need for Rule

The Coast Guard is issuing this rule under authority in 46 U.S.C. 70034 (previously 33 U.S.C. 1231). The COTP has determined that the likely combination of recreactional vessels, commercial vessels, and an unknown number of spectators in close proximity to these various recurring marine events in and on the navigable waters of the United States pose a extra or unusual hazards to the safety of life on those waters. Therefore, the COTP has established special local regulations around the event locations listed in this rule to help miniminze risks to safety of life during these events. This rule consolidates and makes minor formatting updates to existing regulations.

IV. Discussion of Comments, Changes, and the Rule

As noted above, we received no comments on our NPRM published March 19, 2020. There are no changes in the regulatory text of this rule from the proposed rule in the NPRM.

This rule reorganizes five separate regulations of a similar nature currently listed in the Code of Federal Regulations (CFR) into a single regulation, makes minor formatting changes for consistency, moves six existing events into this regulation, updates the dates listed for events, and lists these regulations in table form.

V. Regulatory Analyses

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

A. Regulatory Planning and Review

Executive Orders 12866 and 13563 direct agencies to assess the costs and benefits of available regulatory alternatives and, if regulation is necessary, to select regulatory approaches that maximize net benefits. Executive Order 13771 directs agencies to control regulatory costs through a budgeting process. This rule has not been designated a ''significant regulatory action,'' under Executive Order 12866. Accordingly, this rule has not been reviewed by the Office of Management and Budget (OMB), and pursuant to OMB guidance it is exempt from the requirements of Executive Order 13771.

This regulatory action determination is based on the size, location, and duration of these special local regulations. These regulations will be in effect only during the recurring marine events listed in this regulations for which the COTP has determined pose risks to the safety of life on waters of the United States. The size, location, and duration of these regulations will be limited to the extent necessary to minimize these risks. Moreover, the COTP will make advance notice of the enforcement of these regulations through the Local Notice to Mariners and/or Broacast Notice to Mariners. This regulation also provides a means for

anyone needing to transit through or within a regulated area to seek permission from the COTP.

B. Impact on Small Entities

The Regulatory Flexibility Act of 1980, 5 U.S.C. 601–612, as amended, requires Federal agencies to consider the potential impact of regulations on small entities during rulemaking. The term ''small entities'' comprises small businesses, not-for-profit organizations that are independently owned and operated and are not dominant in their fields, and governmental jurisdictions with populations of less than 50,000. The Coast Guard received no comments from the Small Business Administration on this rulemaking. The Coast Guard certifies under 5 U.S.C. 605(b) that this rule will not have a significant economic impact on a substantial number of small entities.

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

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

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

C. Collection of Information

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

D. Federalism and Indian Tribal Governments

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

Also, this rule does not have tribal implications under Executive Order 13175, Consultation and Coordination with Indian Tribal Governments, because it does not have a substantial direct effect on one or more Indian tribes, on the relationship between the Federal Government and Indian tribes, or on the distribution of power and responsibilities between the Federal Government and Indian tribes.

E. Unfunded Mandates Reform Act

The Unfunded Mandates Reform Act of 1995 (2 U.S.C. 1531–1538) requires Federal agencies to assess the effects of their discretionary regulatory actions. In particular, the Act addresses actions that may result in the expenditure by a State, local, or tribal government, in the aggregate, or by the private sector of $100,000,000 (adjusted for inflation) or more in any one year. Though this rule will not result in such an expenditure, we do discuss the effects of this rule elsewhere in this preamble.

F. Environment

We have analyzed this rule under Department of Homeland Security Directive 023–01, Rev. 1, associated implementing instructions, and Environmental Planning COMDTINST 5090.1 (series), which guide the Coast Guard in complying with the National Environmental Policy Act of 1969 (42 U.S.C. 4321–4370f), and have determined that this action is one of a category of actions that do not individually or cumulatively have a significant effect on the human environment. This rule involves involves the consolidation of and minor formatting changes for five existing special local regulations. It is categorically excluded from further review under paragraph L61 of Appendix A, Table 1 of DHS Instruction Manual 023–01–001–01, Rev. 1. A Memorandum for Record for Categorically Excluded Actions supporting this determination is available in the docket. For instructions on locating the docket, see the **ADDRESSES** section of this preamble.

G. Protest Activities

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

List of Subjects in 33 CFR Part 100

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

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

PART 100—SAFETY OF LIFE ON NAVIGABLE WATERS

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

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

■ 2. Revise § 100.903 to read as follows:

§ 100.903 Recurring marine events in the Lake Michigan Captain of the Port Zone.

(a) *General.* (1) The regulations in this section, along with the regulations of § 100.901, apply to the marine events listed in table 1 to this section.

(2) The regulations in this section will be enforced for the duration of each event, on or about the dates indicated. Notice of the exact dates and times of the effective period of the regulations in this section with respect to each event, the location of the regulated area, and details concerning of the event will be made public by publication in the Local Notices to Mariners and/or Broadcast Notice to Mariners over VHF–FM radio.

(3) The dates and times of these events are subject to change. In the event of a change to these events, the Coast Guard will publish a Notice of Enforcement with the exact dates and times that the regulated area will be enforced.

(4) Sponsors of events listed in table 1 to § this section are still required to submit applications for marine event permits in accordance with § 100.15.

(b) *Special Local Regulations.* (1) No vessel may enter, transit through, or anchor within the regulated area of any event listed in table 1 to this section which has been advertised in accordance with paragraph (a)(2) above without the permission of the Coast Guard Patrol Commander.

(2) Vessel operators desiring to enter or operate within the regulated area

shall contact the Coast Guard Patrol Commander to obtain permission to do so. Vessel operators given permission to enter or operate within the regulated area must comply with all directions given to them by the Coast Guard Patrol Commander.

(3) All geographic coordinates in table 1 to this section are North American Datum of 1983 (NAD 83).

TABLE 1 TO § 100.903

Event	Sector Lake Michigan special local regulations	Date
(1) Harborfest Dragon Boat Race ..	South Haven, MI: All waters of the Black River, within an area bound by the following coordinates: 42°24.227′ N, 086°16.683′ W, then southeast to 42°24.210′ N, 086°16.667′ W, then northeast to 42°24.320′ N, 086°16.442′ W, then northwest to 42°24.337′ N, 086°16.457′ W, then returning to the point of origin	2 days; in mid-to-late June.
(2) Summer in the City Waterski Show.	Green Bay, WI: All waters of the Fox River from the Main Street Bridge to the West Walnut Street Bridge between coordinates: 44°31.089′ N, 088°00.904′ W, then southwest to 44°30.900′ N, 088°01.091′ W	Each Wednesday of July and August.
(3) Celebrate Americafest Ski Show.	Green Bay, WI: All waters of the Fox River from the West Walnut Street Bridge to the mouth of the East River between coordinates: 44°30.912′ N, 088°01.100′ W, then northeast to 44°31.337′ N, 088°00.640′ W	1 day; on or around July 4.
(4) Grand Haven Coast Guard Festival.	Grand Haven, MI: All waters of the Grand River, within an area bound by the following coordinates: 43°04.000′ N, 086°14.200′ W, then east to 43°03.933′ N, 086°14.067′ W, then south to 43°03.750′ N, 086°14.167′ W, then west to 43°03.800′ N, 086°14.283′ W, then returning to the point of origin	2 weeks; in late July and/or early August.
(5) Milwaukee Venetian Boat Parade.	Milwaukee, WI: All waters of Lake Michigan within the Milwaukee Harbor and the Milwaukee River from McKinley Marina, along the Veteran's Park shoreline, to the Milwaukee Art Museum between coordinates: 43°02.066′ N, 087°52.966′ W, then southwest to 43°02.483′ N, 087°53.683′ W, then south to 43°02.366′ N, 087°53.700′ W	1 day; the third Saturday of August.
(6) Milwaukee Open Water Swim ...	Milwaukee, WI: All waters of the Milwaukee River from the confluence with the Kinnickinnic River to the I–794 Bridge between coordinates: 43°01.532′ N, 087°54.182′ W, then northwest to 43°02.154′ N, 087°54.597′ W	1 day; the first or second Saturday of August.
(7) Sister Bay Marinafest Ski Show	Sister Bay, WI: All waters of Sister Bay within an 800 foot radius of the following coordinates: 45°11.585′ N, 087°07.392′ W	1 day; the last week of August or first week of September.
(8) Milwaukee Harborfest Boat Parade.	Milwaukee, WI: All waters of the Milwaukee River from the North Holton Street Bridge to the confluence with the Kinnickinnic River between coordinates: 43°03.284′ N, 087°54.267′ W, then south to 43°01.524′ N, 087°54.173′ W *and* All water of the Kinnickinnic River from the confluence with the Milwaukee River to the Municipal Mooring Basin between coordinates: 43°01.524′ N, 087°54.173′ W, then south to 43°00.829′ N, 087°54.075′ W	1 day; the first or second weekend of September.
(9) Milwaukee River Challenge	Milwaukee, WI: All waters of the Milwaukee River from the confluence with the Menomonee River and the East Pleasant Street Bridge between coordinates: 43°01.915′ N, 087°54.627′ W, then north to 43°03.095′ N, 087°54.468′ W *and* All waters of the Menomonee River from the North 25th Street Bridge to the confluence with the Milwaukee River between coordinates: 43°01.957′ N, 087°56.682′ W, then east to 43°01.915′ N, 087°54.627′ W	1 day; the third Saturday of September.

Event	Marine safety unit Chicago special local regulations	Date
(10) Chinatown Chamber of Commerce Dragon Boat Race.	Chicago, IL: All waters of the South Branch of the Chicago River from the West 18th Street Bridge to the Amtrak Bridge between coordinates: 41°51.467′ N, 087°38.100′ W, then southwest to 41°51.333′ N, 087°38.217′ W	2 days; The second Friday and Saturday of July.
(11) Southland Regatta	Blue Island, IL: All waters of the Calumet Sag Channel from the South Halstead Street Bridge to the Crawford Avenue Bridge between coordinates: 41°39.450′ N, 087°38.483′ W, then southwest to 41°39.083′ N, 087°43.483′ W *and* All waters of the Little Calumet River from the Ashland Avenue Bridge to the junction of the Calumet Sag Channel between coordinates: 41°39.117′ N, 087°39.633′ W, then northeast to 41°39.374′ N, 087°39.001′ W	2 days; the first Sunday of November and the Saturday prior to it.

§§ 100.906, 100.907, 100.909, and 100.910 [Removed]

■ 3. Remove §§ 100.906, 100.907, 100.909, and 100.910

Dated: May 5, 2020.

T.J. Stuhlreyer,

Captain, U.S. Coast Guard, Captain of the Port Lake Michigan.

[FR Doc. 2020–09878 Filed 6–1–20; 8:45 am]

BILLING CODE 9110–04–P

DEPARTMENT OF HOMELAND SECURITY

Coast Guard

33 CFR Part 117

[Docket No. USCG–2017–0108]

RIN 1625–AA09

Drawbridge Operation Regulation; Tombigbee River, Near Jackson, Alabama

AGENCY: Coast Guard, DHS.

ACTION: Final rule.

SUMMARY: The Coast Guard is changing the operating schedule that governs the Norfolk Southern Railroad (NSRR) vertical lift bridge across the Tombigbee River, mile 89.9, near Jackson, between Washington and Clarke Counties, Alabama. This rule moves the current onsite bridge tender control station to a geographically remote centralized control point located in Decatur, AL.

DATES: This rule is effective July 2, 2020.

ADDRESSES: To view documents mentioned in this preamble as being available in the docket, go to *http://www.regulations.gov.* Type USCG–2017–0108 in the ''SEARCH'' box and click ''SEARCH.'' Click on Open Docket Folder on the line associated with this rulemaking.

FOR FURTHER INFORMATION CONTACT: If you have questions about this rulemaking, call or email Mr. Doug Blakemore, Eighth Coast Guard District Bridge Administrator; telephone (504) 671–2128, email *Douglas.A.Blakemore@uscg.mil.*

SUPPLEMENTARY INFORMATION:

I. Table of Abbreviations

CFR Code of Federal Regulations
DHS Department of Homeland Security
FR Federal Register
OMB Office of Management and Budget
NPRM Notice of Proposed Rulemaking (Advance, Supplemental)
NSRR Norfolk Southern Railroad
§ Section
U.S.C. United States Code

II. Background Information and Regulatory History

The NSRR vertical lift bridge is maintained in the open to vessel position except when trains need to pass or when maintenance is performed. This bridge has a 44.09′ above normal pool elevation vertical clearance in the closed to vessel position and a vertical clearance of 73′ above normal pool elevation when raised to its maximum height. The bridge has a 300′ horizontal clearance. This bridge is located on a major commercial waterway used primarily by tugs, tows and barges. The drawbridge is regulated under 33 CFR 117.5 and opens on signal.

NSRR has developed a system of closed circuit cameras (CCTV), infrared sensors, VHF and landline communications, positive train control dispatch, programmable logic control, display monitors, vessel identification systems and procedures that allow a remote operator to perform all assignments of an onsite drawtender.

In December 2016 NSRR requested to operate the Tombigbee River bridge from a remote NSRR location in Decatur, AL. NSRR informed the Coast Guard that the bridge would operate under the following conditions.

(1) The draw would be maintained in the fully open to navigation position for vessels at all times, except during periods when it would be closed for the passage of rail traffic or to perform periodic maintenance authorized in accordance with the regulations.

(2) The draw would be remotely operated by the drawtender located at Norfolk Southern's drawbridge in Decatur, Alabama. The estimated duration that the bridge would remained closed for the passage of rail traffic would be 10 to 15 minutes per operation.

(3) When a train approached the bridge, the drawtender would initiate the bridge closing warning signal, consisting of radio calls via VHF–FM-channels 13 and 16 and activation of flashing red warning lights at each end of the span. The radio calls would be broadcast at five (5) minutes prior to bridge closing and at two (2) minutes prior to bridge closing. Photoelectric (infrared) boat detectors would monitor the waterway beneath the bridge for the presence of vessels.

(4) The drawtender would continuously monitor waterway traffic in the area using closed-circuit cameras mounted on the bridge. The draw would only be closed if the drawtender's visual inspection indicated that the channel was clear and there were no vessels transiting in the area. The drawtender would maintain constant surveillance of the navigation channel to ensure that no conflict with maritime traffic existed. Additionally, the draw would not be closed if the S11 bascule bridge that is located immediately west of the railroad bridge was in the open-to-navigation position. If two or more closed-circuit cameras were to become inoperable or if there was inclement weather, the draw

would only be operated by a drawtender located on site at the bridge.

(5) At the end of the two-minute warning period, if no vessels were detected by the drawtender, the draw closing sequence would automatically proceed.

(6) Upon passage of the train, the draw would be returned to the fully open-to-navigation position to allow marine traffic to pass. The warning lights would continue to flash red until the draw was returned to the fully open-to-navigation position at which time they would deactivate.

(7) After the passage of each train, the draw would be returned to its fully open-to-navigation position.

(8) To request openings of the draw when the bascule span was in the closed-to-navigation position, mariners would be required to contact Norfolk Southern Railway via VHF–FM channel 13 or by telephone at the number displayed on the signs posted at the bridge.

(9) The draw would be operated locally if:

(i) Communication became lost between the drawbridge and the drawtender in Decatur, Alabama;

(ii) More than two closed-circuit cameras were not working;

(iii) The marine radio became inoperable;

(iv) Weather conditions warrant; or

(v) Ordered by the Coast Guard.

On July 12, 2017, the Coast Guard published a notice of proposed rulemaking (NPRM) entitled ''Drawbridge Operation Regulation; Tombigbee River, near Jackson, Alabama'' in the **Federal Register** at 82 FR 32157. In that NPRM we stated that the District Commander could authorize a drawbridge to operate under an automated system or from a remote location. This NPRM proposed changing the drawbridge regulation on this bridge to allow the bridge to be remotely operated at a NSRR location in Decatur, AL. There was little discussion of the proposed rule.

During the comment period that ended September 11, 2017 the Coast Guard received three comments. Two were from vessel operators and one was from a union representing maintenance employees. All three entities opposed the rule change.

The Coast Guard considered these comments and on March 14, 2018 informed NSRR that the Coast Guard did not have sufficient information to address the above public concerns and thus could not finalize the proposed rule. This letter is in the docket.

On December 18, 2018 the Coast Guard visited the NSRR bridge control center in Decatur, Alabama to view their camera displays, communications systems and automated information systems (AIS) associated with their bridge remote operations.

In February 2019 NSRR provided the Coast Guard with documentation that addressed the following: Bridge demographics, Tombigbee River demographics, waterway safety, emergency response, vessel navigation assessments, remote operation system capabilities, maintenance capabilities, bridge casualty information, operational requirements and operating procedures.

After reviewing all NSRR information and public comments the Coast Guard has verified, to the extent of its authority and jurisdiction that NSRR has the capabilities to operate the bridge remotely.

III. Legal Authority and Need for Rule

The Coast Guard is issuing this rule under authority 33 U.S.C. 499. The Eighth Coast Guard District Commander has determined that this change to the operating schedule of the NSRR vertical lift bridge across the Tombigbee River, mile 89.9 to allow the bridge to be operated from the remote location is reasonable. The purpose of this rule is to allow NSRR to operate the bridge from a NSRR location in Decatur, AL and meet the reasonable needs of vessels that use the Tombigbee River.

IV. Discussion of Comments, Changes and the Final Rule

There were 3 comments submitted on our NPRM published on July 12, 2017. Two comments came from vessel operators on the Tombigbee River. One comment was provided by a labor union representing maintenance employees. There were a total of 14 concerns addressed in the three comments. All three commenters were against relocating the bridge tender to a remote location.

To address these concerns the Coast Guard separated the above comments into three general concerns: Removing the bridge tender would create significant delays to opening the bridge to vessel traffic, removing the bridge tender would create unsafe navigation conditions, and other general concerns. Below is the Coast Guard's evaluation for each of these areas.

Removing the bridge tender will not create unreasonable delays to opening the bridge to vessel traffic. Since the current onsite bridge tender does not perform routine maintenance or make bridge repairs, there will be no added time to maintain the bridge or respond to an outage or emergency. Emergency repairs and routine maintenance are conducted by NSRR bridge and building personnel who are located at the site of the bridge. NSRR procedures require that emergency response personnel arrive at the bridge within 1–2 hours of notification. If there is a failure to the bridge, NSRR will secure the bridge in the open to vessel position until the bridge is repaired.

Additionally locating the bridge tender in a remote location should not create added delays because of simultaneous bridge operations. The NSRR bridge tender, located in Decatur, AL will control three bridges located on Lake Pontchartrain, LA, the Tombigbee River, AL and the Tennessee River, AL. The Tombigbee River bridge closes to vessel traffic 8 times each day. The Tennessee River bridge is maintained in the closed to vessel position and opens to vessel traffic 7 times each day. The Lake Pontchartrain bridge is maintained in the open to vessel position and closes to vessel traffic 12 times each day. This equates to 27 bridge openings or closings (movements) per day which can be reasonably controlled by one bridge tender.

Processing simultaneous requests for bridge openings should also not create unreasonable delays. NSRR simultaneous operations procedures state that the bridge tender open and close one bridge at a time. The cycle time to open and close each NSRR bridge is about 8 minutes. Vessels, if 3rd in the queue to open, could be delayed by 24 minutes. The Coast Guard does not consider this to be unreasonable.

Dispatching a bridge tender to the Tombigbee River bridge because of a remote operation system failure or inclement weather will also not delay vessels. NSRR procedures require the bridge to be secured in the open to vessel traffic position if inclement weather prevents the remote bridge tender from operating the bridge or if there are failures to remote sensors at the Tombigbee River bridge. In this scenario NSRR will dispatch a bridge tender to the bridge; however, since the bridge is secured in the open to vessel traffic position, there will be no added vessel delays.

This rule will not create unsafe navigation conditions.

As stated above there are on average 27 bridge movements for the three bridges controlled by the bridge tender in Decatur, AL. These bridge movements can be safely processed by a single bridge tender.

NSRR has installed sensors that monitor the channel for vessels or other obstructions. These channel sensors are interlocked with the bridge control system to prevent or halt bridge

operations while a vessel is in the channel.

Communication failures are addressed in NSRR procedures. If there are failures to both channel 13 and 16 radios, then NSRR will secure the bridge in the open to vessel traffic position until both radios are repaired. NSRR procedures require that a bridge tender be dispatched to the bridge if communications become severed with vessels.

NSRR has additionally installed an automatic identification system (AIS) that tracks and identifies vessels equipped with AIS equipment. This provides the bridge tender with a tool to identify vessels on the Tombigbee River before they arrive at the bridge.

There were other general concerns brought by the commenters that have been addressed by the Coast Guard or did not fall under Coast Guard authority.

One commenter stated that they could not address the NSRR request because it was not included in the docket. As stated in the Background Information and Regulatory History section of this final rule, the Coast Guard notified NSRR on March 14, 2018 that there was insufficient information to address public concerns and thus the Coast Guard could not finalize the proposed rule. This letter is in the docket. NSRR addressed this Coast Guard letter and provided the Coast Guard with a formal proposal that included information on bridge demographics, waterway demographics, emergency response, maintenance, navigation assessments, bridge structural history, rail safety, control system compatibility, remote system components and requirements, operations requirements, waterway safety and bridge tender procedures. This information is not included in the docket because it contains NSRR company confidential information. The Coast Guard has reviewed these documents and has determined that they sufficiently address the concerns brought by the commenters.

One commenter stated that NSRR would prioritize rail traffic over vessel traffic. There is no data to support this statement. There have been no reports that this bridge has not or did not operate according to Coast Guard regulations.

One commenter stated concern that there would be no on site presence to keep trespassers off the bridge or remove debris from the bridge. These concerns have been sent to NSRR. The Coast Guard did not address this because it does not fall under Coast Guard jurisdiction.

One commenter stated that this rule change would terminate jobs and had no correlation to railroad efficiency. These concerns have been sent to NSRR. The Coast Guard did not address this because it does not fall under Coast Guard jurisdiction.

After considering all of the comments we received, the Coast Guard believes that changing the operating schedule that governs the Norfolk Southern Railroad (NSRR) vertical lift bridge across the Tombigbee River, mile 89.9, near Jackson, between Washington and Clarke Counties, AL by moving the current onsite bridge tender control station to a geographically remote bridge control center located in Decatur, AL will provide for the reasonable needs of navigation and can be performed safely.

V. Regulatory Analyses

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

A. Regulatory Planning and Review

Executive Orders 12866 and 13563 direct agencies to assess the costs and benefits of available regulatory alternatives and, if regulation is necessary, to select regulatory approaches that maximize net benefits. Executive Order 13771 directs agencies to control regulatory costs through a budgeting process. This rule has not been designated a ''significant regulatory action,'' under Executive Order 12866. Accordingly, it 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 ability that vessels will be able to transit under the bridge given advance notice and the bridge will open in case of an emergency. We believe this change to the drawbridge operation regulations at 33 CFR 117.5 will meet the reasonable needs of navigation.

B. Impact on Small Entities

The Regulatory Flexibility Act of 1980 (RFA), 5 U.S.C. 601–612, as amended, requires federal agencies to consider the potential impact of regulations on small entities during rulemaking. The term ''small entities'' comprises small businesses, not-for-profit organizations that are independently owned and operated and are not dominant in their fields, and governmental jurisdictions with populations of less than 50,000. The Coast Guard received no comments from the Small Business Administration on this rule. The Coast Guard certifies under 5 U.S.C. 605(b) that this rule will not have a significant economic impact on a substantial number of small entities.

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

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

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

C. Collection of Information

This rule calls for no new collection of information under the Paperwork Reduction Act of 1995 (44 U.S.C. 3501–3520).

D. Federalism and Indian Tribal Government

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

Also, this rule does not have tribal implications under Executive Order 13175, Consultation and Coordination with Indian Tribal Governments,

because it does not have a substantial direct effect on one or more Indian tribes, on the relationship between the Federal Government and Indian tribes, or on the distribution of power and responsibilities between the Federal Government and Indian tribes.

E. Unfunded Mandates Reform Act

The Unfunded Mandates Reform Act of 1995 (2 U.S.C. 1531–1538) requires Federal agencies to assess the effects of their discretionary regulatory actions. In particular, the Act addresses actions that may result in the expenditure by a State, local, or tribal government, in the aggregate, or by the private sector of $100,000,000 (adjusted for inflation) or more in any one year. Though this rule will not result in such an expenditure, we do discuss the effects of this rule elsewhere in this preamble.

F. Environment

We have analyzed this rule under Department of Homeland Security Management Directive 023–01 and Commandant Instruction M16475.lD, which guides the Coast Guard in complying with the National Environmental Policy Act of 1969 (NEPA) (42 U.S.C. 4321–4370f), and have made a determination that this action is one of a category of actions which do not individually or cumulatively have a significant effect on the human environment. This rule simply promulgates the operating regulations or procedures for drawbridges. This action is categorically excluded from further review, under figure 2–1, paragraph (32)(e), of the Instruction.

A Record of Environmental Consideration and a Memorandum for the Record are not required for this 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.

List of Subjects in 33 CFR Part 117

Bridges.

For the reasons discussed in the preamble, the Coast Guard amends 33 CFR part 117 as follows:

PART 117—DRAWBRIDGE OPERATION REGULATIONS

■ 1. The authority citation for part 117 continues to read as follows:

Authority: 33 U.S.C. 499; 33 CFR 1.05–1; and Department of Homeland Security Delegation No. 0170.1.

■ 2. Revise § 117.118 to read as follows:

§ 117.118 Tombigbee River.

(a) The draw of the Meridian and Bigbee Railroad (MNBR) vertical lift span bridge across the Tombigbee River, mile 128.6 (Black Warrior Tombigbee (BWT) Waterway mile 173.6), at Naheola, shall operate as follows:

(1) The draw shall be maintained in the fully open-to-navigation position for vessels at all times, except during periods when it is closed for the passage of rail traffic.

(2) When a train approaches the bridge, it will stop and a crewmember from the train will observe the waterway for approaching vessels. If vessels are observed approaching the bridge, they will be allowed to pass prior to lowering the bridge. The crewmember will then announce via radiotelephone on VHF–FM channel 16 that the bridge is preparing to be lowered. If, after two minutes, no response has been received, the crewmember will initiate the lowering sequence.

(3) After the train has completely passed over the bridge, the crewmember will initiate the raising sequence. When the bridge is in the fully open-to-navigation position, the crewmember will announce via radiotelephone on VHF–FM channel 16 that the bridge is in the fully open-to-navigation position.

(4) To request openings of the bridge when the lift span is in the closed-to-navigation position, mariners may contact the MNBR via VHF–FM channel 16 or by telephone at 205–654–4364.

(b) The draw of the Norfolk Southern Railroad (NSRR) Vertical Lift Bridge across the Tombigbee River, mile 89.9, near Jackson, Washington and Clarke Counties, Alabama shall be operated as follows:

(1) The draw shall be kept in the open-to-vessel position, except during periods when it will close for the passage of rail traffic or to perform periodic maintenance authorized in accordance with subpart A of this part.

(2) When a train approaches the bridge, the draw tender will initiate the bridge closing warning signal, consisting of radio calls via VHF–FM channels 13 and 16 and activation of flashing red warning lights at each end of the span. The radio calls will be broadcast at five (5) minutes prior to bridge closing and at two (2) minutes prior to bridge closing. At the end of the two-minute warning period, if there are no vessels passing beneath the bridge or there have been no requests to pass beneath the bridge then the draw will automatically close. Upon passage of the train, the draw will return to the open-to-vessel position. The warning lights will continue to flash red until the draw is completely opened.

(3) The draw shall be remotely operated by the draw tender at Norfolk Southern Railroad's bridge control center in Decatur, Alabama. Closed Circuit TVs, infrared detectors and an Automatic Identification System have been installed at the bridge. Vessels can contact the NSRR draw tender via VHF–FM channel 13 or by telephone at the number displayed on the signs posted at the bridge to request an opening of the draw when the vertical lift span is in the closed-to-vessel position.

(4) NSRR will immediately provide an on-site bridge tender if:

(i) Any component of the remote operations system fails and prevents the remote operator from being able to visually identify vessels, communicate with vessels, detect vessels immediately underneath the bridge or visually identify trains approaching the bridge.

(ii) Anytime NSRR cannot meet Federal Railway Administration (FRA) or any other government agency safety requirements.

(iii) Anytime that the NSRR procedures or equipment to close or open the bridge listed in paragraph (b)(2) of this section fail.

(iv) When weather reaches a point where the remote draw tender cannot visually identify a vessel from the remote location.

(v) At the direction of the District Commander.

Dated: May 4, 2020.

John P. Nadeau,

Rear Admiral, U.S. Coast Guard, Commander, Eighth Coast Guard District.

[FR Doc. 2020–09853 Filed 6–1–20; 8:45 am]

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DEPARTMENT OF HOMELAND SECURITY

Coast Guard

33 CFR Part 165

[Docket Number USCG–2020–0125]

RIN 1625–AA00

Safety Zones; Annual Events Requiring Safety Zones in the Captain of the Port Lake Michigan Zone

AGENCY: Coast Guard, DHS.

ACTION: Final rule.

SUMMARY: The Coast Guard is updating the rules that regulate vessel traffic and control navigation on portions of

waterways in the Captain of the Port Lake Michigan zone during events that will introduce safety concerns to life and property on the navigable waters of the United States. This rule reorganizes the table listing existing safety zones into four separate tables organized by the State in which the safety zone occurs, makes minor formatting changes for consistency, updates the dates listed for some events, consolidates one safety zone, and removes six safety zones that are no longer necessary.

DATES: This rule is effective July 2, 2020.

ADDRESSES: To view documents mentioned in this preamble as being available in the docket, go to *https://www.regulations.gov,* type USCG–2020–0125 in the ''SEARCH'' box and click ''SEARCH.'' Click on Open Docket Folder on the line associated with this rule.

FOR FURTHER INFORMATION CONTACT: If you have questions on this rule, call or email Chief Petty Officer Kyle Weitzell, Waterways Management Division, Sector Lake Michigan, U.S. Coast Guard; telephone 414–747–7148, email *Kyle.W.Weitzell@uscg.mil.*

SUPPLEMENTARY INFORMATION:

I. Table of Abbreviations

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

II. Background Information and Regulatory History

On March 19, 2020, the Coast Guard published a notice of proposed rulemaking (NPRM) titled ''Safety Zones; Annual Events Requiring Safety Zones in the Captain of the Port Zone Lake Michigan Zone'' (85 FR 15749). There we stated why we issued the NPRM, and invited comments on our proposed regulatory action to revise existing safety zones within the Captain of the Port Lake Michigan (COTP) zone. During the comment period that ended April 20, 2020, we received no comments.

III. Legal Authority and Need for Rule

The Coast Guard is issuing this rule under authority in 46 U.S.C. 70034 (previously 33 U.S.C. 1231). The COTP has determined that potential hazards associated with the events exist and these safety zones have been established to protect safety of life and property for the maritime public and event participants from the hazards associated with these events. This rule consolidates and makes minor formatting updates to existing regulations.

IV. Discussion of Comments, Changes, and the Rule

As noted above, we received no comments on our NPRM published March 19, 2020. There are no changes in the regulatory text of this rule from the proposed rule in the NPRM.

This rule reorganizes the table listing existing safety zones into four separate tables organized by the State in which the safety zone occurs, makes minor formatting changes for consistency, updates the dates listed for some events, consolidates one safety zone, and removes six safety zones that are no longer necessary.

V. Regulatory Analyses

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

A. Regulatory Planning and Review

Executive Orders 12866 and 13563 direct agencies to assess the costs and benefits of available regulatory alternatives and, if regulation is necessary, to select regulatory approaches that maximize net benefits. Executive Order 13771 directs agencies to control regulatory costs through a budgeting process. This rule has not been designated a ''significant regulatory action,'' under Executive Order 12866. Accordingly, this rule has not been reviewed by the Office of Management and Budget (OMB), and pursuant to OMB guidance it is exempt from the requirements of Executive Order 13771.

This regulatory action determination is based on the size, location, and duration of these safety zones. These regulations will be in effect only during the events listed in this regulations for which the COTP has determined pose risks to the safety of life and property for the maritime public and event participants. The size, location, and duration of these regulations will be limited to the extent necessary to minimize these risks. Moreover, the COTP will make advance notice of the enforcement of these regulations through the Local Notice to Mariners and/or Broacast Notice to Mariners. This regulation also provides a means for anyone needing to transit through or within a published safety zone to seek permission from the COTP.

B. Impact on Small Entities

The Regulatory Flexibility Act of 1980, 5 U.S.C. 601–612, as amended, requires Federal agencies to consider the potential impact of regulations on small entities during rulemaking. The term ''small entities'' comprises small businesses, not-for-profit organizations that are independently owned and operated and are not dominant in their fields, and governmental jurisdictions with populations of less than 50,000. The Coast Guard received no comments from the Small Business Administration on this rulemaking. The Coast Guard certifies under 5 U.S.C. 605(b) that this rule will not have a significant economic impact on a substantial number of small entities.

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

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

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

C. Collection of Information

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

D. Federalism and Indian Tribal Governments

A rule has implications for federalism under Executive Order 13132, Federalism, if it has a substantial direct

effect on the States, on the relationship between the National Government and the States, or on the distribution of power and responsibilities among the various levels of government. We have analyzed this rule under that order and have determined that it is consistent with the fundamental federalism principles and preemption requirements described in Executive Order 13132.

Also, this rule does not have tribal implications under Executive Order 13175, Consultation and Coordination with Indian Tribal Governments, because it does not have a substantial direct effect on one or more Indian tribes, on the relationship between the Federal Government and Indian tribes, or on the distribution of power and responsibilities between the Federal Government and Indian tribes.

E. Unfunded Mandates Reform Act

The Unfunded Mandates Reform Act of 1995 (2 U.S.C. 1531–1538) requires Federal agencies to assess the effects of their discretionary regulatory actions. In particular, the Act addresses actions that may result in the expenditure by a State, local, or tribal government, in the aggregate, or by the private sector of $100,000,000 (adjusted for inflation) or more in any one year. Though this rule will not result in such an expenditure, we do discuss the effects of this rule elsewhere in this preamble.

F. Environment

We have analyzed this rule under Department of Homeland Security Directive 023–01, Rev. 1, associated implementing instructions, and Environmental Planning COMDTINST 5090.1 (series), which guide the Coast Guard in complying with the National Environmental Policy Act of 1969(42 U.S.C. 4321–4370f), and have determined that this action is one of a category of actions that do not individually or cumulatively have a significant effect on the human environment. This rule involves the consolidation and making formatting changes of existing safety zones. It is categorically excluded from further review under paragraph L60(a) of Appendix A, Table 1 of DHS Instruction Manual 023–01–001–01, Rev. 1. A Record of Environmental Consideration supporting this determination is available in the docket. For instructions on locating the docket, see the **ADDRESSES** section of this preamble.

G. Protest Activities

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

List of Subjects in 33 CFR Part 165

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

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

PART 165—REGULATED NAVIGATION AREAS AND LIMITED ACCESS AREAS

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

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

■ 2. Revise § 165.929 to read as follows:

§ 165.929 Safety Zones; annual events requiring safety zones in the Captain of the Port Lake Michigan Zone.

(a) *Regulations.* The following regulations apply to the safety zones listed in Tables 1 through 4 of this section.

(1) The general regulations in § 165.23.

(2) All vessels must obtain permission from the Captain of the Port (COTP) Lake Michigan or his or her designated representative to enter, move within, or exit a safety zone established in this section when the safety zone is enforced. Vessels and persons granted permission to enter one of the safety zones listed in this section must obey all lawful orders or directions of the COTP Lake Michigan or his or her designated representative. Upon being hailed by the U.S. Coast Guard by siren, radio, flashing light or other means, the operator of a vessel must proceed as directed.

(3) The enforcement dates and times for each of the safety zones listed in Tables 1 through 4 of this section are subject to change, but the duration of enforcement would remain the same, or nearly the same, as stated in Tables 1 through 4 of this section. In the event of a change, the COTP Lake Michigan will provide notice to the public by publishing a Notice of Enforcement in the **Federal Register**, as well as, issuing a Broadcast Notice to Mariners.

(b) *Definitions.* The following definitions apply to this section:

(1) *Designated representative* means any Coast Guard commissioned, warrant, or petty officer designated by the COTP Lake Michigan to monitor a safety zone, permit entry into a safety zone, give legally enforceable orders to persons or vessels within a safety zone, and take other actions authorized by the COTP Lake Michigan.

(2) *Public Vessel* means a vessel that is owned, chartered, or operated by the United States, or by a State or political subdivision thereof.

(3) *Rain date* refers to an alternate date and/or time in which the safety zone would be enforced in the event of inclement weather.

(c) *Suspension of enforcement.* The COTP Lake Michigan may suspend enforcement of any of these zones earlier than listed in this section. Should the COTP Lake Michigan suspend any of these zones earlier than the listed duration in this section, he or she may make the public aware of this suspension by Broadcast Notice to Mariners and/or on-scene notice by his or her designated representative.

(d) *Exemption.* Public Vessels, as defined in paragraph (b) of this section, are exempt from the requirements in this section.

(e) *Waiver.* For any vessel, the COTP Lake Michigan or his or her designated representative may waive any of the requirements of this section upon finding that operational conditions or other circumstances are such that application of this section is unnecessary or impractical for the purposes of safety or security.

TABLE 1 TO § 165.929—SAFETY ZONES IN THE STATE OF ILLINOIS

Event	Location [1]	Enforcement date [2]
(1) Cochrane Cup	Blue Island, IL. All waters of the Calumet Saganashkee Channel from the South Halstead Street Bridge at 41°39.442′ N, 087°38.474′ W; to the Crawford Avenue Bridge at 41°39.078′ N, 087°43.127′ W; and the Little Calumet River from the Ashland Avenue Bridge at 41°39.098′ N, 087°39.626′ W; to the junction of the Calumet Saganashkee Channel at 41°39.373′ N, 087°39.026′ W.	1 day—The first Saturday of May; 6:30 a.m. to 5 p.m.

TABLE 1 TO § 165.929—SAFETY ZONES IN THE STATE OF ILLINOIS—Continued

Event	Location [1]	Enforcement date [2]
(2) Thunder on the Fox	Elgin, IL. All waters of the Fox River from the Kimball Street Bridge, located at approximate position 42°02.499′ N, 088°17.367′ W, then 1,250 yards north to a line crossing the river perpendicularly running through position 42°03.101′ N, 088°17.461′ W.	3 days—Friday, Saturday, and Sunday of the third weekend in June; 10 a.m. to 7 p.m. each day.
(3) Start of the Chicago to Mackinac Race.	Chicago, IL. All waters of Lake Michigan in the vicinity of the Chicago Harbor Entrance at Chicago, IL, within a rectangle that is bounded by a line drawn from 41°53.251 N, 087°35.393 W; then east to 41°53.251 N, 087°34.352 W; then south to 41°52.459 N, 087°34.364 W; then west to 41°52.459 N, 087°35.393 W; then north back to the point of origin.	2 days—Either the third or fourth weekend of June; 8 a.m. to 6 p.m. each day.
(4) Taste of Chicago Fireworks	Chicago, IL. All waters of Monroe Harbor and Lake Michigan bounded by a line drawn from 41°53.380′ N, 087°35.978′ W; then southeast to 41°53.247′ N, 087°35.434′ W; then south to 41°52.809′ N, 087°35.434′ W; then southwest to 41°52.453′ N, 087°36.611′ W; then north to 41°53.247′ N, 087°36.573′ W; then northeast returning to the point of origin.	1 day—On or around July 4; 9 p.m. to 11 p.m.
(5) Evanston Fourth of July Fireworks.	Evanston, IL. All waters of Lake Michigan, in the vicinity of Centennial Park Beach, within the arc of a circle with a 500-foot radius from the fireworks launch site located in position 42°02.933′ N, 087°40.350′ W.	1 day—On or around July 4; 9 p.m. to 11 p.m..
(6) Glencoe Fourth of July Celebration Fireworks.	Glencoe, IL. All waters of Lake Michigan in the vicinity of Lake Front Park, within the arc of a circle with a 1,000-foot radius from a barge in position 42°08.404′ N, 087°44.930′ W.	1 day—On or around July 4; 9 p.m. to 11 p.m.
(7) Lakeshore Country Club Independence Day Fireworks.	Glencoe, IL. All waters of Lake Michigan within the arc of a circle with a 600-foot radius from a center point fireworks launch site in approximate position 42°09.130′ N, 087°45.530′ W.	1 day—On or around July 4; 9 p.m. to 11 p.m.
(8) Joliet Independence Day Celebration Fireworks.	Joliet, IL. All waters of the Des Plains River, at mile 288, within the arc of a circle with a 500-foot radius from the fireworks launch site located in position 41°31.522′ N, 088°05.244′ W.	1 day—On or around July 4; 9 p.m. to 11 p.m.
(9) Shore Acres Country Club Independence Day Fireworks.	Lake Bluff, IL. All waters of Lake Michigan within the arc of a circle with a 600-foot radius from approximate position 42°17.847′ N, 087°49.837′ W.	1 day—On or around July 4; 9 p.m. to 11 p.m.
(10) Independence Day Fireworks	Wilmette, IL. All waters of Lake Michigan and the North Shore Channel within the arc of a circle with a 1,000-foot radius from the fireworks launch site located at approximate center position 42°04.674′ N, 087°40.856′ W.	1 day—On or around July 4; 8:30 p.m. to 10:15 p.m.
(11) Joliet Waterway Daze Fireworks.	Joliet, IL. All waters of the Des Plaines River, at mile 287.5, within the arc of a circle with a 300-foot radius from the fireworks launch site located in position 41°31.250′ N, 088°05.283′ W.	2 days—Friday and Saturday of the third weekend of July; 9 p.m. to 11 p.m. each day.
(12) Chicago Venetian Night Fireworks.	Chicago, IL. All waters of Monroe Harbor and all waters of Lake Michigan bounded by a line drawn from 41°53.050′ N, 087°36.600′ W; then east to 41°53.050′ N, 087°36.350′ W; then south to 41°52.450′ N, 087°36.350′ W; then west to 41°52.450′ N, 087°36.617′ W; then north returning to the point of origin.	1 day—Saturday of the last weekend of July; 9 p.m. to 11 p.m.
(13) Chicago Match Cup Race	Chicago, IL. All waters of Chicago Harbor in the vicinity of Navy Pier and the Chicago Harbor break wall bounded by coordinates beginning at 41°53.617′ N, 087°35.433′ W; then south to 41°53.400′ N, 087°35.433′ W; then west to 41°53.400′ N, 087°35.917′ W; then north to 41°53.617′ N, 087°35.917′ W; then back to point of origin.	6 days—During the first two weeks of August; 8 a.m. to 8 p.m.
(14) Ottawa Riverfest Fireworks	Ottawa, IL. All waters of the Illinois River, at mile 239.7, within the arc of a circle with a 300-foot radius from the fireworks launch site located in position 41°20.483′ N, 088°51.333′ W.	1 day—The first Sunday of August; 9 p.m. to 11 p.m.
(15) North Point Marina Venetian Festival Fireworks.	Winthrop Harbor, IL. All waters of Lake Michigan within the arc of a circle with a 1,000-foot radius from the fireworks launch site located in position 42°28.917′ N, 087°47.933′ W.	1 day—The second Saturday of August; 9 p.m. to 11 p.m.
(16) Chicago Air and Water Show	Chicago, IL. All waters and adjacent shoreline of Lake Michigan and Chicago Harbor bounded by a line drawn from 41°55.900′ N at the shoreline, then east to 41°55.900′ N, 087°37.200′ W, then southeast to 41°54.000′ N, 087°36.000′ W, then southwestward to the northeast corner of the Jardine Water Filtration Plant, then due west to the shore.	4 days—Mid-August; 8:30 a.m. to 5 p.m.
(17) Fireworks Display	Winnetka, IL. All waters of Lake Michigan within the arc of a circle with a 900-foot radius from a center point barge located in approximate position 42°06.402′ N, 087°43.115′ W.	1 day—Third Saturday of August; 9:15 p.m. to 10:30 p.m.
(18) Venetian Night Parade	Chicago, IL. All waters of Lake Michigan, in the vicinity of Navy Pier, bounded by coordinates beginning at 41°53.771′ N, 087°35.815′ W; and then south to 41°53.367′ N, 087°35.814′ W; then west to 41°53.363′ N, 087°36.587′ W; then north to 41°53.770′ N, 087°36.601′ W; then east back to the point of origin.	1 day—Last Saturday of August; 6:30 p.m. to 9:30 p.m.
(19) Corn Festival Fireworks	Morris, IL. All waters of the Illinois River within a 560-foot radius from approximate launch position at 41°21.173′ N, 088°25.101′ W.	1 day—The first Saturday of October; 8:15 p.m. to 9:15 p.m.

TABLE 1 TO § 165.929—SAFETY ZONES IN THE STATE OF ILLINOIS—Continued

Event	Location [1]	Enforcement date [2]
(20) Magnificent Mile Fireworks Display.	Chicago, IL. All waters and adjacent shoreline of the Chicago River bounded by the arc of the circle with a 210-foot radius from the fireworks launch site with its center in approximate position of 41°53.350′ N, 087°37.400′ W.	1 day—The third weekend in November; sunset to termination of display.
(21) New Year's Eve Fireworks	Chicago, IL. All waters of Monroe Harbor and Lake Michigan within the arc of a circle with a 1,000-foot radius from the fireworks launch site located on a barge in approximate position 41°52.683′ N, 087°36.617′ W.	1 day—December 31; 11 p.m. to January 1 at 1 a.m.

[1] All coordinates listed in Table 1 of this section reference Datum NAD 1983.
[2] As noted in paragraph (a)(3) of this section, the enforcement dates and times for each of the listed safety zones are subject to change.

TABLE 2 TO § 165.929—SAFETY ZONES IN THE STATE OF INDIANA

Event	Location [1]	Enforcement date and time [2]
(1) Gary Air and Water Show	Gary, IN. All waters of Lake Michigan bounded by a line drawn from 41°37.217′ N, 087°16.763′ W; then east along the shoreline to 41°37.413′ N, 087°13.822′ W; then north to 41°38.017′ N, 087°13.877′ W; then southwest to 41°37.805′ N, 087°16.767′ W; then south returning to the point of origin.	5 days—During the first two weeks of July; 8:30 a.m. to 5 p.m.
(2) Town of Dune Acres Independence Day Fireworks.	Dune Acres, IN. All waters of Lake Michigan within the arc of a circle with a 700-foot radius from the fireworks launch site located in position 41°39.303′ N, 087°05.239′ W.	1 day—On or around July 4; 8:45 p.m. to 10:30 p.m.
(3) Gary Fourth of July Fireworks ...	Gary, IN. All waters of Lake Michigan, approximately 2.5 miles east of Gary Harbor, within the arc of a circle with a 500-foot radius from the fireworks launch site located in position 41°37.322′ N, 087°14.509′ W.	1 day—On or around July 4; 9 p.m. to 11 p.m.
(4) Town of Porter Fireworks Display.	Porter, IN. All waters of Lake Michigan within the arc of a circle with a 1,000-foot radius from the fireworks launch site located in center position 41°39.927′ N, 087°03.933′ W.	1 day—On or around July 4; 8:45 p.m. to 9:30 p.m.
(5) Michigan City Summerfest Fireworks.	Michigan City, IN. All waters of Michigan City Harbor and Lake Michigan within the arc of a circle with a 1,000-foot radius from the fireworks launch site located in position 41°43.700′ N, 086°54.617′ W.	1 day—Sunday of the second complete weekend of July; 8:30 p.m. to 10:30 p.m.
(6) Hammond Marina Venetian Night Fireworks.	Hammond, IN. All waters of Hammond Marina and Lake Michigan within the arc of a circle with a 1,000-foot radius from the fireworks launch site located in position 41°41.883′ N, 087°30.717′ W.	1 day—The first Saturday of August; 9 p.m. to 11 p.m.
(7) Super Boat Grand Prix	Michigan City, IN. All waters of Lake Michigan bounded by a rectangle drawn from 41°43.655′ N, 086°54.550′ W; then northeast to 41°44.808′ N, 086°51.293′ W, then northwest to 41°45.195′ N, 086°51.757′ W; then southwest to 41°44.063′ N, 086°54.873′ W; then southeast returning to the point of origin.	1 day—The first Sunday of August; 9 a.m. to 4 p.m. Rain date: The first Saturday of August; 9 a.m. to 4 p.m.

[1] All coordinates listed in Table 2 of this section reference Datum NAD 1983.
[2] As noted in paragraph (a)(3) of this section, the enforcement dates and times for each of the listed safety zones are subject to change.

TABLE 3 TO § 165.929—SAFETY ZONES IN THE STATE OF MICHIGAN

Event	Location [1]	Enforcement date and time [2]
(1) Michigan Aerospace Challenge Sport Rocket Launch.	Muskegon, MI. All waters of Muskegon Lake, near the West Michigan Dock and Market Corp facility, within the arc of a circle with a 1,500-yard radius from the rocket launch site located in position 43°14.018′ N, 086°15.585′ W.	1 day—The last Saturday of April; 8 a.m. to 4 p.m.
(2) Tulip Time Festival Fireworks ...	Holland, MI. All waters of Lake Macatawa, near Kollen Park, within the arc of a circle with a 1,000-foot radius from the fireworks launch site in approximate center position 42°47.496′ N, 086°07.348′ W.	1 day—The first Saturday of May; 9:30 p.m. to 11:30 p.m. Rain date: The first Friday of May; 9:30 p.m. to 11:30 p.m.
(3) Spring Lake Heritage Festival Fireworks.	Spring Lake, MI. All waters of the Grand River within the arc of a circle with a 700-foot radius from a barge in center position 43°04.375′ N, 086°12.401′ W.	1 day—The third Saturday of June; 9 p.m. to 11 p.m.
(4) Elberta Solstice Festival	Elberta, MI. All waters of Betsie Lake within the arc of a circle with a 500-foot radius from the fireworks launch site located in approximate center position 44°37.607′ N, 086°13.977′ W.	1 day—The last Saturday of June; 9 p.m. to 11 p.m.
(5) World War II Beach Invasion Re-enactment.	St. Joseph, MI. All waters of Lake Michigan in the vicinity of Tiscornia Park in St. Joseph, MI beginning at 42°06.918′ N, 086°29.421′ W; then west/northwest along the north breakwater to 42°06.980′ N, 086°29.682′ W; then northwest 100 yards to 42°07.018′ N, 086°29.728′ W; then northeast 2,243 yards to 42°07.831′ N, 086°28.721′ W; then southeast to the shoreline at 42°07.646′ N, 086°28.457′ W; then southwest along the shoreline to the point of origin.	1 day—The last Saturday of June; 8 a.m. to 2 p.m.

TABLE 3 TO § 165.929—SAFETY ZONES IN THE STATE OF MICHIGAN—Continued

Event	Location [1]	Enforcement date and time [2]
(6) Frankfort Independence Day Fireworks.	Frankfort, MI. All waters of Lake Michigan and Frankfort Harbor, bounded by a line drawn from 44°38.100′ N, 086°14.826′ W; then south to 44°37.613′ N, 086°14.802′ W; then west to 44°37.613′ N, 086°15.263′ W; then north to 44°38.094′ N, 086°15.263′ W; then east returning to the point of origin.	1 day—On or around July 4; 9 p.m. to 11 p.m.
(7) Grand Haven Jaycees Annual Fourth of July Fireworks.	Grand Haven, MI. All waters of the Grand River within the arc of a circle with a 800-foot radius from the fireworks launch site located on the west bank of the Grand River in position 43°3.908′ N, 086°14.240′ W.	1 day—On or around July 4; 9 p.m. to 11:30 p.m.
(8) Celebration Freedom Fireworks	Holland, MI. All waters of Lake Macatawa in the vicinity of Kollen Park within the arc of a circle with a 2,000-foot radius of a center launch position at 42°47.440′ N, 086°07.621′ W.	1 day—On or around July 4; 10 p.m. to 11:59 p.m.
(9) Van Andel Fireworks Show	Holland, MI. All waters of Lake Michigan and the Holland Channel within the arc of a circle with a 1,000-foot radius from the fireworks launch site located in approximate position 42°46.351′ N, 086°12.710′ W.	1 day—On or around July 4; 9 p.m. to 11 p.m.
(10) Freedom Festival Fireworks	Ludington, MI. All waters of Lake Michigan and Ludington Harbor within the arc of a circle with a 800-foot radius from the fireworks launch site located in position 43°57.171′ N, 086°27.718′ W.	1 day—On or around July 4; 9 p.m. to 11 p.m.
(11) Manistee Independence Day Fireworks.	Manistee, MI. All waters of Lake Michigan, in the vicinity of the First Street Beach, within the arc of a circle with a 1,000-foot radius from the fireworks launch site located in position 44°14.854′ N, 086°20.757′ W.	1 day—On or around July 4; 9 p.m. to 11 p.m.
(12) City of Menominee 4th of July Celebration Fireworks.	Menominee, MI. All waters of Green Bay, in the vicinity of Menominee Marina, within the arc of a circle with a 900-foot radius from a center position at 45°06.417′ N, 087°36.024′ W.	1 day—On or around July 4; 9 p.m. to 11 p.m.
(13) White Lake Independence Day Fireworks.	Montague, MI. All waters of White Lake within the arc of a circle with an 800-foot radius from a center position at 43°24.621′ N, 086°21.463′ W.	1 day—On or around July 4; 9:30 p.m. to 11:30 p.m.
(14) Muskegon Summer Celebration July Fourth Fireworks.	Muskegon, MI. All waters of Muskegon Lake, in the vicinity of Hartshorn Municipal Marina, within the arc of a circle with a 700-foot radius from a center position at 43°14.039′ N, 086°15.793′ W.	1 day—On or around July 4; 9 p.m. to 11 p.m.
(15) New Buffalo Business Association Fireworks.	New Buffalo, MI. All waters of Lake Michigan and New Buffalo Harbor within the arc of a circle with a 800-foot radius from the fireworks launch site located in position 41°48.153′ N, 086°44.823′ W.	1 day—On or around July 4; 9:30 p.m. to 11:15 p.m.
(16) Pentwater July Third Fireworks	Pentwater, MI. All waters of Lake Michigan and the Pentwater Channel within the arc of a circle with a 1,000-foot radius from the fireworks launch site located in position 43°46.942′ N, 086°26.625′ W.	1 day—On or around July 4; 9 p.m. to 11 p.m.
(17) Saugatuck Independence Day Fireworks.	Saugatuck, MI. All waters of Kalamazoo Lake within the arc of a circle with a 500-foot radius from the fireworks launch site in center position 42°39.074′ N, 086°12.285′ W.	1 day—On or around July 4; 9 p.m. to 11 p.m.
(18) South Haven Fourth of July Fireworks.	South Haven, MI. All waters of Lake Michigan and the Black River within the arc of a circle with a 1,000-foot radius from the fireworks launch site located in center position 42°24.125′ N, 086°17.179′ W.	1 day—On or around July 4; 9:30 p.m. to 11:30 p.m.
(19) St. Joseph Fourth of July Fireworks.	St. Joseph, MI. All waters of Lake Michigan and the St. Joseph River within the arc of a circle with a 1,000-foot radius from the fireworks launch site in position 42°06.867′ N, 086°29.463′ W.	1 day—On or around July 4; 9 p.m. to 11 p.m.
(20) Venetian Festival Fireworks	St. Joseph, MI. All waters of Lake Michigan and the St. Joseph River, near the east end of the south pier, within the arc of a circle with a 1,000-foot radius from the fireworks launch site located in position 42°06.800′ N, 086°29.250′ W.	1 day—Saturday of the third complete weekend of July; 9 p.m. to 11 p.m.
(21) Grand Haven Coast Guard Festival Fireworks.	Grand Haven, MI. All waters of the Grand River within the arc of a circle with an 800-foot radius from the fireworks launch site located on the west bank of the Grand River in position 43°03.907′ N, 086°14.247′ W.	1 day—The last week of July or the first week of August; 9 p.m. to 11 p.m.
(22) Saugatuck Venetian Night Fireworks.	Saugatuck, MI. All waters of Kalamazoo Lake within the arc of a circle with a 500-foot radius from the fireworks launch site located on a barge in position 42°39.073′ N, 086°12.285′ W.	1 day—The last Saturday of July; 9 p.m. to 11 p.m.
(23) Waterfront Festival Fireworks ..	Menominee, MI. All waters of Green Bay, in the vicinity of Menominee Marina, within the arc of a circle with a 1,000-foot radius from a center position at 45°06.447′ N, 087°35.991′ W.	1 day—On or around August 3; 9 p.m. to 11 p.m.
(24) New Buffalo Ship and Shore Fireworks.	New Buffalo, MI. All waters of Lake Michigan and New Buffalo Harbor within the arc of a circle with a 800-foot radius from the fireworks launch site located in position 41°48.150′ N, 086°44.817′ W.	1 day—On or around August 10; 9:30 p.m. to 11:15 p.m.
(25) Pentwater Homecoming Fireworks.	Pentwater, MI. All waters of Lake Michigan and the Pentwater Channel within the arc of a circle with a 1,000-foot radius from the fireworks launch site located in position 43°46.942′ N, 086°26.633′ W.	1 day—The Saturday following the second Thursday of August; 9 p.m. to 11 p.m.

[1] All coordinates listed in Table 3 of this section reference Datum NAD 1983.

[2] As noted in paragraph (a)(3) of this section, the enforcement dates and times for each of the listed safety zones are subject to change.

TABLE 4 TO § 165.929—SAFETY ZONES IN THE STATE OF WISCONSIN

Event	Location [1]	Enforcement date [2]
(1) Fireworks at Pier Wisconsin	Milwaukee, WI. All waters of Milwaukee Harbor, including Lakeshore Inlet and the marina at Pier Wisconsin, within the arc of a circle with a 300-foot radius from the fireworks launch site on Pier Wisconsin located at approximate position 43°02.178′ N, 087°53.625′ W.	Dates and times will be issued by Notice of Enforcement and Broadcast Notice to Mariners.
(2) Events at Lakeshore State Park and/or Henry Maier Festival Park.	Milwaukee, WI. All waters of Lake Michigan within Milwaukee Harbor, including the Harbor Island Lagoon, enclosed by a line connecting the following points: 43°02.000′ N, 087°53.883′ W; then south to 43°01.733′ N, 087°53.883′ W; then east to 43°01.733′ N, 087°53.417′ W; then north to 43°02.000′ N, 087°53.417′ W; then west to the point of origin..	Dates and times will be issued by Notice of Enforcement and Broadcast Notice to Mariners.
(3) Operations at Marinette Marine	Marinette, WI. All waters of the Menominee River between the Highway 41 Bridge and the Ogden Street Bridge from coordinates: 45°06.186′ N, 087°37.592′ W; then southeast to 45°05.760′ N, 087°35.883′ W.	Dates and times will be issued by Notice of Enforcement and Broadcast Notice to Mariners.
(4) Public Fireworks Display	Green Bay, WI. All waters of the Fox River in the vicinity of the Main Street and Walnut Street Bridge within an area bounded by the following coordinates; 44°31.211′ N, 088°00.833′ W; then southwest along the river bank to 44°30.944′ N, 088°01.159′ W; then southeast to 44°30.890′ N, 088°01.016′ W; then northeast along the river bank to 44°31.074′ N, 088°00.866′ W; then northwest returning to the point of origin.	1 day—On or around March 15; 11:50 a.m. to 12:30 p.m.
(5) St. Patrick's Day Fireworks	Manitowoc, WI. All waters of the Manitowoc River within the arc of a circle with a 250-foot radius from a center point launch position at 44°05.492′ N, 087°39.332′ W.	1 day—The third Saturday of March; 5:30 p.m. to 7 p.m.
(6) Rockets for Schools Rocket Launch.	Sheboygan, WI. All waters of Lake Michigan and Sheboygan Harbor, near the Sheboygan South Pier, within the arc of a circle with a 1,500-yard radius from the rocket launch site located with its center in position 43°44.914′ N, 087°41.869′ W.	1 day—The first Saturday of May; 8 a.m. to 5 p.m.
(7) Celebrate De Pere Fireworks	De Pere, WI. All waters of the Fox River, near Voyageur Park, within the arc of a circle with a 500-foot radius from the fireworks launch site located in position 44°27.167′ N, 088°03.833′ W.	1 day—The Saturday or Sunday before Memorial Day; 8:30 p.m. to 10 p.m.
(8) International Bayfest	Green Bay, WI. All waters of the Fox River, near the Western Lime Company 1.13 miles above the head of the Fox River, within the arc of a circle with a 1,000-foot radius from the fireworks launch site located in position 44°31.408′ N, 088°00.710′ W.	1 day—The second Friday of June; 9 p.m. to 11 p.m.
(9) Sheboygan Harborfest Fireworks.	Sheboygan, WI. All waters of Lake Michigan and Sheboygan Harbor within the arc of a circle with a 1,000-foot radius from the fireworks launch site located in position 43°44.914′ N, 087°41.897′ W.	1 day—On or around June 15; 8:45 p.m. to 10:45 p.m.
(10) Harborfest Music and Family Festival.	Racine, WI. All waters of Lake Michigan and Racine Harbor, near the Racine Launch Basin Entrance Light, within the arc of a circle with a 200-foot radius from the fireworks launch site located in position 42°43.722′ N, 087°46.673′ W.	2 days—Friday and Saturday of the third complete weekend of June; 9 p.m. to 11 p.m. each day.
(11) Ephraim Fireworks	Ephraim, WI. All waters of Eagle Harbor and Lake Michigan within the arc of a circle with a 750-foot radius from the fireworks launch site located on a barge in position 45°09.304′ N, 087°10.844′ W.	1 day—The third Saturday of June; 9 p.m. to 11 p.m.
(12) Olde Ellison Bay Days Fireworks.	Ellison Bay, WI. All waters of Green Bay, in the vicinity of Ellison Bay Wisconsin, within the arc of a circle with a 400-foot radius from the fireworks launch site located on a barge in approximate center position 45°15.595′ N, 087°05.043′ W.	1 day—The fourth Saturday of June; 9 p.m. to 10 p.m.
(13) Fish Creek Independence	Fish Creek, WI. All waters of Green Bay, in the vicinity of Fish Creek Harbor, within the arc of a circle with a 1,000-foot radius from the fireworks launch site located on a barge in position 45°07.867′ N, 087°14.617′ W.	1 day—On or around July 4; 9 p.m. to 11 p.m.
(14) Gills Rock Fireworks	Gills Rock, WI. All waters of Green Bay near Gills Rock, WI within a 1,000-foot radius of the launch vessel in approximate position at 45°17.470′ N, 087°01.728′ W.	1 day—On or around July 4; 8:30 p.m. to 10:30 p.m.
(15) Fire over the Fox Fireworks	Green Bay, WI. All waters of the Fox River including the mouth of the East River from the Canadian National Railroad Bridge in approximate position 44°31.467′ N, 088°00.633′ W then southwest to the Main St. Bridge in approximate position 44°31.102′ N, 088°00.963′ W.	1 day—On or around July 4; 9 p.m. to 11 p.m.
(16) Kenosha Independence Day Fireworks.	Kenosha, WI. All waters of Lake Michigan and Kenosha Harbor within the arc of a circle with a 1,000-foot radius from the fireworks launch site located in position 42°35.283′ N, 087°48.450′ W.	1 day—On or around July 4; 9 p.m. to 11 p.m.
(17) Holiday Celebration Fireworks	Kewaunee, WI. All waters of Kewaunee Harbor and Lake Michigan within the arc of a circle with a 1,000-foot radius from the fireworks launch site located in position 44°27.481′ N, 087°29.735′ W.	1 day—On or around July 4; 8:30 p.m. to 10:30 p.m.

TABLE 4 TO § 165.929—SAFETY ZONES IN THE STATE OF WISCONSIN—Continued

Event	Location [1]	Enforcement date [2]
(18) Manitowoc Independence Day Fireworks.	Manitowoc, WI. All waters of Lake Michigan and Manitowoc Harbor, in the vicinity of south breakwater, within the arc of a circle with a 1,000-foot radius from the fireworks launch site located in position 44°05.395′ N, 087°38.751′ W.	1 day—On or around July 4; 9 p.m. to 11 p.m.
(19) Marinette Fourth of July Celebration Fireworks.	Marinette, WI. All waters of the Menominee River, in the vicinity of Stephenson Island, within the arc of a circle with a 900-foot radius from the fireworks launch site in center position 45°6.232′ N, 087°37.757′ W.	1 day—On or around July 4; 9 p.m. to 11 p.m.
(20) City of Menasha 4th of July Fireworks.	Menasha, WI. All waters of Lake Winnebago and the Fox River within the arc of a circle with an 800-foot radius from the fireworks launch site located in center position 44°12.017′ N, 088°25.904′ W.	1 day—On or around July 4; 9 p.m. to 10:30 p.m.
(21) U.S. Bank Fireworks	Milwaukee, WI. All waters and adjacent shoreline of Milwaukee Harbor, in the vicinity of Veteran's Park, within the arc of a circle with a 1,200-foot radius from the center of the fireworks launch site which is located on a barge in approximate position 43°02.362′ N, 087°53.485′ W.	1 day—On or around July 4; 8:30 p.m. to 11 p.m.
(22) Neenah Fireworks	Neenah, WI. All waters of Lake Winnebago within a 700-foot radius of an approximate launch position at 44°11.126′ N, 088°26.941′ W.	1 day—On or around July 4; 8:45 p.m. to 10:30 p.m.
(23) Fourthfest of Greater Racine Fireworks.	Racine, WI. All waters of Racine Harbor and Lake Michigan within the arc of a circle with a 900-foot radius from a center point position at 42°44.259′ N, 087°46.635′ W.	1 day—On or around July 4; 9 p.m. to 11 p.m.
(24) Sheboygan Fourth of July Celebration Fireworks.	Sheboygan, WI. All waters of Lake Michigan and Sheboygan Harbor, in the vicinity of the south pier, within the arc of a circle with a 1,000-foot radius from the fireworks launch site located in position 43°44.917′ N, 087°41.850′ W.	1 day—On or around July 4; 9 p.m. to 11 p.m.
(25) Sturgeon Bay Independence Day Fireworks.	Sturgeon Bay, WI. All waters of Sturgeon Bay, in the vicinity of Sunset Park, within the arc of a circle with a 1,000-foot radius from the fireworks launch site located on a barge in position 44°50.562′ N, 087°23.411′ W.	1 day—On or around July 4; 9 p.m. to 11 p.m.
(26) Annual Trout Festival Fireworks.	Kewaunee, WI. All waters of Kewaunee Harbor and Lake Michigan within the arc of a circle with a 1,000-foot radius from the fireworks launch site located in position 44°27.493′ N, 087°29.750′ W.	1 day—Friday of the second complete weekend of July; 9 p.m. to 11 p.m.
(27) Marinette Logging and Heritage Festival Fireworks.	Marinette, WI. All waters of the Menominee River, in the vicinity of Stephenson Island, within the arc of a circle with a 900-foot radius from the fireworks launch site in position 45°06.232′ N, 087°37.757′ W.	1 day—On or around July 13; 9 p.m. to 11 p.m.
(28) Bay View Lions Club South Shore Frolics Fireworks.	Milwaukee, WI. All waters of Lake Michigan and Milwaukee Harbor, in the vicinity of South Shore Yacht Club, within the arc of a circle with a 900-foot radius from the fireworks launch site in position 42°59.658′ N, 087°52.808′ W.	3 days—Friday, Saturday, and Sunday of the second or third weekend of July; 9 p.m. to 11 p.m. each day.
(29) Milwaukee Air and Water Show.	Milwaukee, WI. All waters of Lake Michigan in the vicinity of McKinley Park and Bradford Beach located within an area that is approximately 5,000 yards by 1,500 yards. The area will be bounded by the points beginning at 43°02.455′ N, 087°52.880′ W; then southeast to 43°02.230′ N, 087°52.061′ W; then northeast to 43°04.451′ N, 087°50.503′ W; then northwest to 43°04.738′ N, 087°51.445′ W; then southwest to 43°02.848′ N, 087°52.772′ W; then returning to the point of origin.	3 days—Third weekend in July; 8 a.m. to 5 p.m.
(30) Port Washington Fish Day Fireworks.	Port Washington, WI. All waters of Port Washington Harbor and Lake Michigan, in the vicinity of the WE Energies coal dock, within the arc of a circle with a 1,000-foot radius from the fireworks launch site located in position 43°23.117′ N, 087°51.900′ W.	1 day—The third Saturday of July; 9 p.m. to 11 p.m.
(31) Miesfeld's Lakeshore Weekend Fireworks.	Sheboygan, WI. All waters of Lake Michigan and Sheboygan Harbor within an 800-foot radius from the fireworks launch site located at the south pier in approximate position 43°44.917′ N, 087°41.967′ W.	1 day—On or around July 29; 9 p.m. to 10:30 p.m.
(32) EAA Airventure	Oshkosh, WI. All waters of Lake Winnebago in the vicinity of Willow Harbor within an area bounded by a line connecting the following coordinates: Beginning at 43°56.822′ N, 088°29.904′ W; then north approximately 5,100 feet to 43°57.653′ N, 088°29.904′ W, then east approximately 2,300 feet to 43°57.653′ N, 088°29.374′ W; then south to shore at 43°56.933′ N, 088°29.374′ W; then southwest along the shoreline to 43°56.822′ N, 088°29.564′ W; then west returning to the point of origin.	7 days—The last complete week of July, beginning Monday and ending Sunday; 8 a.m. to 8 p.m. each day.
(33) Roma Lodge Italian Festival Fireworks.	Racine, WI. All waters of Lake Michigan and Racine Harbor within the arc of a circle with a 1,000-foot radius from the fireworks launch site located in position 42°44.067′ N, 087°46.333′ W.	2 days—Friday and Saturday of the last complete weekend of July; 9 p.m. to 11 p.m.
(34) Port Washington Maritime Heritage Festival Fireworks.	Port Washington, WI. All waters of Port Washington Harbor and Lake Michigan, in the vicinity of the WE Energies coal dock, within the arc of a circle with a 1,000-foot radius from the fireworks launch site located in position 43°23.117′ N, 087°51.900′ W.	1 day—Saturday of the last complete weekend of July or the second weekend of August; 9 p.m. to 11 p.m.

TABLE 4 TO § 165.929—SAFETY ZONES IN THE STATE OF WISCONSIN—Continued

Event	Location [1]	Enforcement date [2]
(35) Sturgeon Bay Yacht Club Evening on the Bay Fireworks.	Sturgeon Bay, WI. All waters of Sturgeon Bay within the arc of a circle with a 500-foot radius from the fireworks launch site located on a barge in approximate position 44°49.297′ N, 087°21.447′ W.	1 day—The first Saturday of August; 8:30 p.m. to 10:30 p.m.
(36) Algoma Shanty Days Fireworks.	Algoma, WI. All waters of Lake Michigan and Algoma Harbor within the arc of a circle with a 1,000-foot radius from the fireworks launch site located in a center position of 44°36.400′ N, 087°25.900′ W.	1 day—Sunday of the second complete weekend of August; 9 p.m. to 11 p.m.
(37) Sister Bay Marinafest Fireworks.	Sister Bay, WI. All waters of Sister Bay within an 800-foot radius of the launch vessel in approximate position 45°11.585′ N, 087°07.392′ W.	1 day—On or around September 3 and 4; 8:15 p.m. to 10 p.m.
(38) ISAF Nations Cup Grand Final Fireworks Display.	Sheboygan, WI. All waters of Lake Michigan and Sheboygan Harbor, in the vicinity of the south pier in Sheboygan, Wisconsin, within a 500-foot radius from the fireworks launch site located on land in position 43°44.917′ N, 087°41.850′ W.	1 day—On or around September 13; 7:45 p.m. to 8:45 p.m.
(39) Downtown Milwaukee Fireworks.	Milwaukee, WI. All waters of the Milwaukee River in the vicinity of the State Street Bridge within the arc of a circle with a 300-foot radius from a center point fireworks launch site in approximate position 43°02.559′ N, 087°54.749′ W.	1 day—The third Thursday of November; 6 p.m. to 8 p.m.

[1] All coordinates listed in Table 4 of this section reference Datum NAD 1983.
[2] As noted in paragraph (a)(3) of this section, the enforcement dates and times for each of the listed safety zones are subject to change.

§ 165.935 [Removed]

■ 3. Remove § 165.935.

Dated: May 5, 2020.

T. J. Stuhlreyer,

Captain, U.S. Coast Guard, Captain of the Port Lake Michigan.

[FR Doc. 2020–09877 Filed 6–1–20; 8:45 am]

BILLING CODE 9110–04–P

DEPARTMENT OF HOMELAND SECURITY

Coast Guard

33 CFR Part 165

[Docket Number USCG–2020–0037]

RIN 1625–AA00

Safety Zones; Coast Guard Sector Ohio Valley Annual and Recurring Safety Zones Update

AGENCY: Coast Guard, DHS.

ACTION: Final rule.

SUMMARY: The Coast Guard is amending and updating its safety zones regulations for annual events that take place in the Coast Guard Sector Ohio Valley area. This action is necessary to update the current list of recurring safety zones with revisions, additional events, and removal of events that no longer take place in Sector Ohio Valley. This regulation restricts vessel traffic from the safety zones during the events unless authorized by the Captain of the Port Sector Ohio Valley or a designated representative.

DATES: This rule is effective June 2, 2020.

ADDRESSES: To view documents mentioned in this preamble as being available in the docket, go to *https://www.regulations.gov,* type USCG–2020–0037 in the ''SEARCH'' box and click ''SEARCH.'' Click on Open Docket Folder on the line associated with this rule.

FOR FURTHER INFORMATION CONTACT: If you have questions on this rule, call or email Petty Officer Riley Jackson, Sector Ohio Valley, U.S. Coast Guard; telephone (502) 779–5347, email *Riley.S.Jackson@uscg.mil.*

SUPPLEMENTARY INFORMATION:

I. Table of Abbreviations

CFR Code of Federal Regulations
COTP Captain of the Port Sector Ohio Valley
DHS Department of Homeland Security
FR Federal Register
NPRM Notice of proposed rulemaking
§ Section
U.S.C. United States Code
AOR Area of Responsibility

II. Background Information and Regulatory History

The Captain of the Port Sector Ohio Valley (COTP) is amending 33 CFR 165.801 to update the table of annual fireworks displays and other marine-related events in Coast Guard Sector Ohio Valley. These events include air shows, fireworks displays, and other marine related events requiring a limited access area restricting vessel traffic for safety purposes.

On February 14, 2020, the Coast Guard published a notice of proposed rulemaking (NPRM) titled ''Safety Zones; Coast Guard Sector Ohio Valley Annual and Recurring Safety Zones Update'' (85 FR 8509). There we stated why we issued the NPRM, and invited comments on our proposed regulatory action related to those recurring safety zones. During the comment period that ended on March 16, 2020, no comments were received.

Under 5 U.S.C. 553(d)(3), the Coast Guard finds that good cause exists for making it effective less than 30 days after publication in the **Federal Register**. Delaying the effective date of this rule would be impracticable and contrary to the public interest because immediate action is necessary to respond to the potential safety hazards associated with these marine events.

III. Legal Authority and Need for Rule

The Coast Guard is issuing this rule under authority in 46 U.S.C. 70034 (previously 33 U.S.C. 1231). Based on the nature of these marine events, large numbers of participants and spectators, and event locations, the COTP has determined that the events listed in this rule could pose a risk to participants or waterways users if the normal vessel traffic were to interfere with the events. Possible hazards include risks of injury or death from near or actual contact among participant vessels and spectators or mariners traversing through the regulated area. This purpose of this rule is to ensure the safety of all waterway users, including event participants and spectators, during the scheduled events.

IV. Discussion of Comments, Changes, and the Rule

As noted above, we received no comments on our NPRM published February 14, 2020. There are no changes in the regulatory text of this rule from the proposed rule on the NPRM.

V. Regulatory Analyses

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

A. Regulatory Planning and Review

Executive Orders 12866 and 13563 direct agencies to assess the costs and benefits of available regulatory alternatives and, if regulation is necessary, to select regulatory approaches that maximize net benefits. Executive Order 13771 directs agencies to control regulatory costs through a budgeting process. This rule has not been designated a ''significant regulatory action,'' under Executive Order 12866. Accordingly, this rule has not been reviewed by the Office of Management and Budget (OMB), and pursuant to OMB guidance it is exempt from the requirements of Executive Order 13771.

This regulatory action determination is based on the size, location, and duration of the safety zones. These safety zones are limited in size and duration, and are usually positioned away from high vessel traffic areas. Moreover, the Coast Guard would issue a Broadcast Notice to Mariners via VHF–FM marine channel 16 about the zones, and the rule would allow vessels to seek permission to enter the zones.

B. Impact on Small Entities

The Regulatory Flexibility Act of 1980, 5 U.S.C. 601–612, as amended, requires Federal agencies to consider the potential impact of regulations on small entities during rulemaking. The term ''small entities'' comprises small businesses, not-for-profit organizations that are independently owned and operated and are not dominant in their fields, and governmental jurisdictions with populations of less than 50,000. The Coast Guard received no comments from the Small Business Administration on this rulemaking. The Coast Guard certifies under 5 U.S.C. 605(b) that this rule will not have a significant economic impact on a substantial number of small entities.

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

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

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

C. Collection of Information

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

D. Federalism and Indian Tribal Governments

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

Also, this rule does not have tribal implications under Executive Order 13175, Consultation and Coordination with Indian Tribal Governments, because it does not have a substantial direct effect on one or more Indian tribes, on the relationship between the Federal Government and Indian tribes, or on the distribution of power and responsibilities between the Federal Government and Indian tribes.

E. Unfunded Mandates Reform Act

The Unfunded Mandates Reform Act of 1995 (2 U.S.C. 1531–1538) requires Federal agencies to assess the effects of their discretionary regulatory actions. In particular, the Act addresses actions that may result in the expenditure by a State, local, or tribal government, in the aggregate, or by the private sector of $100,000,000 (adjusted for inflation) or more in any one year. Though this rule will not result in such an expenditure, we do discuss the effects of this rule elsewhere in this preamble.

F. Environment

We have analyzed this rule under Department of Homeland Security Directive 023–01, Rev. 1, associated implementing instructions, and Environmental Planning COMDTINST 5090.1 (series), which guide the Coast Guard in complying with the National Environmental Policy Act of 1969 (42 U.S.C. 4321–4370f), and have determined that this action is one of a category of actions that do not individually or cumulatively have a significant effect on the human environment. It is categorically excluded from further review under paragraph L(60a) of Appendix A, Table 1 of DHS Instruction Manual 023–01–001–01, Rev. 1. A Record of Environmental Consideration supporting this determination is available in the docket. For instructions on locating the docket, see the **ADDRESSES** section of this preamble. We prepare a preliminary REC for these types of field regulations because the DHS Instruction Manual (and U.S. Coast Guard Environmental Planning Implementing Procedures) direct that a REC be prepared for these specified field regulations when certain conditions apply—see L59(a), L60(a), and L60(d).

G. Protest Activities

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

List of Subjects in 33 CFR Part 165

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

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

PART 165—REGULATED NAVIGATION AREAS AND LIMITED ACCESS AREAS

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

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

Department of Homeland Security Delegation No. 0170.1.

■ 2. In § 165.801, revise table 1 to read as follows:

§ 165.801 Annual fireworks displays and other events in the Eighth Coast Guard District requiring safety zones.

* * * * *

TABLE 1 OF § 165.801—SECTOR OHIO VALLEY ANNUAL AND RECURRING SAFETY ZONES

Date	Sponsor/name	Sector Ohio Valley location	Safety zone
1. 3 days—Third or Fourth weekend in April.	Henderson Breakfast Lions Club Tri-Fest	Henderson, KY	Ohio River, Miles 802.5–805.5 (Kentucky).
2. Multiple days—April through November.	Pittsburgh Pirates Season Fireworks	Pittsburgh, PA	Allegheny River, Miles 0.2–0.9 (Pennsylvania).
3. Multiple days—April through November.	Cincinnati Reds Season Fireworks	Cincinnati, OH	Ohio River, Miles 470.1–470.4; extending 500 ft. from the State of Ohio shoreline (Ohio).
4. Multiple days—April through November.	Pittsburgh Riverhounds Season Fireworks	Pittsburgh, PA	Monongahela River, Miles 0.22–0.77 (Pennsylvania).
5. 1 day—First week in May.	Belterra Park Gaming Fireworks	Cincinnati, OH	Ohio River, Miles 460.0–462.0 (Ohio).
6. 3 days in May	U.S. Rowing Southeast Youth Championship Regatta.	Oak Ridge, TN	Clinch River, Miles 48.5–52 (Tennessee).
7. 1 day—One Friday in May prior to Memorial Day.	Live on the Levee Memorial Day Fireworks/ City of Charleston.	Charleston, WV	Kanawha River, Mile 58.1–59.1 (West Virginia).
8. 1 day—Saturday before Memorial Day.	Venture Outdoors Festival	Pittsburgh, PA	Allegheny River, Miles 0.0–0.25; Monongahela River, Miles 0.0–0.25 (Pennsylvania).
9. 3 days in June	CMA Festival	Nashville, TN	Cumberland River, Miles 190.7–191.1 extending 100 feet from the left descending bank (Tennessee).
10. 1 day in June	Cumberland River Compact/Nashville Splash Bash.	Nashville, TN	Cumberland River, Miles 189.7–192.1 (Tennessee).
11. 2 days—A weekend in June.	Rice's Landing Riverfest	Rice's Landing, PA	Monongahela River, Miles 68.0–68.8 (Pennsylvania).
12. 2 days—Second Friday and Saturday in June.	City of Newport, KY/Italianfest	Newport, KY	Ohio River, Miles 468.6–471.0 (Kentucky and Ohio).
13. 1 day in June	Friends of the Festival, Inc./Riverbend Festival Fireworks.	Chattanooga, TN	Tennessee River, Miles 462.7–465.2 (Tennessee).
14. 1 day—Second or Third week of June.	TriState Pottery Festival Fireworks	East Liverpool, OH	Ohio River, Miles 42.5–45.0 (Ohio).
15. 3 days—One of the last three weekends in June.	Hadi Shrine/Evansville Freedom Festival Air Show.	Evansville, IN	Ohio River, Miles 790.0–796.0 (Indiana).
16. 1 day—One weekend in June.	West Virginia Symphony Orchestra/Symphony Sunday.	Charleston, WV	Kanawha River, Miles 59.5–60.5 (West Virginia).
17. 1 day—Last weekend in June or first weekend in July.	Riverview Park Independence Festival	Louisville, KY	Ohio River, Miles 617.5–620.5 (Kentucky).
18. 1 day—Last weekend in June or First weekend in July.	City of Point Pleasant/Point Pleasant Sternwheel Fireworks.	Point Pleasant, WV	Ohio River, Miles 265.2–266.2, Kanawha River Miles 0.0–0.5 (West Virginia).
19. 1 day—Last weekend in June or first weekend in July.	City of Aurora/Aurora Firecracker Festival	Aurora, IN	Ohio River, Mile 496.7; 1400 ft. radius from the Consolidated Grain Dock located along the State of Indiana shoreline at (Indiana and Kentucky).
20. 1 day—Last week of June or first week of July.	PUSH Beaver County/Beaver County Boom	Beaver, PA	Ohio River, Miles 25.2–25.6 (Pennsylvania).
21. 1 day—Last weekend in June or first week in July.	Evansville Freedom Celebration/4th of July Fireworks.	Evansville, IN	Ohio River, Miles 790.0–796.0 (Indiana).
22. 1 day—Last week in June or first week of July.	Newburgh Fireworks Display	Newburgh, IN	Ohio River, Miles 777.3–778.3 (Indiana).
23. 1 day—Last week in June or First week in July.	Rising Sun Fireworks	Rising Sun, IN	Ohio River, Miles 506.0–507.0 (Indiana).
24. 1 day—Weekend before the 4th of July.	Kentucky Dam Marine/Kentucky Dam Marina Fireworks.	Gilbertsville, KY	350 foot radius, from the fireworks launch site, on the entrance jetties at Kentucky Dam Marina, on the Tennessee River at Mile Marker 23 (Kentucky).
25. 1 day in July	Town of Cumberland City/Lighting up the Cumberlands.	Cumberland City, TN	Cumberland River, Miles 103.0–105.5 (Tennessee).

TABLE 1 OF § 165.801—SECTOR OHIO VALLEY ANNUAL AND RECURRING SAFETY ZONES—Continued

Date	Sponsor/name	Sector Ohio Valley location	Safety zone
26. 1 day in July	Chattanooga Presents/Pops on the River	Chattanooga, TN	Tennessee River, Miles 462.7–465.2 (Tennessee).
27. 1 day in July	Randy Boyd/Independence Celebration Fireworks Display.	Knoxville, TN	Tennessee River, Miles 625.0–628.0 (Tennessee).
28. 1 day—July 3rd	Moors Resort and Marina/Kentucky Lake Big Bang.	Gilbertsville, KY	600 foot radius, from the fireworks launch site, on the entrance jetty to Moors Resort and Marina, on the Tennessee River at mile marker 30.5. (Kentucky).
29. 1 day—3rd or 4th of July.	City of Paducah, KY	Paducah, KY	Ohio River, Miles 934.0–936.0; Tennessee River, Miles 0.0–1.0 (Kentucky).
30. 1 day—3rd or 4th of July.	City of Hickman, KY/Town of Hickman Fireworks.	Hickman, KY	700 foot radius from GPS coordinate 36°34.5035 N, 089°11.919 W, in Hickman Harbor located at mile marker 921.5 on the Lower Mississippi River (Kentucky).
31. 1 day—July 4th	City of Knoxville/Knoxville Festival on the 4th	Knoxville, TN	Tennessee River, Miles 646.3–648.7 (Tennessee).
32. 1 day in July	Nashville NCVC/Independence Celebration ...	Nashville, TN	Cumberland River, Miles 189.7–192.3 (Tennessee).
33. 1 day in July	Shoals Radio Group/Spirit of Freedom Fireworks.	Florence, AL	Tennessee River, Miles 254.5–257.4 (Alabama).
34. 1 day—4th of July (Rain date—July 5th).	Monongahela Area Chamber of Commerce/ Monongahela 4th of July Celebration.	Monongahela, PA	Monongahela River, Miles 032.0–033.0 (Pennsylvania).
35. 1 day—July 4th	Cities of Cincinnati, OH and Newport, KY/July 4th Fireworks.	Newport, KY	Ohio River, Miles 469.6–470.2 (Kentucky and Ohio).
36. 1 day—July 4th	Wellsburg 4th of July Committee/Wellsburg 4th of July Freedom Celebration.	Wellsburg, WV	Ohio River, Miles 73.5–74.5 (West Virginia).
37. 1 day—week of July 4th.	Wheeling Symphony fireworks	Wheeling, WV	Ohio River, Miles 90–92 (West Virginia).
38. 1 day—First week or weekend in July.	Summer Motions Inc./Summer Motion	Ashland, KY	Ohio River, Miles 322.1–323.1 (Kentucky).
39. 1 day—week of July 4th.	Chester Fireworks	Chester, WV	Ohio River mile 42.0–44.0 (West Virginia).
40. 1 day—First week of July.	Toronto 4th of July Fireworks	Toronto, OH	Ohio River, Mile 58.2–58.8 (Ohio).
41. 1 day—First week of July.	Cincinnati Symphony Orchestra	Cincinnati, OH	Ohio River, Miles 460.0–462.0 (Ohio).
42. 1 day—First weekend or week in July.	Queen's Landing Fireworks	Greenup, KY	Ohio River, Miles 339.3–340.3 (West Virginia).
43. 1 day—First week or weekend in July.	Gallia County Chamber of Commerce/Gallipolis River Recreation Festival.	Gallipolis, OH	Ohio River, Miles 269.5–270.5 (Ohio).
44. 1 day—First week or weekend in July.	Kindred Communications/Dawg Dazzle	Huntington, WV	Ohio River, Miles 307.8–308.8 (West Virginia).
45. 1 day—First week or weekend in July.	Greenup City	Greenup, KY	Ohio River, Miles 335.2–336.2 (Kentucky).
46. 1 day—First week or weekend in July.	Middleport Community Association	Middleport, OH	Ohio River, Miles 251.5–252.5 (Ohio).
47. 1 day—First week or weekend in July.	People for the Point Party in the Park	South Point, OH	Ohio River, Miles 317–318 (Ohio).
48. 1 day—One of the first two weekends in July.	City of Bellevue, KY/Bellevue Beach Park Concert Fireworks.	Bellevue, KY	Ohio River, Miles 468.2–469.2 (Kentucky & Ohio).
49. 1 day— First Week of July.	Pittsburgh 4th of July Celebration	Pittsburgh, PA	Ohio River, Miles 0.0–0.5, Allegheny River, Miles 0.0–0.5, and Monongahela River, Miles 0.0–0.5 (Pennsylvania).
50. 1 day—First week or weekend in July.	City of Charleston/City of Charleston Independence Day Celebration.	Charleston, WV	Kanawha River, Miles 58.1–59.1 (West Virginia).
51. 1 day—First week or weekend in July.	Portsmouth River Days	Portsmouth, OH	Ohio River, Miles 355.5–357.0 (Ohio).
52. 1 day—During the first week of July.	Louisville Bats Baseball Club/Louisville Bats Firework Show.	Louisville, KY	Ohio River, Miles 602.0–605.0 (Kentucky).
53. 1 day—During the first week of July.	Waterfront Independence Festival/Louisville Orchestra Waterfront 4th.	Louisville, KY	Ohio River, Miles 602.0–605.0 (Kentucky).
54. 1 day—During the first week of July.	Celebration of the American Spirit Fireworks/ All American 4th of July.	Owensboro, KY	Ohio River, Miles 754.0–760.0 (Kentucky).
55. 1 day—During the first week of July.	Riverfront Independence Festival Fireworks ..	New Albany, IN	Ohio River, Miles 606.5–609.6 (Indiana).
56. 1 day in July	Grand Harbor Marina/Grand Harbor Marina July 4th Celebration.	Counce, TN	Tennessee-Tombigbee Waterway, Miles 448.5–451.0 (Tennessee).
57. 1 day—During the first two weeks of July.	City of Maysville Fireworks	Maysville, KY	Ohio River, Miles 408–409 (Kentucky).

TABLE 1 OF § 165.801—SECTOR OHIO VALLEY ANNUAL AND RECURRING SAFETY ZONES—Continued

Date	Sponsor/name	Sector Ohio Valley location	Safety zone
58. 1 day—One of the first two weekends in July.	Madison Regatta, Inc./Madison Regatta	Madison, IN	Ohio River, Miles 554.0–561.0 (Indiana).
59. 1 day—Third Saturday in July.	Pittsburgh Irish Rowing Club/St. Brendan's Cup Currach Regatta.	Pittsburgh, PA	Ohio River, Miles 7.0–9.0 (Pennsylvania).
60. 1 day—Third or fourth week in July.	Upper Ohio Valley Italian Heritage Festival/ Upper Ohio Valley Italian Heritage Festival Fireworks.	Wheeling, WV	Ohio River, Miles 90.0–90.5 (West Virginia).
61. 1 day—Saturday Third or Fourth full week of July (Rain date—following Sunday).	Oakmont Yacht Club/Oakmont Yacht Club Fireworks.	Oakmont, PA	Allegheny River, Miles 12.0–12.5 (Pennsylvania).
62. 2 days—One weekend in July.	Marietta Riverfront Roar Fireworks	Marietta, OH	Ohio River, Miles 171.6–172.6 (Ohio).
63. 1 Day in July	Three Rivers Regatta	Knoxville, TN	Tennessee River, Miles 642–653 (Tennessee).
64. 1 day—Last weekend in July or first weekend in August.	Fort Armstrong Folk Music Festival	Kittanning, PA	Allegheny River, Mile 45.1–45.5 (Pennsylvania).
65. 1 day—First week of August.	Kittaning Folk Festival	Kittanning, PA	Allegheny River, Miles 44.0–46.0 (Pennsylvania).
66. 1 day—First week in August.	Gliers Goetta Fest LLC	Newport, KY	Ohio River, Miles 469.0–471.0.
67. 1 day—First or second week of August.	Bellaire All-American Days	Bellaire, OH	Ohio River, Miles 93.5–94.5 (Ohio).
68. 1 day—Second full week of August.	PA FOB Fireworks Display	Pittsburgh, PA	Allegheny River, Miles 0.8–1.0 (Pennsylvania).
69. 1 day—Second Saturday in August.	Guyasuta Days Festival/Borough of Sharpsburg.	Pittsburgh, PA	Allegheny River, Miles 005.5–006.0 (Pennsylvania).
70. 1 day—In the Month of August.	Pittsburgh Foundation/Bob O'Connor Cookie Cruise.	Pittsburgh, PA	Ohio River, Mile 0.0–0.5 (Pennsylvania).
71. 1 day—Third week of August.	Beaver River Regatta Fireworks	Beaver, PA	Ohio River, Miles 25.2–25.8 (Pennsylvania).
72. 1 day—One weekend in August.	Parkersburg Homecoming Festival-Fireworks	Parkersburg, WV	Ohio River, Miles 183.5–185.5 (West Virginia).
73. 1 day—One weekend in August.	Ravenswood River Festival	Ravenswood, WV	Ohio River, Miles 220–221 (West Virginia).
74. 1 day—The second or third weekend of August.	Green Turtle Bay Resort/Grand Rivers Marina Day.	Grand Rivers, KY	420 foot radius, from the fireworks launch site, at the entrance to Green Turtle Bay Resort, on the Cumberland River at mile marker 31.5. (Kentucky).
75. 1 day—last 2 weekends in August/first week of September.	Wheeling Dragon Boat Race	Wheeling, WV	Ohio River, Miles 90.4–91.5 (West Virginia).
76. Sunday, Monday, or Thursday from August through February.	Pittsburgh Steelers Fireworks	Pittsburgh, PA	Allegheny River, Miles 0.0–0.25, Ohio River, Miles 0.0–0.1, Monongahela River, Miles 0.0–0.1. (Pennsylvania).
77. 1 day—Labor Day	Portsmouth Labor Day Fireworks/Hamburg Fireworks.	Portsmouth, OH	Ohio River, Mile 355.8–356.8 (Ohio).
78. 1 day—one weekend before Labor Day.	Riverfest/Riverfest Inc	Nitro, WV	Kanawha River, Miles 43.1–44.2 (West Virginia).
79. 2 days—Sunday before Labor Day and Labor Day.	Cincinnati Bell, WEBN, and Proctor and Gamble/Riverfest.	Cincinnati, OH	Ohio River, Miles 469.2–470.5 (Kentucky and Ohio) and Licking River, Miles 0.0–3.0 (Kentucky).
80. 1 day—Labor Day or first week of September.	Labor Day Fireworks Show	Marmet, WV	Kanawha River, Miles 67.5–68 (West Virginia).
81. 1 day in September	Nashville Symphony/Concert Fireworks	Nashville, TN	Cumberland River, Miles 190.1–192.3 (Tennessee).
82. 1 day—Second weekend in September.	City of Clarksville/Clarksville Riverfest	Clarksville, TN	Cumberland River, Miles 124.5–127.0 (Tennessee).
83. 3 days—Second or third week in September.	Wheeling Heritage Port Sternwheel Festival Foundation/Wheeling Heritage Port Sternwheel Festival.	Wheeling, WV	Ohio River, Miles 90.2–90.7 (West Virginia).
84. 1 day—One weekend in September.	Boomtown Days—Fireworks	Nitro, WV	Kanawha River, Miles 43.1–44.2 (West Virginia).

TABLE 1 OF § 165.801—SECTOR OHIO VALLEY ANNUAL AND RECURRING SAFETY ZONES—Continued

Date	Sponsor/name	Sector Ohio Valley location	Safety zone
85. 1 day—One weekend in September.	Ohio River Sternwheel Festival Committee fireworks.	Marietta, OH	Ohio River, Miles 171.5–172.5 (Ohio).
86. 1 day—One weekend in September.	Tribute to the River	Point Pleasant, WV	Ohio River, Miles 264.6–265.6 (West Virginia).
87. 1 day—One weekend in September.	Aurora Fireworks	Aurora, IN	Ohio River, Mile 496.3–497.3 (Ohio).
88. 1 day—Last two weekends in September.	Cabana on the River	Cincinnati, OH	Ohio River, Mile 483.2–484.2 (Ohio).
89. Multiple days—September through January.	University of Pittsburgh Athletic Department/University of Pittsburgh Fireworks.	Pittsburgh, PA	Ohio River, Miles 0.0–0.1, Monongahela River, Miles 0.0–0.1, Allegheny River, Miles 0.0–0.25 (Pennsylvania).
90. 1 day—First three weeks of October.	Leukemia & Lymphoma Society/Light the Night.	Pittsburgh, PA	Ohio River, Mile 0.0–0.5, Allegheny River, Mile 0.0–0.5, and Monongahela River, Mile 0.0–0.5 (Pennsylvania).
91. 1 day in October	Leukemia and Lymphoma Society/Light the Night Walk Fireworks.	Nashville, TN	Cumberland River, Miles 189.7–192.1 (Tennessee).
92. 1 day—First two weeks in October.	Yeatman's Fireworks	Cincinnati, OH	Ohio River, Miles 469.0–470.5 (Ohio).
93. 1 day in October	Outdoor Chattanooga/Swim the Suck	Chattanooga, TN	Tennessee River, Miles 452.0–454.5 (Tennessee).
94. 1 day in October	Chattajack	Chattanooga, TN	Tennessee River, Miles 462.7–465.5 (Tennessee).
95. 1 day—One weekend in October.	West Virginia Motor Car Festival	Charleston, WV	Kanawha River, Miles 58–59 (West Virginia).
96. 2 days—One of the last three weekends in October.	Monster Pumpkin Festival	Pittsburgh, PA	Allegheny River, Mile 0.0–0.25 (Pennsylvania).
97. 1 day—Friday before Thanksgiving.	Pittsburgh Downtown Partnership/Light Up Night.	Pittsburgh, PA	Allegheny River, Miles 0.0–1.0 (Pennsylvania).
98. 1 day—Friday before Thanksgiving.	Kittanning Light Up Night Firework Display	Kittanning, PA	Allegheny River, Miles 44.5–45.5 (Pennsylvania).
99. 1 day—Friday before Thanksgiving.	Santa Spectacular/Light up Night	Pittsburgh, PA	Ohio River, Mile 0.0–0.5, Allegheny River, Mile 0.0–0.5, and Monongahela River, Mile 0.0–0.5 (Pennsylvania).
100. 1 day—Friday before Thanksgiving.	Monongahela Holiday Show	Monongahela, PA	Ohio River, Miles 31.5–32.5 (Pennsylvania).
101. 1 day in November.	Friends of the Festival/Cheer at the Pier	Chattanooga, TN	Tennessee River, Miles 462.7–465.2 (Tennessee).
102. 1 day—Third week of November.	Gallipolis in Lights	Gallipolis, OH	Ohio River, Miles 269.2–270 (Ohio).
103. 1 day—December 31.	Pittsburgh Cultural Trust/Highmark First Night Pittsburgh.	Pittsburgh, PA	Allegheny River, Miles 0.5–1.0 (Pennsylvania).
104. 7 days—Scheduled home games.	University of Tennessee/UT Football Fireworks.	Knoxville, TN	Tennessee River, Miles 645.6–648.3 (Tennessee).

* * * * *

Dated: April 3, 2020.

A. M. Beach,

Captain, U. S. Coast Guard, Captain of the Port, Sector Ohio Valley.

[FR Doc. 2020–11418 Filed 6–1–20; 8:45 am]

BILLING CODE 9110–04–P

DEPARTMENT OF HOMELAND SECURITY

Coast Guard

33 CFR Part 165

[Docket Number USCG–2020–0203]

RIN 1625–AA00

Safety Zone; Pensacola Bay, Pensacola Beach, FL

AGENCY: Coast Guard, DHS.

ACTION: Temporary final rule.

SUMMARY: The Coast Guard is establishing a temporary safety zone for the navigable waters within 100 yards from the pilings, work equipment, and structures of the Pensacola Bay Bridge, Pensacola Beach, FL. This temporary safety zone is necessary to provide for the safety of life and property on these navigable waters during a bridge construction project on the waterway. Entry into or transiting in this zone is prohibited to all vessels, mariners, and persons unless specifically authorized by the Captain of the Port Sector Mobile (COTP) or a designated representative.

DATES: This rule is effective without actual notice from June 2, 2020 through 8 a.m. on December 31, 2021. For purposes of enforcement, actual notice will be used from 8 a.m. on April 27, 2020 through June 2, 2020.

ADDRESSES: To view documents mentioned in this preamble as being available in the docket, go to *http://www.regulations.gov,* type USCG–2020–0203 in the ''SEARCH'' box and click

''SEARCH.'' Click on Open Docket Folder on the line associated with this rule.

FOR FURTHER INFORMATION CONTACT: If you have questions on this rule, call or email Lieutenant Commander Kelley Brown, Sector Mobile, Waterways Management Division, U.S. Coast Guard; telephone 251–441–5940, email *Kelley.M.Brown@uscg.mil.*

SUPPLEMENTARY INFORMATION:

I. Table of Abbreviations

BNM Broadcast Notice to Mariners
CFR Code of Federal Regulations
COTP Captain of the Port Sector Mobile
DHS Department of Homeland Security
FR Federal Register
NPRM Notice of proposed rulemaking
§ Section
U.S.C. United States Code

II. Background Information and Regulatory History

The Coast Guard is issuing this temporary final rule without prior notice and opportunity to comment pursuant to authority under section 4(a) of the Administrative Procedure Act (APA) (5 U.S.C. 553(b)). This provision authorizes an agency to issue a rule without prior notice and opportunity to comment when the agency for good cause finds that those procedures are ''impracticable, unnecessary, or contrary to the public interest.'' Under 5 U.S.C. 553(b)(3)(B), the Coast Guard finds that good cause exists for not publishing a notice of proposed rulemaking (NPRM) with respect to this rule because it is impracticable and contrary to the public interest. It is impracticable to publish an NPRM because we must establish this safety zone by April 27, 2020 and lack sufficient time to provide a reasonable comment period and then consider those comments before issuing the rule. It is also contrary to the public interest as it would delay the safety measures necessary to protect life and property from the possible hazards associated with the bridge construction project.

Under 5 U.S.C. 553(d)(3), the Coast Guard finds that good cause exists for making this rule effective less than 30 days after publication in the **Federal Register**. Delaying the effective date of this rule is contrary to public interest because it would delay the safety measures necessary to respond to potential safety hazards associated with this project. Immediate action is needed to protect vessels and mariners from the safety hazards associated with the bridge construction project on the waterway.

III. Legal Authority and Need for Rule

The Coast Guard is issuing this rule under authority in 33 U.S.C. 1231. The Captain of the Port Sector Mobile (COTP) has determined that potential hazards associated with the bridge construction project on April 27, 2020 will be a safety concern for any vessels or persons within 100 yards from the pilings, work equipment, and structures of the Pensacola Bay Bridge, Pensacola Beach, FL. This rule is needed to protect the public, mariners, and vessels from the potential hazards associated with the bridge construction project on the waterway.

IV. Discussion of the Rule

The Coast Guard is establishing a temporary safety zone, effective for 24 hours a day, starting at 8 a.m. on April 27, 2020 through 8 a.m. on December 31, 2020. The safety zone encompasses the navigable waters within 100 yards from the pilings, work equipment, and structures of the Pensacola Bay Bridge, Pensacola Beach, FL. The location and duration of this safety zone is intended to protect persons and vessels during the bridge construction project that will take place on this navigable waterway. No person or vessel will be permitted to enter or transit within the safety zone, unless specifically authorized by the COTP or a designated representative. Public notifications will be made to the local maritime community through Broadcast Notice to Mariners (BNM). Mariners and other members of the public may also contact the COTP or designated representative to inquire about the safety zone by telephone at 251–441–5490.

V. Regulatory Analyses

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

A. Regulatory Planning and Review

Executive Orders 12866 and 13563 direct agencies to assess the costs and benefits of available regulatory alternatives and, if regulation is necessary, to select regulatory approaches that maximize net benefits. Executive Order 13771 directs agencies to control regulatory costs through a budgeting process. This rule has not been designated a ''significant regulatory action,'' under Executive Order 12866. Accordingly, this rule has not been reviewed by the Office of Management and Budget (OMB), and pursuant to OMB guidance it is exempt from the requirements of Executive Order 13771.

This regulatory determination is based on the size, location, and duration, of the safety zone. This temporary safety zone will only restrict navigation within 100 yards from the pilings, work equipment and structures of the Pensacola Bay Bridge, Pensacola Beach, FL for duration of the bridge construction. Moreover, the Coast Guard will issue a Local Notice to Mariners (LNM) about the zone, and the rule would allow vessels to seek permission to enter the zone.

B. Small Entities

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

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

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

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

C. Collection of Information

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

D. Federalism and Indian Tribal Governments

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

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

E. Unfunded Mandates Reform Act

The Unfunded Mandates Reform Act of 1995 (2 U.S.C. 1531–1538) requires Federal agencies to assess the effects of their discretionary regulatory actions. In particular, the Act addresses actions that may result in the expenditure by a State, local, or tribal government, in the aggregate, or by the private sector of $100,000,000 (adjusted for inflation) or more in any one year. Though this rule will not result in such expenditure, we do discuss the effects of this rule elsewhere in this preamble.

F. Environment

We have analyzed this rule under Department of Homeland Security Directive 023–01, which guides the Coast Guard in complying with the National Environmental Policy Act of 1969 (42 U.S.C. 4321–4370f), and have determined that this action is one of a category of actions that do not individually or cumulatively have a significant effect on the human environment. This rule involves a safety zone that will prohibit 100 mariners and the public 100 yards from the pilings, work equipment and structures of the Pensacola Bay Bridge, Pensacola Beach, FL. It is categorically excluded from further review under paragraph L60 (a) of Appendix A, Table 1 of DHS Instruction Manual 023–01–001–01, Rev.01. A Record of Environmental Consideration (REC) supporting this determination is available in the docket where indicated under **ADDRESSES**.

G. Protest Activities

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

List of Subjects 33 CFR Part 165

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

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

PART 165—REGULATED NAVIGATION AREAS AND LIMITED ACCESS AREAS

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

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

■ 2. Add § 165.T08–0203 to read as follows:

§ 165.T08–0203 Safety Zone; Pensacola Bay Bridge, Pensacola Beach, FL

(a) *Location.* The following area is a safety zone: All navigable waters within 100 yards from the pilings, work equipment, and structures of the Pensacola Bay Bridge, Pensacola Beach, FL.

(b) *Enforcement period.* This section will be enforced from April 27, 2020 until December 31, 2021.

(c) *Regulations.* (1) The general regulations contained in § 165.23 as well as the regulations in this section apply to the regulated area.

(2) Entry into this zone is prohibited unless authorized by the Captain of the Port Sector Mobile (COTP) or a designated representative.

(3) Persons or vessels seeking to enter into or transit through the zone must request permission from the COTP or a designated representative. They may be contacted on VHF–FM channels 15 and 16 or by telephone at 251–441–5976.

(4) If permission is granted, all persons and vessels must comply with the instructions of the COTP or designated representative.

(d) *Informational broadcasts.* The COTP or a designated representative will inform the public through broadcast notices to mariners of the enforcement period for the safety zone.

Dated: April 29, 2020.

L.A. Allen,

Captain, U.S. Coast Guard, Captain of the Port Sector Mobile.

[FR Doc. 2020–09857 Filed 6–1–20; 8:45 am]

BILLING CODE 9110–04–P

DEPARTMENT OF HOMELAND SECURITY

Coast Guard

33 CFR Part 165

[Docket Number USCG–2020–0274]

RIN 1625–AA00

Safety Zone; Tug Valerie B and Barge Kokosing IV operating in the Straits of Mackinac, MI

AGENCY: Coast Guard, DHS.

ACTION: Temporary final rule.

SUMMARY: The Coast Guard is establishing a temporary safety zone for the navigable water within a 500-yard radius of a tug and barge in the Straits of Mackinac. The safety zone is needed to protect personnel, vessels, and the marine environment from the potential hazards created by the work, inspection, surveying and the removal of cables for the Straits of Mackinac. Entry of vessels or persons into the zone is prohibited unless specifically authorized by the Captain of the Port Sault Sainte Marie or their designated representive.

DATES: This rule is effective without actual notice from June 2, 2020 through September 15, 2020. For the purposes of enforcement, actual notice will be issued from June 10, 2020, through June 2, 2020.

ADDRESSES: To view documents mentioned in this preamble as being available in the docket, go to *https://www.regulations.gov,* type USCG–2020–0274 in the ''SEARCH'' box and click ''SEARCH.'' Click on Open Docket Folder on the line associated with this rule.

FOR FURTHER INFORMATION CONTACT: If you have questions on this rule, call or email CWO4 Robert A. Gruschow, Sector Sault Sainte Marie Waterways Management Division, U.S. Coast Guard at (906)253–2462 or email *ssmprevention@uscg.mil.*

SUPPLEMENTARY INFORMATION:

I. Table of Abbreviations

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

II. Background Information and Regulatory History

The Coast Guard is issuing this temporary rule without prior notice and opportunity to comment pursuant to authority under section 4(a) of the Administrative Procedure Act (APA) (5 U.S.C. 553(b)). This provision authorizes an agency to issue a rule without prior notice and opportunity to comment when the agency for good cause finds that those procedures are ''impracticable, unnecessary, or contrary to the public interest.'' Under 5 U.S.C. 553(b)(B), the Coast Guard finds that good cause exists for not publishing a notice of proposed rulemaking (NPRM) with respect to this rule because doing so would be impracticable. The final details of the specific dates, vessels names, and safety zone distances concerning the safety zones were not finalized within a sufficient time to allow for notice and a subsequent 30-day comment period before work, inspection, surveying and removal of multiple cables. Delaying this rule to allow for a notice and comment period would be impracticable because it would inhibit the Coast Guard's ability to protect the public from the potential hazards associated with aforementioned operation commencing on June 10, 2020.

Under 5 U.S.C. 553(d)(3), the Coast Guard finds that good cause exists for making this rule effective less than 30 days after publication in the **Federal Register**. For the same reasons discussed in the preceding paragraph, delaying the effective date of this rule would be impracticable because immediate action is needed to respond to the potential safety hazards associated with the work, inspections, and surveying of underwater infrastructure.

III. Legal Authority and Need for Rule

The Coast Guard is issuing this rule under authority in 46 U.S.C. 70034 (previously 33 U.S.C. 1231). The Captain of the Port Sault Sainte Marie (COTP) has determined that potential hazards associated with the work, inspection, and surveying of underwater infrastructure in the Straits of Mackinac starting June 10, 2020, will be a safety concern for anyone within a 500-yard radius of the tug and barge. This rule is needed to protect personnel, vessels, and the marine environment in the navigable waters within the safety zone while the operation is conducted.

IV. Discussion of the Rule

This rule establishes a safety zone from June 10, 2020, to September 15, 2020. The safety zone will cover all navigable waters within 500 yards of a tug and barge being used to work, inspect, survey and remove cables in the Straits of Mackinac. The duration of the zone is intended to protect personnel, vessels, and the marine environment in these navigable waters while the operation is conducted. No vessel or person will be permitted to enter the safety zone without obtaining permission from the COTP or a designated representative.

V. Regulatory Analyses

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

A. Regulatory Planning and Review

Executive Orders 12866 and 13563 direct agencies to assess the costs and benefits of available regulatory alternatives and, if regulation is necessary, to select regulatory approaches that maximize net benefits. Executive Order 13771 directs agencies to control regulatory costs through a budgeting process. This rule has not been designated a ''significant regulatory action,'' under Executive Order 12866. Accordingly, this rule has not been reviewed by the Office of Management and Budget (OMB), and pursuant to OMB guidance it is exempt from the requirements of Executive Order 13771.

This regulatory action determination is based on the size and location of the safety zone. Vessel traffic will be able to safely transit around this safety zone which would impact a small designated area of the Straits of Mackinac. Moreover, the Coast Guard will issue a Broadcast Notice to Mariners via VHF–FM marine channel 16 about the zone, and the rule would allow vessels to seek permission to enter the zone.

B. Impact on Small Entities

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

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

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

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

C. Collection of Information

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

D. Federalism and Indian Tribal Governments

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

Also, this rule does not have tribal implications under Executive Order 13175, Consultation and Coordination

with Indian Tribal Governments, because it does not have a substantial direct effect on one or more Indian tribes, on the relationship between the Federal Government and Indian tribes, or on the distribution of power and responsibilities between the Federal Government and Indian tribes.

E. Unfunded Mandates Reform Act

The Unfunded Mandates Reform Act of 1995 (2 U.S.C. 1531–1538) requires Federal agencies to assess the effects of their discretionary regulatory actions. In particular, the Act addresses actions that may result in the expenditure by a State, local, or tribal government, in the aggregate, or by the private sector of $100,000,000 (adjusted for inflation) or more in any one year. Though this rule will not result in such an expenditure, we do discuss the effects of this rule elsewhere in this preamble.

F. Environment

We have analyzed this rule under Department of Homeland Security Directive 023–01, Rev. 1, associated implementing instructions, and Environmental Planning COMDTINST 5090.1 (series), which guide the Coast Guard in complying with the National Environmental Policy Act of 1969 (42 U.S.C. 4321–4370f), and have determined that this action is one of a category of actions that do not individually or cumulatively have a significant effect on the human environment. This rule involves a safety zone that will prohibit entry within 500 yards of a tug and barge used to work, inspect, survey and remove cables in the Straits of Mackinac. It is categorically excluded from further review under paragraph L[60(a)] of Appendix A, Table 1 of DHS Instruction Manual 023–01–001–01, Rev. 1. A Record of Environmental Consideration supporting this determination is available in the docket. For instructions on locating the docket, see the **ADDRESSES** section of this preamble.

G. Protest Activities

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

List of Subjects in 33 CFR Part 165

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

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

PART 165—REGULATED NAVIGATION AREAS AND LIMITED ACCESS AREAS

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

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

■ 2. Add § 165.T09–0274 to read as follows:

§ 165.T09–0274 Safety Zone; Tug Valerie B and Barge Kokosing IV operating in the Straits of Mackinac, MI.

(a) *Location.* The following areas are safety zones: All navigable water within 500 yards of the Tug Valerie B and Barge Kokosing IV while conducting work, inspection, surveying and removing cables in the Straits of Mackinac.

(b) *Definitions.* As used in this section, *designated representative* means a Coast Guard Patrol Commander, including a Coast Guard coxswain, petty officer, or other officer operating a Coast Guard vessel and a Federal, State, and local officer designated by or assisting the Captain of the Port Sault Sainte Marie (COTP) in the enforcement of the safety zone.

(c) *Regulations.* (1) In accordance with the general regulations in § 165.23, entry into, transiting, or anchoring within the safety zone described in paragraph (a) is prohibited unless authorized by the Captain of the Port, Sault Sainte Marie or his designated representative.

(2) Before a vessel operator may enter or operate within the safety zones, they must obtain permission from the Captain of the Port, Sault Sainte Marie, or his designated representative via VHF Channel 16 or telephone at (906) 635–3233. Vessel operators given permission to enter or operate in the safety zone must comply with all orders given to them by the Captain of the Port, Sault Sainte Marie or his designated representative.

(d) *Enforcement period.* This section will be enforced from June 10, 2020 to September 15, 2020.

Dated: May 28, 2020.

P.S. Nelson,

Captain, U.S. Coast Guard, Captain of the Port Sault Sainte Marie.

[FR Doc. 2020–11944 Filed 6–1–20; 8:45 am]

BILLING CODE 9110–04–P

DEPARTMENT OF HOMELAND SECURITY

Coast Guard

33 CFR Part 165

[Docket No. USCG–2020–0226]

Safety Zone; Marine Events Within the Eighth Coast Guard District

AGENCY: Coast Guard, DHS.

ACTION: Notice of enforcement of regulation.

SUMMARY: The Coast Guard will enforce a Safety Zone for the St. John the Baptist Independence Day fireworks display from 8:45 p.m. through 9:45 p.m. on July 3, 2020, to provide for the safety of life on navigable waterways during this event. Our regulation for marine events within the Eighth Coast Guard District identifies the regulated area for this event on the Lower Mississippi River, by Reserve, Louisiana. During the enforcement periods, the operator of any vessel in the regulated area must comply with directions from the Patrol Commander or any Official Patrol displaying a Coast Guard ensign.

DATES: The regulations in 33 CFR 165.801, Table 5, line 2 will be enforced from 8:45 p.m. through 9:45 p.m. on July 3, 2020.

FOR FURTHER INFORMATION CONTACT: If you have questions about this notice of enforcement, call or email Lieutenant Commander Corinne Plummer, Sector New Orleans, U.S. Coast Guard; telephone 504–365–2375, email *Corinne.M.Plummer@uscg.mil*.

SUPPLEMENTARY INFORMATION: The Coast Guard will enforce the safety zone located in 33 CFR 165.801, Table 5, line 2 for the St. John the Baptist Independence Day Celebration event. The regulations will be enforced from 8:45 p.m. through 9:45 p.m. on July 3, 2020. This action is being taken to provide for the safety of life on these navigable waterways during this event. Our regulations for marine events within the Eighth Coast Guard District, 33 CFR 165.801, as updated by **Federal Register** document (83 FR 55488), specifies the location of the regulated area on the Mississippi River between mile markers 137.5 and 138.5 on the Mississippi River near Reserve, Louisiana. During the enforcement period, as reflected in § 165.801(a)–(d), if you are the operator of a vessel in the safety zone, you must comply with directions from the Captain of the Port Sector New Orleans or a designated representative.

In addition to this notice of enforcement in the **Federal Register** the

Coast Guard plans to provide notification of this enforcement period via a Marine Safety Information Bulletin and/or Broadcast Notice to Mariners.

Dated: May 18, 2020.

K. M. Luttrell,

Captain, U.S. Coast Guard, Captain of the Port Sector New Orleans.

[FR Doc. 2020–11056 Filed 6–1–20; 8:45 am]

BILLING CODE 9110–04–P

ENVIRONMENTAL PROTECTION AGENCY

40 CFR Part 52

[EPA–R09–OAR–2019–0541; FRL–10009–19–Region 9]

Clean Air Plans; 2008 8-Hour Ozone Nonattainment Area Requirements; Phoenix-Mesa, Arizona

AGENCY: Environmental Protection Agency (EPA).

ACTION: Final rule.

SUMMARY: The Environmental Protection Agency (EPA) is taking final action on a state implementation plan (SIP) revision submitted by the State of Arizona on behalf of the Maricopa Association of Governments (MAG) to meet Clean Air Act (CAA or ''the Act'') requirements for the 2008 ozone national ambient air quality standards (NAAQS or ''standards'') in the Phoenix-Mesa (''Phoenix'') ozone nonattainment area (NAA). The EPA is finalizing approval of the portions of the ''MAG 2017 Eight-Hour Ozone Moderate Area Plan for the Maricopa Nonattainment Area (December 2016)'' (''MAG 2017 Ozone Plan'' or ''Plan'') that address the requirements for emissions inventories, a demonstration of attainment by the applicable attainment date, reasonably available control measures (RACM), reasonable further progress (RFP), motor vehicle emission budgets for transportation conformity, vehicle inspection and maintenance (I/M) programs, new source review (NSR) rules, and offsets. The EPA is finalizing a disapproval of the portion of the MAG 2017 Ozone Plan that addresses the requirements for contingency measures for failure to attain or to make RFP. However, based on a separate finding that the Phoenix 2008 ozone NAA (''Phoenix NAA'') attained the 2008 ozone standards by the applicable attainment date, we previously determined that the requirement for the State to submit a SIP revision addressing attainment contingency measures no longer applies for the Phoenix NAA. We are also finalizing our determination that the requirement for the State to submit a SIP revision addressing RFP contingency measures no longer applies for the Phoenix NAA. Finally, we are finalizing approval of the portions of a SIP revision, the ''MAG 2014 Eight-Hour Ozone Plan—Submittal of Marginal Area Requirements for the Maricopa Nonattainment Area (June 2014)'' (''MAG 2014 Ozone Plan''), on which we previously deferred action.

DATES: This rule is effective on July 2, 2020.

ADDRESSES: The EPA has established a docket for this action under Docket ID No. EPA–R09–OAR–2019–0541. 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 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: Nancy Levin, EPA Region IX, 75 Hawthorne Street, San Francisco, CA 94105. Phone: (415) 972–3848 or by email at *levin.nancy@epa.gov.*

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

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I. Proposed Action

On October 3, 2019, the EPA proposed action on a SIP revision submitted by the State of Arizona on behalf of MAG to meet CAA requirements for the 2008 ozone NAAQS [1] in the Phoenix NAA.[2] We also proposed to approve the portions of a SIP revision, the MAG 2014 Ozone Plan, on which we previously deferred action. Our proposed action contains more information on the MAG 2017 Ozone Plan, the MAG 2014 Ozone Plan, and our evaluation of these submittals.

II. Public Comments and EPA Responses

The EPA's proposed action provided a 30-day public comment period. During this period, we received comments from two commenters: (1) Arizona Center for Law in the Public Interest (ACLPI) on behalf of ACLPI, the Sierra Club-Grand Canyon Chapter, and their supporters and members who live and work in the Phoenix metropolitan area; and (2) the Arizona Department of Environmental Quality (ADEQ). We summarize the comments and provide our responses below. All the comments received are included in the docket for this action.

Commenter #1—ACLPI

Comment 1.a: The commenter asserted that MAG should do more to combat worsening ozone pollution, particularly given the area's economic expansion and population, but that in this Plan, MAG relied on existing controls, tightening fuel standards, and fleet turnover, which are not enough to achieve attainment. Specifically, ACLPI noted that the Act and the 2008 Ozone SIP Requirements Rule (SRR) require implementation of RACM to achieve attainment as expeditiously as practicable and to meet RFP requirements; and that ''[s]tates should consider all available measures, including those being implemented in other areas.'' The commenter stated that ''MAG did not incorporate any new control measures in the Plan'' and that the Plan's reliance on existing control measures, tighter fuel standards, and fleet turnover, is ''clearly not enough to reach attainment in the Phoenix NAA.'' The commenter also asserted that economic expansion and population growth in the Phoenix area will continue to drive onroad and nonroad mobile source emissions upwards, and that ''MAG and its member agencies should lead the way in finding more effective and long-lasting solutions to Phoenix's ozone pollution problem.''

Response: We do not agree that the controls reflected in the Plan are insufficient to achieve attainment of the 2008 ozone NAAQS in the Phoenix NAA. For the reasons described in our proposal and in response to ACLPI's other comments in this document, we find that the Plan adequately demonstrates that the area will attain the 2008 Ozone NAAQS by the attainment date and meets all other applicable requirements, including RACM requirements. In particular, the Plan documents that the State did consider whether additional measures

[1] Since the 2008 primary and secondary NAAQS for ozone are identical, for convenience, we refer to both as ''the 2008 ozone NAAQS'' or ''the 2008 ozone standard.''

[2] 84 FR 52838.

were reasonably available as part of its RACM analysis, but determined that no new control measures were needed to attain the NAAQS or achieve RFP in the Phoenix NAA at this time.[3] As described in our proposal, this analysis follows the approach outlined in the SRR, which provides that states need only adopt those control measures that ''will advance the attainment date or contribute to RFP for the area.'' [4] ACLPI has not provided any information or analysis that undermines our conclusion that the MAG 2017 Ozone Plan meets this requirement.

Comment 1.b: ACLPI commented that the area exceeded the 2008 ozone standard multiple days in 2015 through 2019, and that the design value for the 2017 attainment year exceeded the 2008 ozone NAAQS when ''unsupported 'exceptional events' exceedances on June 20, 2015 are included in the calculation.'' The commenter also stated that, even assuming these exceedances were properly excluded, the design value for 2018 was 77 parts per billion (ppb). On this basis, the commenter asserted that ''any paper 'attainment' of the 2008 standard in 2017 was fleeting and not the result of permanent emission reductions.'' Finally, the commenter stated that 2018 monitoring data indicate that ozone concentrations have increased since 2016 and that the Phoenix metropolitan area is ranked 7th on the American Lung Association's list of the most ozone-polluted cities in the U.S.

Response: Under the CAA, a determination of whether an area has attained by the attainment date is a separate action from the review of an attainment demonstration in a SIP revision. The EPA's review of the SIP revision occurs under CAA section 110(k), while a determination of whether an area has failed to attain is governed by CAA section 181(b)(2). Under section 181(b)(2), the EPA must determine whether an ozone NAA has attained the applicable NAAQS ''[w]ithin 6 months following the applicable attainment date (including any extension thereof).'' In this instance, the EPA has already undertaken a separate final action to determine, pursuant to section 181(b)(2), that the Phoenix NAA attained the 2008 ozone NAAQS by the ''Moderate'' area attainment date, based on 2015–2017 monitoring data.[5] That separate action was based, in part, on our prior concurrence with ADEQ's demonstration that, based on the weight of evidence, the ozone exceedances that occurred on June 20, 2015, were caused by wildfire ozone exceptional events.[6] These separate actions are beyond the scope of this final rule.

We do not consider the exceedances of the 2008 ozone standard in 2018 and 2019, years after the area's applicable attainment date, to be relevant to the approvability of the State's demonstration that this area would attain the 2008 ozone NAAQS by the attainment date, as discussed in our response to comment 1.d.

Comment 1.c: ACLPI stated that the EPA's approval of the Plan ''would defer or significantly delay taking meaningful actions to protect . . . vulnerable residents, contravening the Act's express policy that 'protection of public health is the highest priority' '' (quoting CAA section 319(b)(3)(A)).

The commenter further asserted that MAG and its member agencies should act now to ''promote and implement clean mobility measures,'' such as converting all or part of government fleets to zero-emission vehicles and offering tax incentives and rebate programs to residents who purchase electric vehicles, to bring the Phoenix area into compliance with ozone standards ''with an adequate margin of safety and to ensure that such compliance is maintained.'' In addition, the commenter argued that ''MAG should do more to control ozone precursor emissions from gas-powered lawn equipment.'' Finally, citing MAG's RACM analysis in Chapter 4 of the Plan, the commenter argued that MAG should evaluate additional control measures from the EPA's menu of control measures and measures adopted by the Sacramento Metropolitan Air Quality Management District, at least as contingency measures.

Response: Our approval is based on our finding that the Plan meets all of the applicable requirements of the Act, as described in our proposal and in this document. Under CAA section 110(k)(3), the EPA is required to approve any SIP submittal that meets all such requirements. The EPA cannot require states to adopt measures that are more stringent than necessary to meet CAA requirements. While we encourage ADEQ, MAG, and Maricopa and Pinal Counties to consider adopting the measures suggested by the commenter, we have determined that these measures are not necessary to provide for attainment of the 2008 ozone NAAQS in the Phoenix NAA by the attainment date or to meet RFP requirements, and are therefore not needed to meet RACM requirements. As noted in our response to comment 1.b, the EPA has determined, pursuant to section 181(b)(2), that the Phoenix NAA attained the 2008 ozone NAAQS by the ''Moderate'' area attainment date. In addition, for the reasons described in our response to comment 1.f, we find that RFP contingency measures are not required for the Phoenix NAA at this time. Therefore, ADEQ, MAG, and the counties are not required to adopt any additional control measures for purposes of the MAG 2017 Ozone Plan.

Furthermore, the commenter's reliance on CAA section 319(b)(3)(A) is misplaced. This provision establishes five principles that the EPA must follow in developing implementing regulations for exceptional events, including that ''protection of public health is the highest priority.'' [7] As noted in our response to comment 1.b, we previously concurred with ADEQ's demonstration that, based on the weight of evidence, the ozone exceedances that occurred on June 20, 2015, were caused by wildfire ozone exceptional events.[8] This was done through a separate Agency action and is beyond the scope of this final rule. Requirements for exceptional events demonstrations are not directly relevant to the EPA's action on an attainment plan pursuant to CAA section 110(k)(3).

Comment 1.d: ACLPI asserted that ''the EPA should disapprove the Plan's attainment demonstration because it does not demonstrate that the Phoenix NAA attained the 2008 standard by the July 20, 2018 attainment date or made RFP goals.'' The commenter stated that MAG erred in omitting ozone exceedances that occurred on June 20, 2015, from the 2015–2017 design value calculation. The commenter also argued that the ''EPA cannot simply ignore the fact that monitors in the Phoenix NAA have continued to record numerous violations of the 2008 ozone standard in 2018 and 2019, or that the 8-hour ozone design value for the Phoenix NAA in 2018 was 77 ppb.''

Response: We do not agree with the commenter's argument that the EPA should disapprove the attainment demonstration because it did not demonstrate that the area factually attained or achieved RFP, or with the commenter's assertions concerning

[3] Plan Chapter 4.

[4] 80 FR 12264, 12282 (March 6, 2015).

[5] 84 FR 60920 (November 12, 2019).

[6] Letter dated May 7, 2019, from Elizabeth J. Adams, Director, Air Division, EPA Region IX, to Timothy S. Franquist, Director, Air Quality Division, ADEQ.

[7] CAA section 319(b)(3)(A)(i).

[8] Letter dated May 7, 2019, from Elizabeth J. Adams, Director, Air Division, EPA Region IX, to Timothy S. Franquist, Director, Air Quality Division, ADEQ.

exceptional events and the consideration of monitoring data collected after the Moderate attainment date.

MAG has satisfied the legal and regulatory criteria for attainment demonstrations. Contrary to the commenter's suggestion, the CAA does not require an attainment demonstration to show that an area has attained the NAAQS based on monitored values, or that it has achieved emissions reductions corresponding to RFP. Such demonstrations would not be practical, given that attainment demonstrations are generally required to be submitted to the EPA well before the milestone and attainment dates.[9] Rather, the CAA requires states to submit SIP revisions that ''provide for attainment'' of the NAAQS by the attainment date and ''require'' RFP.[10]

To address the requirements to provide for attainment and submit an attainment demonstration, the MAG 2017 Ozone Plan includes an attainment demonstration using air quality modeling that shows that existing control measures are sufficient for the Phoenix area to attain the 2008 ozone standard by 2017. In particular, to predict future ozone levels, the modeled attainment demonstration uses a baseline design value derived from historical monitoring data, historical meteorological data from the baseline period, emissions inventories representing the baseline design value period, and modeled reductions in emissions based on SIP control measures. The modeled attainment demonstration is intended to assess whether SIP controls are adequate to reduce ambient ozone to a level at or below the NAAQS by the attainment date.[11]

The modeled attainment demonstration showed that the emissions reductions would provide for attainment of the 2008 ozone NAAQS by the attainment date. As a separate matter, as described in our response to comment 1.b, the monitoring data for 2015–2017 show attainment, and the EPA has already determined in a prior final Agency action that the area attained the 2008 ozone NAAQS by the attainment date based on these data.[12] Data from 2018 and preliminary data from 2019 for the area do not alter our assessment of the modeled attainment demonstration for the 2008 ozone NAAQS. However, we note that the Phoenix area is currently designated and classified as a ''Marginal'' NAA for the 2015 ozone NAAQS and has a maximum attainment date of August 3, 2021.[13] The EPA will consider the monitoring data from 2018 through 2020 to determine whether the area attained the 2015 ozone NAAQS by the attainment deadline.[14] If these data show that the area has not attained, the area would be reclassified to a Moderate NAA for the 2015 ozone NAAQS, and the State would be required to submit a new attainment plan that addresses the Moderate area requirements for the 2015 ozone NAAQS.[15] Therefore, while the 2018–2019 monitoring data for the Phoenix NAA are not pertinent to our action on the 2017 MAG Ozone Plan, these data will be relevant to our determination of whether the area has attained the 2015 ozone standard.

Comment 1.e: The commenter argued that approval of the attainment demonstration would be ''problematic, given the weaknesses of MAG's modeling'' that the EPA identified in the proposed rule.

Response: We do not agree that the ''weaknesses'' identified in our proposal concerning meteorological inputs and model performance are obstacles to approving the attainment demonstration in the MAG 2017 Ozone Plan. As an initial matter, it is important to note that the EPA's ''Modeling Guidance for Demonstrating Attainment of Air Quality Goals for Ozone, $PM_{2.5,}$ and Regional Haze'' (''Modeling Guidance'') states, ''[b]y definition, models are simplistic approximations of complex phenomena'' and ''all models have strengths and weaknesses.'' [16] Accordingly, the Modeling Guidance recommends conducting evaluations of both meteorological inputs and air quality model performance to evaluate the reliability of the modeling results. These are important aspects of the attainment demonstration. However, the Modeling Guidance recommendations are not regulatory requirements, and there are no recommended pass/fail thresholds for any particular evaluation metric. The guidance recommendations are generally applicable to evaluating model performance, but there are no specific requirements that are applicable or must be met in all cases. The particular analyses used may vary on a case-by-case basis, depending on the availability of modeled and observational data (both meteorological and air quality data).

In evaluating the meteorological inputs to the modeling, MAG followed the recommendations of the Modeling Guidance by conducting an ''operational evaluation'' focusing on ''the values and distributions of specific meteorological parameters as paired with and compared to observed data.'' [17] Specifically, MAG used a series of statistical metrics to compare wind speed, wind direction, temperature, and water vapor mixing ratio values from the model to observations from weather stations in the NAA. As described in our proposal, temperature and water vapor mixing ratios showed good agreement with observations, with little bias. The modeled wind speed showed an overestimate at low wind speeds and an underestimate at high wind speed. Modeled wind direction showed poorer performance for wind directions from the south-east. MAG asserted that modeling wind speed and direction in Phoenix is difficult due to the complex terrain in the area, but that results are comparable to the benchmarks described in the Modeling Guidance.[18]

The Modeling Guidance explains that these benchmarks are to be ''used as a means of assessing general confidence in the meteorological model data'' rather than as ''as a 'pass/fail' indicator of the acceptability of a model simulation.'' [19] The fact the metrological parameters used in MAG's modeling are comparable to these benchmarks, despite the challenges presented by the complex terrain of the area, supports a conclusion that the meteorological inputs used by MAG ''represent a reasonable approximation of the actual meteorology that occurred during the modeling period.'' [20]

In addition to an operational evaluation of meteorological inputs based on statistical comparisons, the Modeling Guidance also recommends that states conduct a phenomenological

[9] See, *e.g.,* CAA section 181(a)(1) (setting the attainment date for Moderate areas of 6 years after November 15, 1990); and 182(b)(1)(A) (requiring submittal of attainment demonstration for Moderate areas 3 years after November 15, 1990 and setting RFP milestone date of 6 years after November 15, 1990).

[10] CAA sections 172(c)(1), (2), and (6).

[11] 40 CFR 51.1108(c)(attainment demonstration must be ''based on photochemical grid modeling or any other analytical method determined . . . to be at least as effective.'').

[12] 84 FR 60920.

[13] 40 CFR 81.303, 51.1303(b).

[14] The 2015 ozone primary and secondary NAAQS are 0.070 parts per million (ppm), while 2008 NAAQS are 0.075 ppm. Both are based on a three-year average of the annual fourth-highest daily maximum 8-hour average ozone concentrations. Accordingly, exceedances of the 2008 NAAQS are also exceedances of the 2015 NAAQS.

[15] CAA section 181(b)(2).

[16] ''Modeling Guidance for Demonstrating Attainment of Air Quality Goals for Ozone, $PM_{2.5}$, and Regional Haze'', November 2018, EPA 454/R–18–009 (''Modeling Guidance''), 169, 24.

[17] Modeling Guidance, 33.

[18] 84 FR 52838, 52844.

[19] Modeling Guidance, 33.

[20] Id. at 32.

evaluation (*i.e.,* a qualitative comparison of observed features versus their depiction in the model data). As noted in our proposal, while the inclusion of such an analysis ''would have provided additional confidence, the model adequately simulates the temporal and spatial variability in ozone concentrations across the area, suggesting the model captures the meteorological phenomena that are important for ozone formation in the Phoenix area.'' [21] Therefore, we find that the absence of a phenomenological evaluation of meteorological data does not undermine the overall adequacy of the modeling.

Concerning air quality model performance evaluation, the EPA's ''Guideline on Air Quality Models'' explains that, ''[t]here are no specific levels of any model performance metric that indicate 'acceptable' model performance.'' [22] Thus, ''[t]he EPA recommends that air agencies conduct a variety of performance tests and weigh them qualitatively to assess model performance.'' [23] Specifically, as part of an operational evaluation, the EPA recommends evaluating the following statistical metrics: mean observed, mean model, mean bias, mean error and/or root mean square error, normalized mean bias and/or fractional bias, normalized mean error and/or fractional error, and the correlation coefficient.[24] In this case, as part of its air quality model evaluation, MAG evaluated each of the recommended (except for the correlation coefficient, for which it substituted the related ''coefficient of determination'') to evaluate ozone model performance.[25] Figures IV–5 through IV–10 of the Modeling technical support document provide time-series plots, scatter plots, spatial maps of mean error and bias, and box plots comparing model performance with previous studies. As described in the proposal, these analyses show that, although there were ''a few periods where peak ozone concentrations were underpredicted in July and overpredicted in August, MAG modeling statistics are within or close to the distribution of other published modeling studies.'' [26] Accordingly, we concluded that, ''[o]verall, the operational evaluation shows good model performance.'' [27] As we further noted in our proposal, the ''addition of some dynamic and diagnostic evaluations as described in the Modeling Guidance would have provided additional confidence.'' [28] However, the Modeling Guidance also explains that, ''[g]iven that air agencies might have limited resources and time to perform diagnostic and dynamic evaluation, the use of these methods may be limited in scope in a typical regulatory modeling application.'' [29] Accordingly, we do not consider the omission of such dynamic and diagnostic evaluations to undercut the adequacy of the modeling.

In sum, the meteorological inputs were reasonable, and the Plan demonstrated good air quality model performance. Furthermore, in addition to the modeling demonstration, the Plan also contains a comprehensive ''weight of evidence'' analysis, consisting of several supplemental analyses that further support the modeled attainment demonstration.[30] These include ozone air quality trends and precursor emission trends, both of which show continued progress and support the conclusion that the attainment demonstration is sound. Other analyses include: an evaluation of the sensitivity of the model to oxides of nitrogen (NO_X) and volatile organic compound (VOC) emissions reductions; a comparison to the EPA's modeling for the Cross-State Air Pollution Rule, which projects the area will be in attainment in 2017; a process analysis using the VOC:NO_X ratio as a photochemical indicator; and an examination of weekday versus weekend effects. These analyses provide assurance that the model is adequately simulating the physical and chemical processes leading to ozone in the atmosphere and that the model responds in a scientifically reasonable way to emissions changes. Therefore, we do not agree with the commenter that we should disapprove the attainment demonstration in the MAG 2017 Ozone Plan based on the modeling.

Comment 1.f: The commenter supported the EPA's proposal to disapprove the contingency measure element of the Plan based on *Bahr* v. *EPA,*[31] but argued that there is no statutory basis for ''excusing'' MAG from including contingency measures in the Plan. The commenter stated that CAA section 172(e) ''expressly prevents EPA from loosening controls applicable to a nonattainment area when a NAAQS is relaxed,'' and the EPA applies the same concept ''where the NAAQS is made more stringent.'' Citing *South Coast Air Quality Management District* v. *EPA* (''*South Coast*''),[32] the commenter noted that contingency measures are ''controls'' because they are ''designed to constrain ozone pollution.'' Citing *South Coast,* the commenter argued that MAG cannot withdraw its contingency measures because ''withdrawing measures from a SIP would also constitute impermissible backsliding.''

Response: The commenter's reliance on CAA section 172(e) is misplaced. This provision applies if the EPA relaxes a NAAQS and requires the EPA to promulgate ''requirements applicable to all areas which have not attained that standard as of the date of such relaxation.'' [33] The commenter alleges that this provision would preclude our determination that a SIP revision providing for contingency measures for the Phoenix NAA for the 2008 ozone NAAQS is no longer required. The promulgation of the 2008 ozone NAAQS was a strengthening from the prior 1997 ozone NAAQS. Accordingly, CAA section 172(e) is not directly applicable.

The commenter further discusses, but mischaracterizes, the EPA's past actions invoking the principles of section 172(e) when revoking an ozone standard. The commenter wrongly suggests that the EPA has applied section 172(e) in cases where the Agency strengthens the NAAQS; this is not true. The EPA has looked to the principles of section 172(e) to develop anti-backsliding regulations when the EPA has revoked ozone standards in order to ensure air quality protections are preserved during the transition to a more protective NAAQS.[34] The EPA has not taken any action to revoke the 2008 ozone NAAQS.[35]

The relevant provision of the CAA, section 172(c)(9), requires nonattainment plans to ''provide for the implementation of specific measures to be undertaken if the area fails to make [RFP], or to attain the [NAAQS] by the attainment date applicable under this part.'' Thus, contingency measures are required for two purposes: attainment

[21] 84 FR 52838, 52844.

[22] ''Guideline on Air Quality Models,'' 40 CFR part 51, appendix W, section 5.2.d.

[23] Modeling Guidance, 69.

[24] Id. at 70–72.

[25] MAG 2017 Ozone Plan, Appendix B, Exhibit 1, (''Modeling Technical Support Document'' or ''Modeling TSD''), section IV.

[26] 84 FR 52838, 52844.

[27] Id.

[28] Id.

[29] Modeling Guidance, 68.

[30] 84 FR 52838, 52845.

[31] 836 F.3d 1218, 1235–1237 (9th Cir. 2016).

[32] 472 F.3d 882, 900–902 (D.C. Cir. 2006).

[33] 42 U.S.C. 7502.

[34] 80 FR 12264 (March 6, 2015) (revoking the 1997 ozone NAAQS); 69 FR 23951 (April 30, 2004) (revoking the 1979 1-hour ozone NAAQS).

[35] 83 FR 62998 (December 6, 2018) (''The EPA is not taking any final action regarding our proposed approach for revoking a prior ozone NAAQS and establishing anti-backsliding requirements; the agency intends to address any revocation of the 2008 ozone NAAQS and any potential anti-backsliding requirements in a separate future rulemaking.'').

contingency measures and RFP contingency measures. On November 12, 2019, the EPA took final action to determine that the Phoenix NAA attained the Moderate area 2008 ozone NAAQS by the attainment date, and Arizona was no longer required to provide a SIP submission that includes attainment contingency measures for the 2008 NAAQS for the Phoenix NAA because attainment contingency measures for this NAAQS would never be required to be implemented.[36] With regard to the RFP contingency measure requirement, we proposed, in conjunction with our proposal on the MAG 2017 Ozone Plan, to find that the RFP contingency measure requirement would also no longer apply to the Phoenix NAA for the 2008 ozone NAAQS.[37] We explained that the EPA's long-standing interpretation is that RFP contingency measures for Moderate areas would be triggered only by a finding that the area failed to attain the standard by the Moderate area attainment date.[38] Because we have determined that the area has attained the standard by the attainment date, the RFP contingency measures have not, and will not, be triggered. Thus, we have determined that a SIP revision addressing RFP contingency measures is no longer needed.

Comment 1.g: The commenter noted that section 107(d)(3)(E)(v) prohibits the EPA from redesignating a NAA to attainment unless ''the State . . . has met *all* requirements applicable to this area'' under section 110 and part D of the CAA, including contingency measures under section 172(c)(9). The commenter also quoted CAA section 110(l), which prohibits the EPA from approving a SIP revision that would interfere with any applicable requirement concerning attainment and RFP or any other applicable requirement of the CAA.

Response: None of the provisions cited by the commenter are relevant either to our disapproval of the contingency measures for the Phoenix NAA or to our determination that a SIP revision addressing contingency measures is no longer required for the Phoenix NAA. CAA section 107(d)(3)(E)(v) applies when the EPA is redesignating an area from nonattainment to attainment. ADEQ has not submitted a redesignation request for the Phoenix NAA, and we have not proposed to redesignate the area. Therefore, CAA section 107(d)(3)(E)(v) does not apply to this action.

CAA section 110(l) prohibits the EPA from approving a SIP revision that would interfere with any applicable requirement of the CAA. Because we are disapproving the contingency measure element of the Plan, this requirement does not apply to our action on the contingency measure portion of the Plan. To the extent the commenter is suggesting that our approval of the remainder of the 2017 MAG Ozone Plan would interfere with any applicable requirement of the CAA, we do not agree. First, in this action, the EPA is not approving the removal of any existing provisions in the approved Arizona SIP, and thus there is no concern that our approval action would interfere with any applicable CAA requirement. Second, to the extent that the commenter is concerned that the EPA's approval of the nonattainment plan without contingency measures contravenes the requirements of the CAA to include such measures, the EPA has determined that such measures are not in fact required for this area for this NAAQS for the reasons described in our response to comment 1.f in this action. Section 110(l) prohibits the EPA's approval of a SIP revision if it would interfere with any applicable requirement concerning attainment and reasonable further progress, or any other applicable requirement of the CAA. Given that attainment contingency measures and RFP contingency measures are no longer applicable requirements, following the EPA's final action to determine the area attained by the attainment date, the EPA's approval of the remainder of the SIP submission is consistent with CAA section 110(l). For the reasons discussed in our proposal and in this document, we find that the Plan meets all applicable CAA requirements. Therefore, our approval of the other elements of the Plan complies with CAA section 110(l).

Comment 1.h: The commenter stated that there was no merit to the EPA's argument that based on the ''milestone'' requirement for ozone NAAs classified as ''Serious'' or higher, the RFP contingency measures are no longer required. In particular, citing *South Coast,* the commenter asserted that ''[t]his provision demonstrates that when Congress intended to exempt nonattainment areas from statutory requirements, it did so expressly.'' The commenter concluded that the EPA must disapprove the contingency measure element of the Plan and require the adoption of additional contingency measures consistent with *Bahr.*

Response: In our proposal, we explained that under CAA section 182(g), ozone nonattainment areas classified Serious or higher are required to meet RFP emissions reduction milestones and to demonstrate compliance with those milestones, except when the milestone coincides with the attainment date and the standard has been attained. We noted that this specific statutory exemption from milestone compliance demonstration submittals for areas that attained by the attainment date indicates that Congress intended that a finding that an area attained the standard—the finding made in a determination of attainment by the attainment date—would serve as a demonstration that RFP requirements for the area have been met. Therefore, a finding that a Serious or above area has attained the NAAQS by the attainment date would also indicate that RFP contingency measures could not be triggered and are therefore no longer necessary.

The commenter points to the absence of a similar exemption (*i.e.,* an exemption from RFP milestone compliance demonstration submittals when the milestone coincides with the attainment date and the standard has been attained) for Moderate areas. The commenter appears to be arguing that this omission indicates that Congress intended to subject Moderate areas to the requirement for RFP contingency measures, even if they attained the NAAQS by the attainment date. Contrary to the commenter's suggestion, however, Congress expressly exempted Moderate areas from all RFP milestone compliance demonstration submittals.[39] Accordingly, unlike for Serious and above areas, Congress did not need to provide a specific exemption for a milestone coinciding with the attainment date for Moderate areas. The overall statutory exemption from requirements for RFP milestone compliance demonstration submittals in Moderate areas supports the EPA's interpretation that RFP contingency measures in Moderate ozone NAAs can be triggered only by a finding that the area has failed to attain the standard by the attainment date.[40] Therefore, while

[36] 84 FR 60920.

[37] 84 FR 52838, 52847.

[38] Id. (citing 57 FR 13498, 13511 (April 16, 1992) and Memorandum dated March 11, 1993, from G.T. Helms, Chief Ozone/Carbon Monoxide Programs Branch, to Air Branch Chief, Regions I–X).

[39] CAA section 182(g)(1) (''6 years after November 15, 1990, and at intervals of every 3 years thereafter, the State shall determine whether each nonattainment area (other than an area classified as Marginal or Moderate)'' has achieved the applicable milestone).

[40] As noted in our proposal, ''a determination of attainment by the attainment date for a Moderate area serves as demonstration that RFP requirements for the area have been met and that RFP contingency measures are no longer needed. Thus,

Continued

we are disapproving the contingency measure element of the Plan, we are also determining that Arizona is no longer required to submit a SIP revision including contingency measures for the Phoenix NAA.

Commenter #2—ADEQ

Comment: ADEQ expressed support for the EPA's proposed action, including disapproval of the contingency measure requirements, provided the EPA finalizes its determination that the Phoenix NAA attained the 2008 ozone standard by the attainment date.

Response: The EPA finalized its determination that the Phoenix NAA attained the 2008 ozone standard by the applicable attainment date on November 12, 2019.[41]

III. Final Action

No comments were submitted that change our assessment of the determinations as described in our proposed action. Therefore, for the reasons discussed in the preceding sections and in our proposed rule, under CAA section 110(k)(3), the EPA is finalizing approval as a revision to the Arizona SIP the following portions of the ''MAG 2017 Eight-Hour Ozone Moderate Area Plan for the Maricopa Nonattainment Area,'' submitted by ADEQ on December 19, 2016:

- Base year and periodic emission inventories as meeting the requirements of CAA sections 172(c)(3), 182(a)(1), and 182(a)(3)(A) and 40 CFR 51.1115(a) and (b);
- RACM demonstration and control strategy as meeting the requirements of CAA section 172(c)(1) and 172(c)(6) and 40 CFR 51.1112(c);
- Attainment demonstration as meeting the requirements of CAA section 182(b)(1)(A)(i) and 40 CFR 51.112 and 51.1108(c);
- Rate of progress plan and RFP demonstration as meeting the requirements of CAA sections 172(c)(2) and 182(b)(1) and 40 CFR 51.1110(a)(3)(i);
- Motor vehicle emissions budgets for the 2017 attainment year because they are consistent with the RFP demonstration and the attainment demonstration approved herein and meet the other criteria in 40 CFR 93.118(e);
- Vehicle I/M provisions as meeting the requirements of 40 CFR part 51, subpart S;
- NSR discussion as demonstrating that the requirements of CAA sections 173 and 182(a)(2)(C) have been met; and
- Offset discussion as demonstrating that the requirements of CAA sections 173 and 182(b)(5) have been met.

The EPA is finalizing disapproval of the contingency measure element of the MAG 2017 Ozone Plan for failing to meet the requirements of CAA sections 172(c)(9) and 182(c)(9). However, based on our November 12, 2019 finding of attainment by the applicable attainment date,[42] we are also finalizing our determination that Arizona is no longer required to submit a SIP revision addressing the contingency measures requirement for failure to meet RFP for the Phoenix 2008 ozone NAA. Therefore, our disapproval does not trigger sanctions or FIP clocks.

Finally, we are finalizing approval of the NSR and offset elements of the MAG 2014 Ozone Plan as meeting the Marginal area requirements of CAA section 182(a)(2)(C) and CAA sections 173 and 182(b)(5), respectively, for the Phoenix 2008 ozone NAA.

IV. Statutory and Executive Order Reviews

Additional information about the following 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 13711: Reducing Regulations and Controlling Regulatory Costs

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

C. Paperwork Reduction Act (PRA)

This action does not impose an information collection burden under the PRA because this action does not impose additional requirements beyond those imposed by state law.

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 beyond those imposed by state law.

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 does not impose additional requirements beyond those imposed by state law. Accordingly, no additional costs to state, local, or tribal governments, or to the private sector, will result from this action.

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: Coordination With Indian Tribal Governments

This action does not have tribal implications, as specified in Executive Order 13175, because 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, and will not impose substantial direct costs on tribal governments or preempt tribal law. 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 impose additional requirements beyond those imposed by state law.

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.

the EPA concludes that RFP contingency measures for Moderate areas are no longer needed if the area has attained the relevant NAAQS.'' 84 FR 52847.

[41] 84 FR 60920.

[42] Id.

J. National Technology Transfer and Advancement Act (NTTAA)

Section 12(d) of the NTTAA directs the EPA to use voluntary consensus standards in its regulatory activities unless to do so would be inconsistent with applicable law or otherwise impractical. The EPA believes that this action is not subject to the requirements of section 12(d) of the NTTAA because application of those requirements would be inconsistent with the CAA.

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

The EPA lacks the discretionary authority to address environmental justice in this rulemaking.

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).

M. Petitions for Judicial Review

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 August 3, 2020. Filing a petition for reconsideration by the Administrator of this final rule does not affect the finality of this rule for the purposes of judicial review nor does it extend the time within which a petition for judicial review may be filed, and shall not postpone the effectiveness of such rule or action. This action may not be challenged later in proceedings to enforce its requirements (see section 307(b)(2)).

List of Subjects in 40 CFR Part 52

Environmental protection, Air pollution control, Incorporation by reference, Intergovernmental relations, Nitrogen dioxide, Ozone, Reporting and recordkeeping requirements, Volatile organic compounds.

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

Dated: May 1, 2020.

John Busterud,

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 is amended in table 1 in paragraph (e), under the heading ''Part D Elements and Plans for the Metropolitan Phoenix and Tucson Areas,'' by adding entries for ''MAG 2017 Eight-Hour Ozone Moderate Area Plan for the Maricopa Nonattainment Area (December 2016)'' and ''MAG 2014 Eight-Hour Ozone Plan—Submittal of Marginal Area Requirements for the Maricopa Nonattainment Area (June 2014), Sections titled ''A Nonattainment Area Preconstruction Permit Program—CAA section 182(a)(2)(C),'' ''New Source Review—CAA, Title I, Part D,'' and ''Offset Requirements: 1:1 to 1 (Ratio of Total Emission Reductions of Volatile Organic Compounds to Total Increased Emissions)—CAA Section 182(a)(4)'' on pages 8 and 9'' after the entry for ''Reasonably Available Control Technology (RACT) Analysis, Negative Declaration and Rules Adoption'' to read 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 nonattainment area or title/subject	State submittal date	EPA approval date	Explanation
The State of Arizona Air Pollution Control Implementation Plan				
* *	* *	*	*	*
Part D Elements and Plans for the Metropolitan Phoenix and Tucson Areas				
* *	* *	*	*	*
MAG 2017 Eight-Hour Ozone Moderate Area Plan for the Maricopa Nonattainment Area (December 2016).	Phoenix-Mesa 2008 8-hour ozone nonattainment area.	December 19, 2016.	[Insert **Federal Register** Citation], June 2, 2020.	Adopted by the Arizona Department of Environmental Quality on December 13, 2016.
MAG 2014 Eight-Hour Ozone Plan—Submittal of Marginal Area Requirements for the Maricopa Nonattainment Area (June 2014), Sections titled ''A Nonattainment Area Preconstruction Permit Program—CAA section 182(a)(2)(C),'' ''New Source Review—CAA, Title I, Part D,'' and ''Offset Requirements: 1:1 to 1 (Ratio of Total Emission Reductions of Volatile Organic Compounds to Total Increased Emissions)—CAA Section 182(a)(4)'' on pages 8 and 9.	Phoenix-Mesa 2008 8-hour ozone nonattainment area.	July 2, 2014	[Insert **Federal Register** Citation], June 2, 2020.	Other provisions of the MAG 2014 Eight-Hour Ozone Plan—Submittal of Marginal Area Requirements for the Maricopa Nonattainment Area (June 2014) were approved on October 16, 2015.
* *	* *	*	*	*

[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. 2020–09732 Filed 6–1–20; 8:45 am]

BILLING CODE 6560–50–P

FEDERAL COMMUNICATIONS COMMISSION

47 CFR Parts 1 and 2

[ET Docket Nos. 03–137 and 13–84, FCC 19–126, FRS 16453]

Human Exposure to Radiofrequency Electromagnetic Fields and Reassessment of FCC Radiofrequency Exposure Limits and Policies

AGENCY: Federal Communications Commission.

ACTION: Final rule; correction; delay of effective date.

SUMMARY: In this document, the Federal Communications Commission delays the effective date of some of the amendments published in a final rule on April 1, 2020, with an effective date of June 1, 2020. The Commission did not intend certain amendments to take effect until after approval by the Office of Management and Budget under the Paperwork Reduction Act.

DATES: Effective May 29, 2020, the effective date of the amendments to 47 CFR 1.1307, 2.1091, 2.1093 (amendatory instructions 2, 7, and 8), published at 85 FR 18131, April 1, 2020, is delayed indefinitely. We will publish a document in the **Federal Register** announcing the effective date.

FOR FURTHER INFORMATION CONTACT: Martin Doczkat, email: *martin.doczkat@fcc.gov;* the Commission's RF Safety Program, *rfsafety@fcc.gov;* or call the Office of Engineering and Technology at (202) 418–2470.

SUPPLEMENTARY INFORMATION: In the Commission's Second Report and Order, Memorandum Opinion and Order, and Termination of Notice of Inquiry, ET Docket No. 03–137, ET Docket No. 13–84, FCC 19–126, adopted November 27, 2019, and released December 4, 2019, the Commission amended its rules related to the methods that may be used for determining and achieving compliance with the Commission's existing limits on human exposure to radiofrequency (RF) electromagnetic fields. The amended rules are intended to provide more efficient, practical, and consistent RF exposure evaluation procedures and mitigation measures to help ensure compliance with the existing RF exposure limits. The summary of the Second Report and Order published at 85 FR 18131, April 1, 2020, incorrectly stated that the entire item would become effective sixty days after publication, June 1, 2020. In fact, the amendments to 47 CFR 1.1307, 2.1091, and 2.1093 require approval by the Office of Management and Budget under the Paperwork Reduction Act. This document indefinitely delays the effective date of 47 CFR 1.1307, 2.1091, and 2.1093, while the Commission seeks OMB approval.

Federal Communications Commission.

Marlene Dortch,

Secretary, Office of the Secretary.

[FR Doc. 2020–11969 Filed 5–29–20; 4:15 pm]

BILLING CODE 6712–01–P

FEDERAL COMMUNICATIONS COMMISSION

47 CFR Part 54

[WC Docket Nos. 19–126, 10–90; FCC 20–5; FR 16801]

Rural Digital Opportunity Fund, Connect America Fund

AGENCY: Federal Communications Commission.

ACTION: Final rule; announcement of effective date.

SUMMARY: In this document, the Federal Communications Commission (Commission) announces that the Office of Management and Budget (OMB) has approved, for a period of three years, an information collection associated with the rules for the Rural Digital Opportunity Fund auction contained in the Commission's *Rural Digital Opportunity Fund Order,* FCC 20–5. This document is consistent with the *Rural Digital Opportunity Fund Order,* which stated that the Commission would publish a document in the **Federal Register** announcing the effective date of the new information collection requirements.

DATES: The amendment to § 54.804(a) published at 85 FR 13773, March 10, 2020, is effective June 2, 2020.

FOR FURTHER INFORMATION CONTACT: Alexander Minard, Wireline Competition Bureau at (202) 418–7400 or TTY (202) 418–0484. For additional information concerning the Paperwork Reduction Act information collection requirements contact Nicole Ongele at (202) 418–2991 or via email: *Nicole.Ongele@fcc.gov.*

SUPPLEMENTARY INFORMATION: The Commission submitted revised information collection requirements for review and approval by OMB, as required by the Paperwork Reduction Act (PRA) of 1995, on April 20, 2020, which were approved by the OMB on May 22, 2020. The information collection requirements are contained in the Commission's *Rural Digital Opportunity Fund Order,* FCC 20–5, published at 85 FR 13773, March 10, 2020. The OMB Control Number is 3060–1252. The Commission publishes this document as an announcement of the effective date of the rules published March 10, 2020. If you have any comments on the burden estimates listed below, or how the Commission can improve the collections and reduce any burdens caused thereby, please contact Nicole Ongele, Federal Communications Commission, Room 1–A620, 445 12th Street SW, Washington, DC 20554. Please include the OMB Control Number, 3060–1252, in your correspondence. The Commission will also accept your comments via email at *PRA@fcc.gov.*

To request materials in accessible formats for people with disabilities (braille, large print, electronic files, audio format), send an email to *fcc504@fcc.gov* or call the Consumer and Governmental Affairs Bureau at (202) 418–0530 (voice), (202) 418–0432 (TTY).

Synopsis

As required by the Paperwork Reduction Act of 1995 (44 U.S.C. 3507), the Commission is notifying the public that it received OMB approval on May 22, 2020, for the information collection requirements contained in 47 CFR 54.804(a), published at 85 FR 13773, March 10, 2020. Under 5 CFR part 1320, an agency may not conduct or sponsor a collection of information unless it displays a current, valid OMB Control Number.

No person shall be subject to any penalty for failing to comply with a collection of information subject to the Paperwork Reduction Act that does not display a current, valid OMB Control Number. The OMB Control Number is 3060–1252.

The foregoing notice is required by the Paperwork Reduction Act of 1995, Public Law 104–13, October 1, 1995, and 44 U.S.C. 3507.

The total annual reporting burdens and costs for the respondents are as follows:

OMB Control Number: 3060–1252.

OMB Approval Date: May 22, 2020.

OMB Expiration Date: May 31, 2023.

Title: Application to Participate in Rural Digital Opportunity Fund Auction, FCC Form 183.

Form No.: FCC Form 183.

Respondents: Business or other for-profit entities, Not-for-profit institutions, and State, Local or Tribal governments.

Number of Respondents and Responses: 500 respondents and 500 responses.

Estimated Time per Response: 7 hours.

Frequency of Response: On occasion reporting requirement.

Obligation to Respond: Required to obtain or retain benefits. Statutory authority for this information collection is contained in 47 U.S.C. 154, 254 and 303(r) of the Communications Act of 1934, as amended.

Total Annual Burden: 3,500 hours.

Total Annual Cost: No Cost.

Nature and Extent of Confidentiality: Although most information collected in FCC Form 183 will be made available for public inspection, the Commission will withhold certain information collected in FCC Form 183 from routine public inspection. Specifically, the Commission will treat certain technical and financial information submitted in FCC Form 183 as confidential and as though the applicant has requested that this information be treated as confidential trade secrets and/or commercial information. In addition, an applicant may use the abbreviated process under 47 CFR 0.459(a)(4) to request confidential treatment of certain financial information contained in its FCC Form 183 application. However, if a request for public inspection for this technical or financial information is made under 47 CFR 0.461, and the applicant has any objections to disclosure, the applicant will be notified and will be required to justify continued confidential treatment of its request. To the extent that a respondent seeks to have other information collected in FCC Form 183 withheld from public inspection, the respondent may request confidential treatment pursuant to 47 CFR 0.459.

Privacy Act Impact Assessment: No impact(s).

Needs and Uses: The Commission will use the information collected to determine whether applicants are eligible to participate in the Rural Digital Opportunity Fund auction. On January 30, 2020 the Commission adopted the *Rural Digital Opportunity Fund Order,* WC Docket Nos. 19–126, 10–90, FCC 20–5 which will commit up to $20.4 billion over the next decade to support up to gigabit speed broadband networks in rural America. The funding will be allocated through a multi-round, reverse, descending clock auction that favors faster services with lower latency and encourages intermodal competition in order to ensure that the greatest possible number of Americans will be connected to the best possible networks, all at a competitive cost.

To implement the Rural Digital Opportunity Fund auction, the Commission adopted new rules for the Rural Digital Opportunity Fund, including the adoption of a two-stage application process. For the Connect America Fund Phase II auction, applicants that wanted to qualify to bid in the auction were required to submit the FCC Form 183 short-form application. Because the Connect America Fund Phase II auction has ended, the Commission intends to repurpose the FCC Form 183 for the Rural Digital Opportunity Fund. Any entity that wishes to participate will be required to submit the FCC Form 183 short-form application to demonstrate its qualifications to bid. Accordingly, the Commission revises this collection to indicate that it now intends to collect this information pursuant to § 54.804(a) of the Commission's rules, replacing § 54.315(a) of the Commission's rules. 47 CFR 54.315(a), 54.804(a). The Commission also makes several revisions to FCC Form 183, including text changes to reflect the Rural Digital Opportunity Fund. Based on the Commission's experience with auctions and consistent with the record, this two-stage collection of information balances the need to collect information essential to conduct a successful auction with administrative efficiency.

Under this information collection, the Commission will collect information that will be used to determine whether an applicant is legally qualified to participate in an auction for Rural Digital Opportunity Fund support. To aid in collecting this information, the Commission will use FCC Form 183, which the public will use to provide the necessary information and certifications. Commission staff will review the information collected on FCC Form 183 as part of the pre-auction process, prior to the start of the auction, and determine whether each applicant satisfies the Commission's requirements to participate in an auction for Rural Digital Opportunity Fund support. Without the information collected on FCC Form 183, the Commission will not be able to determine if an applicant is legally qualified to participate in the auction and has complied with the various applicable regulatory and statutory auction requirements for such participation. This approach is an appropriate assessment of providers for ensuring serious participation without being unduly burdensome.

Federal Communications Commission.

Cecilia Sigmund,

Federal Register Liaison Officer.

[FR Doc. 2020–11791 Filed 6–1–20; 8:45 am]

BILLING CODE 6712–01–P

DEPARTMENT OF COMMERCE

National Oceanic and Atmospheric Administration

50 CFR Part 648

[Docket No. 200527–0147]

RIN 0648–BJ46

Fisheries of the Northeastern United States; Northeast Skate Complex; Framework Adjustment 8 and 2020–2021 Specifications; Correction

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

ACTION: Final rule; correction.

SUMMARY: This action corrects errors in the Season 2 barndoor skate wing possession limit value specified in the **SUPPLEMENTARY INFORMATION** section of the final rule to implement Framework Adjustment 8 to the Northeast Skate Complex Fishery Management Plan, published in the **Federal Register** on April 27, 2020. This action is necessary to minimize confusion to the public, and to ensure the correct values are provided for all possession limits.

DATES: Effective June 1, 2020.

ADDRESSES: Information in the final rule published on April 27, 2020 (85 FR 23240), which includes an Environmental Assessment (EA) and other supporting documents for Framework Adjustment 8, are available via the internet at *www.regulations.gov* and *www.nefmc.org.*

FOR FURTHER INFORMATION CONTACT: Cynthia Ferrio, Fishery Policy Analyst, (978) 281–9180.

SUPPLEMENTARY INFORMATION:

Background

On April 27, 2020, we published a final rule (85 FR 23240) that implemented Framework Adjustment 8 to the Northeast skate fishery, including specifications and possession limits for fishing years 2020 and 2021. This rule published with an error.

Need for Correction

The Framework 8 final rule outlined the final possession limits for the entire skate fishery in the preamble text, in a summary table, and in changes to the

regulatory text. However, within the preamble, there were two typographical errors when noting the new skate wing possession limit for barndoor skates in Season 2 of the skate wing fishery. The first error is in the text on page 23241, where the rule incorrectly indicates that the barndoor skate possession limit in the wing fishery is increasing to 1,025 lb (465 kg) in Season 2. This is incorrect, as the Season 2 possession limit before this framework was 1,025 lb (465 kg). This line should be corrected to read that the barndoor skate possession limit is increasing to 1,250 lb (567 kg) in Season 2.

The second error is also on page 23241, in the table under the subheading ''Table 2—Skate Fishery Possession Limits for Fishing Years 2020 and 2021.'' In the cell describing the barndoor skate wing weight possession limit for Season 2, the value in pounds (1,250 lb) is correct, but the converted value in kilograms (465 kg) is in error. The kilogram value in this table should be corrected to 567 kg.

The correct values were published in the proposed rule (85 FR 6494, February 5, 2020) for this action, and elsewhere in this final rule, including in the regulatory text. Because the errors are not in the regulatory text, there is no need for correction to the CFR.

Correction

In the **Federal Register** of April 27, 2020, in FR Doc. 2020–07805, beginning on page 23240, the following corrections are made:

1. On page 23241, in the second column, in the second full paragraph, ''to 1,025 lb (465 kg) in Season 2'' is corrected to read ''to 1,250 lb (567 kg) in Season 2.''

2. On page 23241, table 2 is corrected to read as follows:

TABLE 2—SKATE FISHERY POSSESSION LIMITS ** FOR FISHING YEARS 2020 AND 2021

Trip type	Season	Wing weight	Whole weight	Barndoor * wing weight	Barndoor * whole weight
Northeast (NE) Multispecies, Scallop, or Monkfish Day-At-Sea (DAS).	Season 1	3,000 lb, *1,361 kg*	6,810 lb, *3,089 kg*	750 lb, *340 kg*	1,703 lb, *772 kg.*
	Season 2	5,000 lb, *2,268 kg*	11,350 lb, *5,148 kg* ..	1,250 lb, *567 kg*	2,838 lb, *1,287 kg.*
NE Multispecies B DAS	All Year	220 lb, *100 kg*	500 lb, *227 kg*	0	0.
Non-DAS	All Year	500 lb, *227 kg*	1,135 lb, *515 kg*	0	0.
Skate Bait under Letter of Authorization	All Year	0	25,000 lb, *11,340 kg*	0	0.

* Barndoor skate possession limits are within the overall skate possession limit for each trip, not in addition to it.
** Possession limits may be modified in-season in order to prevent catch from exceeding quotas.

Classification

The NMFS Administrator, Greater Atlantic Region, has determined that this action is necessary and consistent with the Northeast Skate Complex FMP, other provisions of the Magnuson-Stevens Act, and other applicable law.

The NMFS Assistant Administrator finds good cause under 5 U.S.C. 553(b)(B) to waive prior notice and an opportunity for public comment on this action because the correct information was provided in the proposed rule, and the public had an opportunity to comment on it. This correcting amendment makes only minor, non-substantive corrections to typographical errors that included in the final rule text. It does not change operating practices in the fishery. It does not change any regulatory text. Therefore notice and comment are unnecessary and would be contrary to the public interest. Because this action makes no substantive changes and makes minor corrections, it does not constitute a substantive rule, and it is not subject to the requirement for a 30-day delay in effective date in 5 U.S.C. 553(d).

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

Dated: May 27, 2020.

Samuel D. Rauch III,

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

[FR Doc. 2020–11743 Filed 6–1–20; 8:45 am]

BILLING CODE 3510–22–P

Proposed Rules

Federal Register
Vol. 85, No. 106
Tuesday, June 2, 2020

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.

NUCLEAR REGULATORY COMMISSION

10 CFR Parts 9 and 35

[NRC–2018–0303]

RIN 3150–AK27

Social Security Number Fraud Prevention

AGENCY: Nuclear Regulatory Commission.

ACTION: Proposed rule.

SUMMARY: The U.S. Nuclear Regulatory Commission (NRC) is proposing to amend its regulations to implement the Social Security Number Fraud Prevention Act of 2017. This statute directed agencies to issue regulations that prohibit the inclusion of an individual's Social Security account number (Social Security number or SSN) on any document sent through the mail unless the head of the agency deems it necessary and the appropriate precautions are taken to protect the Social Security number. Applicants, licensees, and members of the public who are required to submit a form containing a Social Security number may be affected.

DATES: Submit comments by July 2, 2020. Comments received after this date will be considered if it is practical to do so, but the NRC is able to ensure consideration only for comments received on or before this date.

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

- *Federal Rulemaking Website:* Go to *https://www.regulations.gov* and search for Docket ID NRC–2018–0303. Address questions about NRC dockets to Carol Gallagher; telephone: 301–415–3463; email: *Carol.Gallagher@nrc.gov.* For technical questions contact the individual listed in the **FOR FURTHER INFORMATION CONTACT** section of this document.
- *Email comments to: Rulemaking.Comments@nrc.gov.* If you do not receive an automatic email reply confirming receipt, then contact us at 301–415–1677.
- *Mail comments to:* Secretary, U.S. Nuclear Regulatory Commission, Washington, DC 20555–0001, ATTN: Rulemakings and Adjudications Staff.

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: Alexa Sieracki, Office of Nuclear Materials Safety and Safeguards, U.S. Nuclear Regulatory Commission, Washington, DC 20555–0001; telephone: 301–415–7509, email: *Alexa.Sieracki@nrc.gov.*

SUPPLEMENTARY INFORMATION:

Table of Contents

I. Obtaining Information and Submitting Comments

A. Obtaining Information

Please refer to Docket ID NRC–2018–0303 when contacting the NRC about the availability of information for this action. You may obtain publicly-available information related to this action by any of the following methods:

- *Federal Rulemaking Website:* Go to *https://www.regulations.gov* and search for Docket ID NRC–2018–0303.
- *NRC's Agencywide Documents Access and Management System (ADAMS):* You may obtain publicly-available documents online in the ADAMS Public Documents collection at *https://www.nrc.gov/reading-rm/adams.html.* To begin the search, select ''*Begin Web-based ADAMS Search.*'' For problems with ADAMS, please contact the NRC's Public Document Room (PDR) reference staff at 1–800–397–4209, 301–415–4737, or by email to *pdr.resource@nrc.gov.*
- *Attention:* The Public Document Room (PDR), where you may examine and order copies of public documents is currently closed. You may submit your request to the PDR via email at *PDR.Resource@nrc.gov* or call 1–800–397–4209 between 8 a.m. and 4 p.m. (EST), Monday through Friday, except Federal holidays.

B. Submitting Comments

Please include Docket ID NRC–2018–0303 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 *https://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. Procedural Background

Because the NRC anticipates that this action will be non-controversial, the NRC is publishing this proposed rule concurrently with a direct final rule in the Rules and Regulations section of this issue of the **Federal Register**. The direct final rule will become effective on August 17, 2020. However, if the NRC receives significant adverse comments by July 2, 2020, then the NRC will publish a document that withdraws the direct final rule. If the direct final rule is withdrawn, the NRC will address the comments in a subsequent final rule. Absent significant modifications to the proposed revisions requiring republication, the NRC will not initiate a second comment period on this action in the event the direct final rule is withdrawn.

A significant adverse comment is a comment where the commenter explains why the rule would be inappropriate, including challenges to the rule's underlying premise or approach, or would be ineffective or unacceptable without a change. A comment is adverse and significant if it meets the following criteria:

(1) The comment opposes the rule and provides a reason sufficient to require a

substantive response in a notice-and-comment process. For example, a substantive response is required in the following circumstances:

(a) The comment causes the NRC to reevaluate (or reconsider) its position or conduct additional analysis;

(b) The comment raises an issue serious enough to warrant a substantive response to clarify or complete the record; or

(c) The comment raises a relevant issue that was not previously addressed or considered by the NRC.

(2) The comment proposes a change or an addition to the rule, and it is apparent that the rule would be ineffective or unacceptable without incorporation of the change or addition.

(3) The comment causes the NRC to make a change (other than editorial) to the rule.

For procedural information and the regulatory analysis, see the direct final rule published in the Rules and Regulations section of this issue of the **Federal Register**.

III. Discussion

The President signed into law the Social Security Number Fraud Prevention Act of 2017 (the Act) on September 15, 2017, to reduce the risk of identity theft by directing agencies to ''issue regulations specifying the circumstances under which inclusion of a social security account number on a document sent by mail is necessary.'' [1] The Act restricts the inclusion of an SSN on any document sent by mail ''unless the head of the agency determines that the inclusion of the SSN on the document is necessary.'' [2] The Act directs agencies to issue regulations that specify when inclusion of an SSN is necessary, include instructions for the partial redaction of SSNs where feasible, and provide a requirement that SSNs not be visible on the outside of any package sent by mail.[3] These regulations must be issued no later than 5 years after the date of enactment of the Act.

The NRC determined that rulemaking was necessary because the Act requires the NRC to amend its regulations. This effort could not be achieved through issuing guidance, as guidance documents are not legally binding and cannot be used to amend regulations. The NRC's rulemaking is narrowly tailored to address the requirements specifically set forth in the Act; therefore, the NRC determined that the direct final rule process was appropriate because the amendments are required by statute, expected to be non-controversial, and unlikely to yield public comment resulting in a significant change to the NRC's proposal. A direct final rule is preferable to a final rule because it allows for the opportunity for public comment, should there be any additional regulations that the public identifies as needing amendment or any additional considerations the NRC needs to evaluate to implement the Act.

IV. Plain Writing

The Plain Writing Act of 2010 (Pub. L. 111–274) requires Federal agencies to write documents in a clear, concise, well-organized manner. The NRC has written this document to be consistent with the Plain Writing Act as well as the Presidential Memorandum, ''Plain Language in Government Writing,'' published June 10, 1998 (63 FR 31883). The NRC requests comment on the proposed rule with respect to clarity and effectiveness of the language used.

V. Paperwork Reduction Act

This proposed rule does not contain any new or amended collections of information subject to the Paperwork Reduction Act of 1995 (44 U.S.C. 3501 *et seq.*). Existing collections of information were approved by the Office of Management and Budget, approval numbers 3150–0043, 3150–0014, 3150–0046, and 3150–0010.

Public Protection Notification

The NRC may not conduct or sponsor, and a person is not required to respond to, a collection of information unless the document requesting or requiring the collection displays a currently valid OMB control number.

Dated: May 28, 2020.

For the Nuclear Regulatory Commission.

Annette L. Vietti-Cook,

Secretary of the Commission.

[FR Doc. 2020–11900 Filed 6–1–20; 8:45 am]

BILLING CODE 7590–01–P

[1] Public Law 115–59, Section 2(b).

[2] Public Law 115–59, Section 2(a).

[3] Public Law 115–59, Section 2(b)(1)–(2).

NUCLEAR REGULATORY COMMISSION

10 CFR Part 72

[NRC–2020–0059]

Guidance for Implementation of 10 CFR 72.48, 'Changes, Tests, and Experiments'

AGENCY: Nuclear Regulatory Commission.

ACTION: Draft regulatory guide; request for comment.

SUMMARY: The U.S. Nuclear Regulatory Commission (NRC) is issuing for public comment draft regulatory guide (DG), DG–3054. This DG is proposed Revision 1 of Regulatory Guide 3.72 of the same name. The proposed revision endorses Nuclear Energy Institute (NEI) 12–04, Revision 2 with exceptions and clarification. NEI 12–04, Revision 2, updates and revises previous guidance to incorporate operating experience and NRC's inspection findings. In addition, RG 3.72, Revision 1, changes the NRC's guidance on departures from a method of evaluation (MOE) and the NRC's approval of an MOE.

DATES: Submit comments by August 3, 2020. Comments received after this date will be considered if it is practical to do so, but the NRC is able to ensure consideration only for comments received on or before this date. Although a time limit is given, comments and suggestions in connection with items for inclusion in guides currently being developed or improvements in all published guides are encouraged at any time.

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

- *Federal Rulemaking Website:* Go to *https://www.regulations.gov* and search for Docket ID NRC–2020–0059. Address questions about NRC docket IDs in *Regulations.gov* to Jennifer Borges; telephone: 301–287–9127; email: *Jennifer.Borges@nrc.gov.* For technical questions, contact the individuals listed in the **FOR FURTHER INFORMATION CONTACT** section of this document.
- *Mail comments to:* Office of Administration, Mail Stop: TWFN–7–A60M, U.S. Nuclear Regulatory Commission, Washington, DC 20555–0001, ATTN: Program Management, Announcements and Editing Staff.

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: Marlone Davis, telephone: 301–415–7447, email: *Marlone.Davis@nrc.gov,* and Harriet Karagiannis, telephone: 301–415–2493, email: *Harriet.Karagiannis@nrc.gov.* Both are staff of the U.S. Nuclear Regulatory Commission, Washington, DC 20555–0001.

SUPPLEMENTARY INFORMATION:

I. Obtaining Information and Submitting Comments

A. Obtaining Information

Please refer to Docket ID NRC–2020–0059 when contacting the NRC about

the availability of information for this action. You may obtain publicly-available information related to this action by any of the following methods:

• *Federal Rulemaking Website:* Go to *https://www.regulations.gov* and search for Docket ID NRC–2020–0059.

• *NRC's Agencywide Documents Access and Management System (ADAMS):* You may obtain publicly-available documents online in the ADAMS Public Documents collection at *https://www.nrc.gov/reading-rm/adams.html.* To begin the search, select ''*Begin Web-based ADAMS Search*.'' For problems with ADAMS, please contact the NRC's Public Document Room (PDR) reference staff at 1–800–397–4209, 301–415–4737, or by email to *pdr.resource@nrc.gov.*

B. Submitting Comments

Please include Docket ID NRC–2020–0059 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 *https://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. Additional Information

The NRC is issuing for public comment a draft guide in the NRC's ''Regulatory Guide'' series. This series was developed to describe methods that are acceptable to the NRC staff for implementing specific parts of the agency's regulations, to explain techniques that the staff uses in evaluating specific issues or postulated events, and to describe information that the staff needs in its review of applications for permits and licenses.

This DG, identified by its task number, DG–3054, titled, ''Guidance for Implementation of 10 CFR 72.48, 'Changes, Tests, And Experiments'' (ADAMS Accession No. ML19269B763). The draft guide is proposed Revision 1 of RG 3.72 of the same name. The proposed revision describes an approach that is acceptable to NRC to meet regulatory requirements related to changes affecting independent spent fuel storage installations (ISFSIs), spent fuel storage cask designs, and monitored retrievable storage installations (MRSs) by endorsing guidance document NEI 12–04, ''Guidelines for 10 CFR 72.48 Implementation,'' Revision 2.

The staff is also issuing for public comment a draft regulatory analysis (ADAMS Accession No. ML19269B764). The staff develops a regulatory analysis to assess the value of issuing or revising a regulatory guide as well as alternative courses of action.

III. Backfitting, Forward Fitting, and Issue Finality

Issuance of this draft regulatory guide in final form would not constitute backfitting as defined in title 10 of the *Code of Federal Regulations* (10 CFR) section 72.62, ''Backfitting,'' and as described in NRC Management Directive 8.4, ''Management of Backfitting, Forward Fitting, Issue Finality, and Information Requests'' (ADAMS Accession No. ML18093B087). As explained in section D., ''Implementation,'' of the draft regulatory guide, licensees would not be required to comply with the positions set forth in this draft regulatory guide.

Dated: May 27, 2020.

For the Nuclear Regulatory Commission.

Stanley J. Gardocki,

Acting Chief, Regulatory Guidance and Generic Issues Branch, Division of Engineering, Office of Nuclear Regulatory Research.

[FR Doc. 2020–11717 Filed 6–1–20; 8:45 am]

BILLING CODE 7590–01–P

DEPARTMENT OF TRANSPORTATION

Federal Aviation Administration

14 CFR Part 39

[Docket No. FAA–2020–0493; Product Identifier 2019–CE–046–AD]

RIN 2120–AA64

Airworthiness Directives; Textron Aviation, Inc. Airplanes

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

ACTION: Notice of proposed rulemaking (NPRM).

SUMMARY: The FAA proposes to supersede Airworthiness Directive (AD) 2019–08–13 for Textron Aviation, Inc. (type certificate previously held by Cessna Aircraft Company) Models 525, 525A, and 525B airplanes with Tamarack active load alleviation system (ATLAS) winglets installed in accordance with Supplemental Type Certificate (STC) SA03842NY. AD 2019–08–13 resulted from mandatory continuing airworthiness information (MCAI) originated by an aviation authority of another country to identify and correct an unsafe condition on an aviation product. The MCAI describes the unsafe condition as malfunction of the ATLAS. This AD results from the identification of corrective actions that, if implemented, allow operators to reactivate the ATLAS and restore operations to normal procedures. The FAA is proposing this AD to address the unsafe condition on these products.

DATES: The FAA must receive comments on this proposed AD by July 17, 2020.

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

• *Federal eRulemaking Portal:* Go to *https://www.regulations.gov.* Follow the instructions for submitting comments.

• *Fax:* (202) 493–2251.

• *Mail:* U.S. Department of Transportation, Docket Operations, M–30, West Building Ground Floor, Room W12–140, 1200 New Jersey Avenue SE, Washington, DC 20590.

• *Hand Delivery:* U.S. Department of Transportation, Docket Operations, M–30, West Building Ground Floor, Room W12–140, 1200 New Jersey Avenue SE, Washington, DC 20590, between 9 a.m. and 5 p.m., Monday through Friday, except Federal holidays.

For Cranfield Aerospace Solutions Limited and Tamarack Aerospace Group service information identified in this AD, contact Cranfield Aerospace Solutions Ltd., Cranfield, Bedford MK43 0AL, United Kingdom; telephone: +44 1234 754 166; FAX: +44 1234 752 375; email: *g.mitchell@cranfieldaerospace.com;* internet: *https://www.cranfieldaerospace.com/service/aircraft-modification-products/et.* You may review copies of the referenced service information at the FAA, Airworthiness Products Section, Operational Safety Branch, 901 Locust, Kansas City, Missouri 64106. For information on the availability of this material at the FAA, call (816) 329–4148.

Examining the AD Docket

You may examine the AD docket on the internet at *https://www.regulations.gov* by searching for and locating Docket No. FAA–2020–0493; or in person at Docket Operations Monday through Friday, except Federal holidays. The AD docket contains this

proposed AD, the regulatory evaluation, any comments received, and other information. The street address for the Docket Office is listed above. Comments will be available in the AD docket shortly after receipt.

FOR FURTHER INFORMATION CONTACT: Steven Dzierzynski, Avionics Engineer, FAA, New York ACO Branch, 1600 Stewart Avenue, Suite 410, Westbury, New York 11590; telephone: (516) 287–7367; fax: (516) 794–5531; email: *steven.dzierzynski@faa.gov.*

SUPPLEMENTARY INFORMATION:

Comments Invited

The FAA invites you to send any written relevant data, views, or arguments about this proposed AD. Send your comments to an address listed under the **ADDRESSES** section. Include ''Docket No. FAA–2020–0493; Product Identifier 2019–CE–046–AD'' at the beginning of your comments. The FAA specifically invites comments on the overall regulatory, economic, environmental, and energy aspects of this proposed AD. The FAA will consider all comments received by the closing date and may amend this proposed AD because of those comments.

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

Discussion

The FAA issued AD 2019–08–13, Amendment 39–19634 (84 FR 24007; May 24, 2019) (''AD 2019–08–13'') for Textron Aviation, Inc. Models 525, 525A, and 525B airplanes with Tamarack ATLAS winglets installed in accordance with STC SA03842NY. AD 2019–08–13 prohibits all flight by revising the operating limitations in the airplane flight manual (AFM) and fabricating and installing a placard, until a modification has been incorporated in accordance with an FAA-approved method. AD 2019–080–13 was based on MCAI originated by the European Aviation Safety Agency (EASA), which is the Technical Agent for the Member States of the European Community. EASA issued AD No. 2019–0086–E, dated April 19, 2019, to address an unsafe condition related to reports of the ATLAS malfunctioning, which could lead to loss of control of the airplane.

Actions Since AD 2019–08–13 Was Issued

Since the FAA issued AD 2019–08–13, Cranfield Aerospace Solutions Limited (Cranfield), the holder of STC SA03842NY, determined that failure of the Tamarack Active Camber Surface (TACS) control units (TCUs) was caused by a printed circuit board attachment screw coming loose, which caused a short circuit in the TCU. EASA revised the MCAI and issued EASA AD No. 2019–0086R1, dated August 9, 2019, to require modifications previously developed by Cranfield to restore the safety of the ATLAS design. Cranfield modified the TCUs with a self-locking screw, an additional flat washer, and linear variable differential transformer potting to prevent detachment from vibration during flight. Cranfield also developed centering strips to modify the trailing edge of the TACS that will return the TACS to faired when TCU power is removed or when the TACS are ''blown'' out of position if ATLAS power is removed.

Installation of the modified TCU will prevent a short circuit of the ATLAS TCU, and installation of the centering strips to the TACS will ensure the TACS remains in a faired position in case of inadvertent power loss to the ATLAS.

Cranfield also revised the Tamarack maintenance manual supplement for airplanes with the Tamarack ATLAS winglets installed to include instructions for continued airworthiness related to the centering strips.

Comments

The FAA gave the public the opportunity to comment on AD 2019–08–13 and received 34 comments. The majority of the commenters were operators and maintenance personnel. The remaining commenters included Tamarack Aerospace Group (Tamarack) and the General Aviation Manufacturers Association (GAMA). The following presents the relevant comments received on AD 2019–08–13 and the FAA's response to each comment.

A. Supportive Comments

Erin Saunders, Victor Ochoa, and an anonymous commenter support the AD action.

B. Comments Regarding the FAA's Justification of an Unsafe Condition Requests for a Thorough Investigation of the Issues

Many commenters questioned or requested clarification of the FAA's determination that there is an unsafe condition. Seven commenters stated the FAA should have completed a more thorough investigation and analysis of the issues. Tamarack, Advanced Jets, LLC (Advanced Jets), and Kenneth Adelman requested the FAA consider that the data extracted from the incident aircraft does not agree with the pilot's description of an aggressive roll rate. John Harris, Andrew Vann, Douglas Sayre, and five other commenters stated that the malfunction of the European aircraft that prompted EASA's emergency AD was caused by the failure of the operator to comply with the manufacturer's mandatory service bulletin. These commenters noted that there have been no failures experienced by aircraft with winglets that have complied with the manufacturer's mandatory service bulletin. Fourteen commenters stated they have been operating for a considerable time with the ATLAS winglets and have not experienced any issues. These commenters further stated that installation of the winglets increases performance, safety, and economy and expressed support for Tamarack as a company.

The FAA has considered the comments pertaining to the pilot's incident report on the European airplane. At the time AD 2019–08–13 was issued, the airplane data from the incident that prompted the EASA AD was not available. However, the FAA analyzed the information from the pilot's incident report and additional information received from EASA to make the decision to issue AD 2019–08–13. Since AD 2019–08–13 was issued, Cranfield provided data to identify the root cause of the unsafe condition and to provide corrective action, which prompted this superseding NPRM.

The FAA agrees with the comments regarding the operator's failure to comply with the manufacturer's service bulletin. However, operators are not required to comply with manufacturer service bulletins unless mandated by the FAA or other civil aviation authority. EASA AD No. 2019–0086–E, dated April 19, 2019, which prompted AD 2019–08–13, did not require incorporation of the service bulletins for TCU modification and installation of the centering strips. This NPRM proposes to require TCU modification and installation of the centering strips using Cranfield Aerospace Solutions Limited Service Bulletin CAS/SB1480, Issue A, dated July 2019 (Cranfield CAS/SB1480, Issue A), which incorporates two earlier service bulletins for those actions.

The fact that commenters' personal experience with ATLAS winglets has been positive does not negate the existence of an unsafe condition. Despite any benefit to individual owners when the system operates

without failure, the FAA determined that an unsafe condition with the ATLAS exists and requires corrective action.

Requests To Clarify the Hazard Caused by a Malfunction

Four commenters disputed the FAA's determination that a malfunction of the ATLAS may reduce the pilot's ability to control the airplane. Tamarack noted that this determination conflicts with the certification basis and system safety analysis of the design and compliance data during certification testing. Advanced Jets stated that the ATLAS has been shown to be safe at speeds under 140 knots even if it malfunctions. Kenneth Adelman stated that any reduction of pilot control when the ATLAS malfunctions is minor and was demonstrated as safe during the original certification of the system.

The FAA disagrees with these comments. The ATLAS complied with the certification basis during certification testing. EASA performed the certification flight tests, and those tests included the ''worst case'' condition where the TACS were deployed in a fully asymmetric failure position that induces the greatest roll input. EASA determined that case to be ''recoverable.'' However, the incident exposed a failure mode that was not anticipated during certification, which is the basis of this NPRM.

Requests To Clarify the FAA's Position on the Use of Speed Tape

Kenneth Adelman, Advanced Jets, and two anonymous commenters questioned the FAA's rejection of the use speed tape to hold the winglets flush. These commenters noted that speed tape is a product that is widely accepted and has been used for decades.

The FAA disagrees. The statement in the AD regarding the use of ''speed tape'' as a corrective action to prevent movement of the TACS during flight is based on discussions between the FAA and EASA. Speed tape is non-structural; therefore, it cannot be relied upon to immobilize the TACS. The corrective action in the EASA AD required disabling the TACS. Furthermore, any modifications mandated through AD action become changes to the type design. As explained in AD 2019–08–13, the speed tape did not have sufficient testing and analysis to support the type design.

The FAA did not change this NPRM as a result of these comments.

C. Comments Regarding the NTSB Investigation

Tamarack, Advanced Jets, GAMA, and six other commenters noted that AD 2019–08–13 contained an incorrect statement regarding the National Transportation Safety Board (NTSB) investigation of a fatal accident and the role the ATLAS may have played in the accident. Most of these commenters stated that the preliminary report released by the NTSB did not reference the ATLAS. These commenters requested the FAA correct or remove the statement if it is not accurate.

The FAA agrees. The preamble language of AD 2019–08–13 contained a statement pertaining to an NTSB investigation into a fatal airplane accident. Although the airplane involved in the accident had the ATLAS STC installed, since the NTSB has not released its factual report, that statement should not have been in the preamble of AD 2019–08–13.

D. Comments Requesting the FAA Rescind the AD

Vincent Phillips, Stanley Jobe, and CJ Holdings requested that the AD be rescinded and the airplanes returned to service. Two of these commenters noted that EASA has revised its emergency AD and urged the FAA to do the same.

The FAA partially agrees. The FAA has determined that an unsafe condition exists on the ATLAS and that action to address the condition is required; therefore, the FAA disagrees with rescinding the AD. However, since AD 2019–08–13 was issued, the root cause of the failure of the ATLAS winglets has been identified. For the reasons explained in more detail in response to other comments, this NPRM proposes to supersede AD 2019–08–13 to allow operation of the airplane after modifying the ATLAS.

E. Comments Requesting Modifications to the AD

Twelve commenters noted that Cranfield's TCU upgrade and centering strips modification eliminate the unsafe condition. These commenters requested the FAA allow the modifications as an alternative to the operational prohibition of AD 2019–08–13. Richard Helms and several other commenters stated that no aircraft with these modifications have experienced upsets. Jerome Simon requested the FAA define an alternative method of compliance (AMOC) so the airplanes could return to flight.

The FAA agrees. This NPRM proposes to supersede AD 2019–08–13. Instead of the operational prohibition of AD 2019–08–13, this NPRM proposes to require modification of the TCU and installation of the centering strips on the TACS using Cranfield CAS/SB1480, Issue A, which incorporates two earlier service bulletins for those actions. This NPRM also proposes revising the Tamarack maintenance manual supplement to add inspections for the centering strips.

F. Comments Regarding the Costs of Compliance

Several commenters requested the FAA modify the cost of compliance to include costs associated with loss of revenue from the inability to fly the airplanes. These commenters stated that AD 2019–08–13 is costing operators anywhere from thousands of dollars per month to millions of dollars in total.

The FAA disagrees. The FAA acknowledges the economic hardship for those who depend on their airplanes for income. However, the cost analysis in AD rulemaking actions typically includes only the actual maintenance costs to comply with the AD and not indirect costs such as down-time and loss of revenue.

G. Comments Requesting Clarification on Type Design Change

GAMA requested clarification on the language in AD 2019–08–13 regarding speed tape as a type design change. GAMA questioned whether a temporary repair while waiting for a permanent design solution should be characterized as a type design change.

The FAA agrees to provide clarification. The language in AD 2019–08–13 is based on the FAA's *Airworthiness Directives Legal Interpretation,* which explained that AD-mandated modifications to an aircraft become part of the FAA-approved type design that must be maintained as required by §§ 39.7 and 39.9 (81 FR 24695, April 27, 2016). Regardless of whether a repair mandated by an AD is intended to be permanent or temporary, the repair becomes a required change to the type design unless and until the AD is superseded or rescinded or the operator obtains an approved AMOC.

H. Comment Requesting Pilot Training

Three commenters requested or suggested the FAA require pilot training and familiarity with emergency procedures in the event of an uncommanded deflection of the ATLAS in flight.

The FAA acknowledges the commenters' request for pilot training related to the uncommanded deflection of the ATLAS in flight. Since AD 2019–08–13 was issued, the root cause of the

failure of the ATLAS winglets has been identified. This NPRM proposes to supersede AD 2019–08–13 to allow operation of the airplane after modifying the ATLAS. The ATLAS modification and associated manual revisions proposed in this NPRM are expected to mitigate the unsafe condition without the need for additional pilot training.

I. Comment Requesting Procedure To Pull ATLAS Circuit Breaker

Kenneth Adelman requested the FAA require adding a line item to the abnormal/emergency section in the Tamarack Winglet AFM Supplement to indicate that, in the event of a TCAS runaway, the circuit breaker should be pulled.

The FAA acknowledges the commenter's request to revise the Tamarack Winglet AFM Supplement. As stated earlier, since AD 2019–08–13 was issued, the root cause of the failure of the ATLAS winglets has been identified. This NPRM proposes to supersede AD 2019–08–13 to allow operation of the airplane after modifying the ATLAS. The ATLAS modification and associated manual revisions proposed in this NPRM are expected to mitigate the unsafe condition, precluding the need for the requested AFM revision.

J. Comments Regarding the FAA's Rulemaking Process

Two commenters questioned the FAA's decision to issue AD 2019–08–13 as an immediately effective rule without prior notice and comment. Richard Helms stated that this decision was neither justified nor reasonable. Advanced Jets noted that the FAA's action is not an emergency because of the amount of time (35 days) between issuance of EASA's emergency AD and the FAA's issuance of AD 2019–08–13.

The FAA acknowledges the commenters' concerns that it took 35 days to issue AD 2019–08–13 without notice and comment. The FAA worked through the unique difficulties associated with this unsafe condition and considered all options. The FAA coordinated with EASA and the design approval holder before determining the best course of action to mitigate the unsafe condition. The risk to the flying public associated with this unsafe condition required immediate action. Allowing notice and comment would have delayed mitigating the unsafe condition significantly longer than 35 days. The FAA also notes that it is proposing to supersede AD 2019–08–13 based on comments received.

Related Service Information Under 1 CFR Part 51

The FAA reviewed the following service documents proposed for compliance with this NPRM:

- Cranfield Aerospace Solutions Limited Service Bulletin CAS/SB1480, Issue A, dated July 2019, which contains instructions to ensure installation of a modified TCU and the TACS centering strips;
- Cranfield Aerospace Solutions Limited Service Bulletin CAS/SB1475, Issue A, dated February 2019, which contains the instructions for installing the centering strips to the TACS; and
- Tamarack Aerospace Group Cessna 525, 525A, & 525B ATLAS Winglet Maintenance Manual Supplement, Report Number: TAG–1100–0101, Issue G, dated September 3, 2019, which adds instructions to inspect the centering strips and adds repetitive inspection intervals to the Airworthiness Limitations section of the supplement for the centering strips.

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 of this NPRM.

Other Related Service Information

The FAA also reviewed the following documents related to this NPRM:

- Tamarack Aerospace Group ATLAS Service Bulletin SBATLAS–57–03, dated July 27, 2018, which contains instructions to remove the ATLAS TCU and return it to the ATLAS repair facility for modification;
- Tamarack Aerospace Group ATLAS Service Bulletin SBATLAS–57–05, dated February 20, 2019, which contains instructions to install centering strips on the TACS; and
- Cranfield Aerospace Solutions Limited Service Bulletin CAS/SB1467, Issue B, dated July 2018, which contains instructions to remove the ATLAS TCU assembly and modify it as specified in CAS/SB1480, Issue A.

FAA's Determination and Requirements of the Proposed AD

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

Costs of Compliance

The FAA estimates that this proposed AD will affect 76 products of U.S. registry. The FAA also estimates that it would take 16 work-hours with a parts cost of $4,314 per product to modify the TCU, 24 work-hours with a parts cost of $199 per product to install the centering strips, and 1 work-hour per product to revise the limitations section as proposed by this AD. The average labor rate is $85 per work-hour.

Based on these figures, the FAA estimates the cost of the proposed AD on U.S. operators to be $607,848, or $7,998 per product.

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

Authority for This Rulemaking

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

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

Regulatory Findings

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

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

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

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

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

List of Subjects in 14 CFR Part 39

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

The Proposed Amendment

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

PART 39—AIRWORTHINESS DIRECTIVES

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

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

§ 39.13 [Amended]

■ 2. The FAA amends § 39.13 by removing Airworthiness Directive (AD) 2019–08–13, Amendment 39–19634 (84 FR 24007, May 24, 2019) and adding the following new AD:

Textron Aviation, Inc. (Type certificate previously held by Cessna Aircraft Company): Docket No. FAA–2020–0493; Product Identifier 2019–CE–046–AD.

(a) Comments Due Date

The FAA must receive comments by July 17, 2020.

(b) Affected ADs

This AD replaces AD 2019–08–13, Amendment 39–19634 (84 FR 24007, May 24, 2019) (''AD 2019–08–13'').

(c) Applicability

This AD applies to Textron Aviation, Inc. (type certificate previously held by Cessna Aircraft Company) Models 525, 525A, and 525B airplanes, certificated in any category, with Tamarack active load alleviation system (ATLAS) winglets installed in accordance with Supplemental Type Certificate SA03842NY.

(d) Subject

Air Transport Association of America (ATA) Code 27: Flight Controls.

(e) Reason

This AD was prompted by mandatory continuing airworthiness information (MCAI) issued by the aviation authority of another country to identify and correct an unsafe condition on an aviation product. The MCAI describes the unsafe condition as malfunction of the ATLAS, which could cause difficulty for the pilot to recover the airplane to safe light. The FAA is issuing this AD to prevent malfunction of the ATLAS and to ensure the Tamarack Active Camber Surface (TACS) remains in a faired position in the case of inadvertent power loss to the ATLAS, which could lead to loss of control of the airplane.

(f) Compliance

Unless already done, do the following actions in paragraphs (g) and (h) of this AD.

(g) Modifications

Before further flight after the effective date of this AD, do the following corrective actions:

(1) Determine whether the serial number of the TACS control unit (TCU) assembly is listed in table 7.8. of Cranfield Aerospace Solutions Limited (Cranfield) Service Bulletin CAS/SB1480, Issue A, dated July 2019 (Cranfield CAS/SB1480, Issue A). If the serial number of the TCU assembly is not listed in table 7.8., replace the TCU assembly with a TCU assembly that has a part number listed in section 5 and a serial number listed in table 7.8 of Cranfield CAS/SB1480, Issue A.

(2) Determine whether centering strips have been installed on the trailing edge of the TACS by following step 7.4. of Cranfield CAS/SB1480, Issue A. If the trailing edge of the TCAS does not have centering strips, install Cranfield modification CAeM/Cessna/1475.

(h) Revision to the Maintenance Manual Supplement

(1) Before further flight after the effective date of this AD, revise the Airworthiness Limitations section (ALS) and Instructions for Continued Airworthiness for your airplane by adding the updates in Tamarack Aerospace Group Cessna 525, 525A & 525B ATLAS Winglet Maintenance Manual Supplement, Modification CAeM/Cessna/1375/1430/1440/1452/1475/1480, Report Number: TAG–1100–0101, Issue G, dated September 3, 2019.

(2) Thereafter, except as provided in paragraph (i) of this AD, no alternative inspection intervals may be approved for the centering strips. Inserting a later issue of the ALS with language identical to that contained in Issue G for the centering strips is acceptable for compliance with the requirements of this paragraph.

(3) The AFM revision and placard required by AD 2019–08–13, if installed, may be removed after completing the modifications required by paragraph (g) of this AD.

(i) Alternative Methods of Compliance (AMOCs)

The Manager, New York ACO Branch, FAA, has the authority to approve AMOCs for this AD, if requested using the procedures found in 14 CFR 39.19. Send information to ATTN: Program Manager, Continued Operational Safety FAA, New York ACO Branch, 1600 Stewart Avenue, Suite 410, Westbury, New York 11590; telephone: (516) 287–7321; fax: (516) 794–5531; email: *9-avs-nyaco-cos*@faa.gov. Before using any approved AMOC on any airplane to which the AMOC applies, notify your appropriate principal inspector (PI) in the FAA Flight Standards District Office (FSDO), or lacking a PI, your local FSDO.

(j) Related Information

Refer to European Union Aviation Safety Agency (EASA) AD No. 2019–0086R1, dated August 9, 2019, for related information. You may examine the MCAI on the internet at *https://www.regulations.gov* by searching for and locating Docket No. FAA–2020–0493. For Cranfield Aerospace Solutions Limited and Tamarack Aerospace Group service information identified in this AD, contact Cranfield Aerospace Solutions Ltd., Cranfield, Bedford MK43 0AL, United Kingdom; telephone: +44 1234 754 166; FAX: +44 1234 752 375; email: *g.mitchell@cranfieldaerospace.com;* internet: *https://www.cranfieldaerospace.com/service/aircraft-modification-products/et.* You may review copies of the referenced service information at the FAA, Airworthiness Products Section, Operational Safety Branch, 901 Locust, Kansas City, Missouri 64106. For information on the availability of this material at the FAA, call (816) 329–4148.

Issued on May 14, 2020.

Lance T. Gant,

Director, Compliance & Airworthiness Division, Aircraft Certification Service.

[FR Doc. 2020–11351 Filed 6–1–20; 8:45 am]

BILLING CODE 4910–13–P

DEPARTMENT OF TRANSPORTATION

Federal Aviation Administration

14 CFR Part 71

[Docket No. FAA–2020–0277; Airspace Docket No. 20–AEA–5]

RIN 2120–AA66

Proposed Amendment of Class E Airspace; Pottsville, PA

AGENCY: Federal Aviation Administration (FAA), DOT.

ACTION: Notice of proposed rulemaking (NPRM).

SUMMARY: This action proposes to amend Class E airspace extending upward from 700 feet above the surface at Schuylkill County (Joe Zerbey) Airport, Pottsville, PA due to the extension of runway 11. This action would also update the geographic coordinates of the airport, and Schuylkill Medical Center Heliport, (formerly Pottsville Hospital). Controlled airspace is necessary for the safety and management of instrument flight rules (IFR) operations in the area.

DATES: Comments must be received on or before July 17, 2020.

ADDRESSES: Send comments on this proposal to: The U.S. Department of Transportation, Docket Operations, 1200 New Jersey Avenue SE, West Building Ground Floor, Room W12–140, Washington, DC 20590–0001; Telephone: (800) 647–5527, or (202)

366–9826. You must identify the Docket No. FAA–2020–0277; Airspace Docket No. 20–AEA–5, at the beginning of your comments. You may also submit comments through the internet at *https://www.regulations.gov.*

FAA Order 7400.11D, Airspace Designations and Reporting Points, and subsequent amendments can be viewed on line at *https://www.faa.gov/air_traffic/publications/.* For further information, you can contact the Airspace Policy Group, Federal Aviation Administration, 800 Independence Avenue SW, Washington, DC 20591; telephone: (202) 267–8783. The Order is also available for inspection at the National Archives and Records Administration (NARA). For information on the availability of FAA Order 7400.11D at NARA, email *fedreg.legal@nara.gov* or go to *https://www.archives.gov/federal-register/cfr/ibr-locations.html.*

FOR FURTHER INFORMATION CONTACT: John Fornito, Operations Support Group, Eastern Service Center, Federal Aviation Administration, 1701 Columbia Avenue, College Park, GA 30337; telephone (770) 883–5664.

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 would amend Class E airspace at Schuylkill County (Joe Zerbey) Airport, Pottsville, PA, to support IFR operations in the area.

Comments Invited

Interested persons are invited to comment on this proposed rulemaking by submitting such written data, views, or arguments, as they may desire. Comments that provide the factual basis supporting the views and suggestions presented are particularly helpful in developing reasoned regulatory decisions on the proposal. Comments are specifically invited on the overall regulatory, aeronautical, economic, environmental, and energy-related aspects of the proposal.

Communications should identify both docket numbers (Docket No. FAA–2020–0277 and Airspace Docket No. 20–AEA–5) and be submitted in triplicate to DOT Docket Operations (see **ADDRESSES** section for the address and phone number.) You may also submit comments through the internet at *https://www.regulations.gov.*

Persons wishing the FAA to acknowledge receipt of their comments on this action must submit with those comments a self-addressed stamped postcard on which the following statement is made: ''Comments to FAA Docket No. FAA–2020–0277; Airspace Docket No. 20–AEA–5.'' The postcard will be date/time stamped and returned to the commenter.

All communications received before the specified closing date for comments will be considered before taking action on the proposed rule. The proposal contained in this document may be changed in light of the comments received. All comments submitted will be available for examination in the public docket both before and after the comment closing date. A report summarizing each substantive public contact with FAA personnel concerned with this rulemaking will be filed in the docket.

Availability of NPRMs

An electronic copy of this document may be downloaded through the internet at *https://www.regulations.gov.* Recently published rulemaking documents can also be accessed through the FAA's web page at *https://www.faa.gov/air_traffic/publications/airspace_amendments/.*

You may review the public docket containing the proposal, any comments received and any final disposition in person in the Dockets Office (see the **ADDRESSES** section for address and phone number) between 9:00 a.m. and 5:00 p.m., Monday through Friday, except federal holidays. An informal docket may also be examined between 8:00 a.m. and 4:30 p.m., Monday through Friday, except federal holidays, at the office of the Eastern Service Center, Federal Aviation Administration, Room 350, 1701 Columbia Avenue, College Park, GA 30337.

Availability and Summary of Documents for Incorporation by Reference

This document proposes to amend FAA Order 7400.11D, Airspace Designations and Reporting Points, dated August 8, 2019, and effective September 15, 2019. FAA Order 7400.11D is publicly available as listed in the **ADDRESSES** section of this document. FAA Order 7400.11D lists Class A, B, C, D, and E airspace areas, air traffic service routes, and reporting points.

The Proposal

The FAA proposes an amendment to Title 14 Code of Federal Regulations (14 CFR) part 71 to amend Class E airspace extending upward from 700 feet above the surface at Schuylkill County (Joe Zerbey) Airport, Pottsville, PA from a 6.8-mile radius to a 7-mile radius. In addition, the FAA proposes to update the airport's geographic coordinates, and the name and geographic coordinates of Schuylkill Medical Center Heliport, to coincide with the FAA's aeronautical database.

Class E airspace designations are published in Paragraph 6005, of FAA Order 7400.11D, dated August 8, 2019, and effective September 15, 2019, which is incorporated by reference in 14 CFR 71.1. The Class E airspace designations listed in this document will be published subsequently in the Order.

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

Regulatory Notices and Analyses

The FAA has determined that this proposed regulation only involves an established body of technical regulations for which frequent and routine amendments are necessary to keep them operationally current. 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 will only affect air traffic procedures and air navigation, it is certified that this proposed 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

This proposal will be subject to an environmental analysis in accordance with FAA Order 1050.1F, ''Environmental Impacts: Policies and Procedures'' prior to any FAA final regulatory action.

Lists of Subjects in 14 CFR Part 71

Airspace, Incorporation by reference, Navigation (air).

The Proposed Amendment

In consideration of the foregoing, the Federal Aviation Administration proposes to amend 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 Federal Aviation Administration Order 7400.11D, Airspace Designations and Reporting Points, dated August 8, 2019, and effective September 15, 2019, is amended as follows:

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

* * * * *

AEA PA E5 Pottsville, PA [Amended]

Schuylkill County (Joe Zerbey) Airport, PA
(Lat. 40°42′24″ N, long. 76°22′23″ W)
Schuylkill Medical Center Heliport
(Lat. 40°41′25″ N, long. 76°11′32″ W)

That airspace extending upward from 700 feet above the surface within a 7-mile radius of Schuylkill County (Joe Zerbey) Airport, and that airspace within a 6-mile radius of the point in space for Schuylkill Medical Center Heliport.

Issued in College Park, Georgia, on May 22, 2020.

Andreese C. Davis,

Manager, Airspace & Procedures Team South, Eastern Service Center, Air Traffic Organization.

[FR Doc. 2020–11521 Filed 6–1–20; 8:45 am]

BILLING CODE 4910–13–P

DEPARTMENT OF TRANSPORTATION

Federal Aviation Administration

14 CFR Part 71

[Docket No. FAA–2020–0242; Airspace Docket No. 20–AEA–4]

RIN 2120–AA66

Proposed Amendment of Class E Airspace; Ithaca, NY

AGENCY: Federal Aviation Administration (FAA), DOT.

ACTION: Notice of proposed rulemaking (NPRM).

SUMMARY: This action proposes to amend Class E surface airspace, and Class E airspace designated as an extension to a Class D surface area at Ithaca Tompkins Regional Airport, Ithaca, NY, due to the decommissioning of the Ithaca VOR/DME, and cancellation of associated approaches. Controlled airspace is necessary for the safety and management of instrument flight rules (IFR) operations in the area.

DATES: Comments must be received on or before July 17, 2020.

ADDRESSES: Send comments on this proposal to: the U.S. Department of Transportation, Docket Operations, 1200 New Jersey Avenue SE, West Building Ground Floor, Room W12–140, Washington, DC 20590–0001; Telephone: (800) 647–5527, or (202) 366–9826. You must identify the Docket No. FAA–2020–0242; Airspace Docket No. 20–AEA–4, at the beginning of your comments. You may also submit comments through the internet at *https://www.regulations.gov.*

FAA Order 7400.11D, Airspace Designations and Reporting Points, and subsequent amendments can be viewed online at *https://www.faa.gov/air_traffic/publications/.* For further information, you can contact the Airspace Policy Group, Federal Aviation Administration, 800 Independence Avenue SW, Washington, DC 20591; telephone: (202) 267–8783. The Order is also available for inspection at the National Archives and Records Administration (NARA). For information on the availability of FAA Order 7400.11D at NARA, email *fedreg.legal@nara.gov* or go to *https://www.archives.gov/federal-register/cfr/ibr-locations.html.*

FOR FURTHER INFORMATION CONTACT: John Fornito, Operations Support Group, Eastern Service Center, Federal Aviation Administration, 1701 Columbia Avenue, College Park, GA 30337; telephone (404) 305–6364.

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 would amend Class E airspace at Ithaca Tompkins Regional Airport, Ithaca, NY, to support IFR operations in the area.

Comments Invited

Interested persons are invited to comment on this proposed rulemaking by submitting such written data, views, or arguments, as they may desire. Comments that provide the factual basis supporting the views and suggestions presented are particularly helpful in developing reasoned regulatory decisions on the proposal. Comments are specifically invited on the overall regulatory, aeronautical, economic, environmental, and energy-related aspects of the proposal.

Communications should identify both docket numbers (Docket No. FAA–2020–0242 and Airspace Docket No. 20–AEA–4) and be submitted in triplicate to DOT Docket Operations (see **ADDRESSES** section for the address and phone number). You may also submit comments through the internet at *https://www.regulations.gov.*

Persons wishing the FAA to acknowledge receipt of their comments on this action must submit with those comments a self-addressed stamped postcard on which the following statement is made: ''Comments to FAA Docket No. FAA–2020–0242; Airspace Docket No. 20–AEA–4.'' The postcard will be date/time stamped and returned to the commenter.

All communications received before the specified closing date for comments will be considered before taking action on the proposed rule. The proposal contained in this document may be changed in light of the comments received. All comments submitted will be available for examination in the public docket both before and after the comment closing date. A report summarizing each substantive public contact with FAA personnel concerned with this rulemaking will be filed in the docket.

Availability of NPRMs

An electronic copy of this document may be downloaded through the internet at *http://www.regulations.gov.* Recently published rulemaking documents can also be accessed through the FAA's web page at *https://www.faa.gov/air_traffic/publications/airspace_amendments/.*

You may review the public docket containing the proposal, any comments received and any final disposition in person in the Dockets Office (see the **ADDRESSES** section for address and phone number) between 9:00 a.m. and 5:00 p.m., Monday through Friday, except federal holidays. An informal

docket may also be examined between 8:00 a.m. and 4:30 p.m., Monday through Friday, except federal holidays at the office of the Eastern Service Center, Federal Aviation Administration, Room 350, 1701 Columbia Avenue, College Park, GA 30337.

Availability and Summary of Documents for Incorporation by Reference

This document proposes to amend FAA Order 7400.11D, Airspace Designations and Reporting Points, dated August 8, 2019, and effective September 15, 2019. FAA Order 7400.11D is publicly available as listed in the **ADDRESSES** section of this document. FAA Order 7400.11D lists Class A, B, C, D, and E airspace areas, air traffic service routes, and reporting points.

The Proposal

The FAA proposes an amendment to Title 14 Code of Federal Regulations (14 CFR) part 71 to amend Class E surface airspace, and Class E airspace designated as an extension to a Class D surface area at Ithaca Tompkins Regional Airport, Ithaca, NY, by removing the northwest extension (2.7 miles each side of the Ithaca VOR/DME 305° radial extending from the 4-mile radius of the airport to 7.4 miles northwest of the Ithaca VOR/DME) for the VOR approach, due to the decommissioning of the Ithaca VOR/DME, and cancellation of the associated approaches. Also, this action would update the airport name in the descriptor by removing the city in the airport's header.

Class E airspace designations are published in Paragraphs 6002, and 6004, respectively of FAA Order 7400.11D, dated August 8, 2019, and effective September 15, 2019, which is incorporated by reference in 14 CFR 71.1. The Class E airspace designations listed in this document will be published subsequently in the Order.

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

Regulatory Notices and Analyses

The FAA has determined that this proposed regulation only involves an established body of technical regulations for which frequent and routine amendments are necessary to keep them operationally current. 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 will only affect air traffic procedures and air navigation, it is certified that this proposed 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

This proposal will be subject to an environmental analysis in accordance with FAA Order 1050.1F, ''Environmental Impacts: Policies and Procedures'' prior to any FAA final regulatory action.

Lists of Subjects in 14 CFR Part 71

Airspace, Incorporation by reference, Navigation (air).

The Proposed Amendment

In consideration of the foregoing, the Federal Aviation Administration proposes to amend 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 Federal Aviation Administration Order 7400.11D, Airspace Designations and Reporting Points, dated August 8, 2019, and effective September 15, 2019, is amended as follows:

Paragraph 6002 Class E Surface Airspace.

* * * * *

AEA NY E2 Ithaca, NY [Amended]

Ithaca Tompkins Regional Airport, NY
(Lat. 43°29′29″ N, long. 76°27′31″ W)

That airspace extending upward from the surface within a 4-mile radius of Ithaca Tompkins Regional Airport and that airspace extending upward from the surface from the 4-mile radius of the airport to the 5.7-mile radius of the airport clockwise from the 329° bearing to the 081° bearing from the airport; that airspace from the 4-mile radius of the airport to the 8.7-mile radius of the airport extending clockwise from the 081° bearing to the 137° bearing from the airport; that airspace from the 4-mile radius of the airport to the 6.6-mile radius of the airport extending clockwise from the 137° bearing to the 170° bearing from the airport; that airspace from the 4-mile radius to the 5.7-mile radius of the airport extending clockwise from the 170° bearing to the 196° bearing from the airport. This Class E airspace is effective during the times and dates established in advance by a Notice to Airmen. The 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 Surface Area.

* * * * *

AEA NY E4 Ithaca, NY [Amended]

Ithaca Tompkins Regional Airport, NY
(Lat. 43°29′29″ N, long. 76°27′31″ W)

That airspace extending upward from the surface from the 4-mile radius of the Ithaca Tompkins Regional Airport to the 5.7-mile radius of the airport; clockwise from the 329° bearing to the 081° bearing from the airport; that airspace from the 4-mile radius of Ithaca Tompkins Regional Airport to the 8.7-mile radius of the airport extending clockwise from the 081° bearing to the 137° from the airport; that airspace from the 4-mile radius of Ithaca Tompkins Regional Airport; to the 6.6-mile radius of the airport, extending clockwise from the 137° bearing to the 170° bearing from the airport; that airspace from the 4-mile radius to the 5.7-mile radius of the Ithaca Tompkins Regional Airport, extending clockwise from the 170° bearing to the 196° bearing from the airport; and within 2.2 each side of the 324° bearing from the airport extending from the 4-mile radius to 7.2 miles northwest of the airport.

Issued in College Park, Georgia, on May 22, 2020.

Andreese C. Davis,

Manager, Airspace & Procedures Team South, Eastern Service Center, Air Traffic Organization.

[FR Doc. 2020–11520 Filed 6–1–20; 8:45 am]

BILLING CODE 4910–13–P

DEPARTMENT OF TRANSPORTATION

Federal Aviation Administration

14 CFR Part 71

[Docket No. FAA–2020–0365; Airspace Docket No. 20–ASW–4]

RIN 2120–AA66

Proposed Amendment of Class E Airspace; Harrison, AR

AGENCY: Federal Aviation Administration (FAA), DOT.

ACTION: Notice of proposed rulemaking (NPRM).

SUMMARY: This action proposes to amend Class E surface airspace, and Class E airspace extending upward from 700 feet above the surface at Boone County Airport, Harrison, AR, due to the decommissioning of the (HRO) RWY 36 Outer Marker (OM) and Compass

Locator and cancellation of associated approaches. Controlled airspace is necessary for the safety and management of instrument flight rules (IFR) operations in the area. This action also would update the airport's designator by removing the city from the second line of the header.

DATES: Comments must be received on or before July 17, 2020.

ADDRESSES: Send comments on this proposal to: The U.S. Department of Transportation, Docket Operations, 1200 New Jersey Avenue SE, West Building Ground Floor, Room W12–140, Washington, DC 20590–0001; Telephone: (800) 647–5527, or (202) 366–9826. You must identify the Docket No. FAA–2020–0365; Airspace Docket No. 20–ASW–4, at the beginning of your comments. You may also submit comments through the internet at *https://www.regulations.gov.*

FAA Order 7400.11D, Airspace Designations and Reporting Points, and subsequent amendments can be viewed on line at *https://www.faa.gov/air_traffic/publications/.* For further information, you can contact the Airspace Policy Group, Federal Aviation Administration, 800 Independence Avenue SW, Washington, DC 20591; telephone: (202) 267–8783. The Order is also available for inspection at the National Archives and Records Administration (NARA). For information on the availability of FAA Order 7400.11D at NARA, email *fedreg.legal@nara.gov* or go to *https://www.archives.gov/federal-register/cfr/ibr-locations.html.*

FOR FURTHER INFORMATION CONTACT: John Fornito, Operations Support Group, Eastern Service Center, Federal Aviation Administration, 1701 Columbia Avenue, College Park, GA 30337; telephone (404) 305–6364.

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 would amend Class E airspace at Boone County Airport, Harrison, AR to support IFR operations in the area.

Comments Invited

Interested persons are invited to comment on this proposed rulemaking by submitting such written data, views, or arguments, as they may desire. Comments that provide the factual basis supporting the views and suggestions presented are particularly helpful in developing reasoned regulatory decisions on the proposal. Comments are specifically invited on the overall regulatory, aeronautical, economic, environmental, and energy-related aspects of the proposal.

Communications should identify both docket numbers (Docket No. FAA–2020–0365 and Airspace Docket No. 20–ASW–4) and be submitted in triplicate to DOT Docket Operations (see **ADDRESSES** section for the address and phone number.) You may also submit comments through the internet at *https://www.regulations.gov.*

Persons wishing the FAA to acknowledge receipt of their comments on this action must submit with those comments a self-addressed stamped postcard on which the following statement is made: ''Comments to FAA Docket No. FAA–2020–0365; Airspace Docket No. 20–ASW–4.'' The postcard will be date/time stamped and returned to the commenter.

All communications received before the specified closing date for comments will be considered before taking action on the proposed rule. The proposal contained in this document may be changed in light of the comments received. All comments submitted will be available for examination in the public docket both before and after the comment closing date. A report summarizing each substantive public contact with FAA personnel concerned with this rulemaking will be filed in the docket.

Availability of NPRMs

An electronic copy of this document may be downloaded through the internet at *http://www.regulations.gov.* Recently published rulemaking documents can also be accessed through the FAA's web page at *https://www.faa.gov/air_traffic/publications/airspace_amendments/.*

You may review the public docket containing the proposal, any comments received and any final disposition in person in the Dockets Office (see the **ADDRESSES** section for address and phone number) between 9:00 a.m. and 5:00 p.m., Monday through Friday, except federal holidays. An informal docket may also be examined between 8:00 a.m. and 4:30 p.m., Monday through Friday, except federal holidays at the office of the Eastern Service Center, Federal Aviation Administration, Room 350, 1701 Columbia Avenue, College Park, GA 30337.

Availability and Summary of Documents for Incorporation by Reference

This document proposes to amend FAA Order 7400.11D, Airspace Designations and Reporting Points, dated August 8, 2019, and effective September 15, 2019. FAA Order 7400.11D is publicly available as listed in the **ADDRESSES** section of this document. FAA Order 7400.11D lists Class A, B, C, D, and E airspace areas, air traffic service routes, and reporting points.

The Proposal

The FAA proposes an amendment to Title 14 Code of Federal Regulations (14 CFR) part 71 to amend Class E surface airspace, by removing the southern extension, and Class E airspace extending upward from 700 feet above the surface, by amending the southern extension and eliminating the northwest extension, at Boone County Airport, Harrison, AR, due to the decommissioning of the (HRO) RWY 36 Outer Marker (OM) and Compass Locator. The FAA found that BAKKY NDB has been decommissioned, and the Harrison VOR approach no longer exists. This results in airspace redesign for Boone County Airport. In addition, the FAA proposes to update the airport's descriptor by removing the unnecessary city name. Also, the FAA proposes to replace the outdated term Airport/Facility Directory with the term Chart Supplement.

Class E airspace designations are published in Paragraphs 6002, and 6005, respectively of FAA Order 7400.11D, dated August 8, 2019, and effective September 15, 2019, which is incorporated by reference in 14 CFR 71.1. The Class E airspace designations listed in this document will be published subsequently in the Order.

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

Regulatory Notices and Analyses

The FAA has determined that this proposed regulation only involves an established body of technical regulations for which frequent and routine amendments are necessary to keep them operationally current. 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 will only affect air traffic procedures and air navigation, it is certified that this proposed 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

This proposal will be subject to an environmental analysis in accordance with FAA Order 1050.1F, ''Environmental Impacts: Policies and Procedures'' prior to any FAA final regulatory action.

Lists of Subjects in 14 CFR Part 71

Airspace, Incorporation by reference, Navigation (air).

The Proposed Amendment

In consideration of the foregoing, the Federal Aviation Administration proposes to amend 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 Federal Aviation Administration Order 7400.11D, Airspace Designations and Reporting Points, dated August 8, 2019, and effective September 15, 2019, is amended as follows:

Paragraph 6002 Class E Surface Airspace.

* * * * *

ASW AR E2 Harrison, AR

Boone County Airport, AR
(Lat. 36°15′41″ N, long. 93°09′17″ W)

That airspace within a 4.3-mile radius of Boone County Airport. 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 6005 Class E Airspace Areas Extending Upward From 700 Feet or More Above the Surface of the Earth.

* * * * *

ASW AR E5 Harrison, AR

Boone County Airport, AR
(Lat. 36°15′41″ N, long. 93°09′17″ W)

That airspace extending upward from 700 feet above the surface within a 6.8-mile radius of Boone County Airport and within 4-miles each side of the 183° bearing from the airport extending form the 6.8-mile radius to 11.7 miles south of the airport.

Issued in College Park, Georgia, on May 22, 2020.

Andreese C. Davis,

Manager, Airspace & Procedures Team South, Eastern Service Center, Air Traffic Organization.

[FR Doc. 2020–11524 Filed 6–1–20; 8:45 am]

BILLING CODE 4910–13–P

DEPARTMENT OF HOMELAND SECURITY

Coast Guard

33 CFR Part 100

[Docket Number USCG–2020–0148]

RIN 1625–AA08

Special Local Regulation; Chesapeake Bay, Between Sandy Point and Kent Island, MD

AGENCY: Coast Guard, DHS.

ACTION: Notice of proposed rulemaking.

SUMMARY: The Coast Guard is proposing to establish special local regulations for certain waters of the Chesapeake Bay. This action is necessary to provide for the safety of life on these navigable waters located between Sandy Point, Anne Arundel County, MD, and Kent Island, Queen Anne's County, MD, during a paddling event on September 27, 2020. This proposed rulemaking would prohibit persons and vessels from entering the regulated area unless authorized by the Captain of the Port Maryland-National Capital Region or the Coast Guard Patrol Commander. We invite your comments on this proposed rulemaking.

DATES: Comments and related material must be received by the Coast Guard on or before July 2, 2020

ADDRESSES: You may submit comments identified by docket number USCG–2020–0148 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, U.S. Coast Guard Sector Maryland-National Capital Region; 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
PATCOM Coast Guard Patrol Commander
§ Section
U.S.C. United States Code

II. Background, Purpose, and Legal Basis

ABC Events, Inc. of Arnold, MD, has notified the Coast Guard that it will be conducting the Bay Bridge Paddle from 8 a.m. to 12:30 p.m. on September 27, 2020. The fifth annual canoe, kayak and stand up paddle board event for elite and intermediate paddlers includes up to 500 paddlers in two classes operating on two race courses in the Chesapeake Bay, under and between the north and south bridges that consist of the William P. Lane, Jr. (US–50/301) Memorial Bridges, located between Sandy Point, Anne Arundel County, MD and Kent Island, Queen Anne's County, MD. The first course, for elite paddlers, is a 9-statute mile/14.5-kilometer race course that starts at the east beach area of Sandy Point State Park at Annapolis, MD, proceeds southerly along the shoreline to a point on the course located between north bridge piers 13 and 13A, then easterly along and between the bridges toward the eastern shore at Kent Island and turns around upon reaching a point near Kent Island, then proceeds westerly along and between the bridges toward the western shore, turns upon reaching a point on the course located between north bridge piers 24 and 25, proceeds northerly to the Sandy Point Shoal Lighthouse, and proceeds westerly to a finish at the east beach area of Sandy Point State Park. The second course, for intermediate paddlers, is a 3.1-statute mile/5-kilometer course that starts at the east beach area of Sandy Point State Park at Annapolis, MD, and follows the elite paddlers to the north bridge, then easterly along and between the bridges toward the eastern shore at Kent Island and turns northerly upon reaching a point on the course located between north bridge piers 24 and 25, and proceeds to a finish at the east beach area of Sandy Point State Park. Hazards from the paddle races include numerous event participants crossing designated navigation channels and interfering

with vessels intending to operate within those channels, as well as operating within approaches to the Sandy Point State Park public boat launch facility and marina. The Captain of the Port (COTP) Maryland-National Capital Region has determined that potential hazards associated with the paddle races would be a safety concern for anyone intending to participate in this event or for vessels that operate within specified waters of the Chesapeake Bay between Sandy Point and Kent Island, MD.

The purpose of this rulemaking is to protect event participants, non-participants and transiting vessels on certain waters of the Chesapeake Bay before, during, and after the scheduled event. The Coast Guard is proposing this rulemaking under authority in 46 U.S.C. 70034 (previously 33 U.S.C. 1231).

III. Discussion of Proposed Rule

The COTP Maryland-National Capital Region is proposing to establish special local regulations from 7 a.m. on September 27, 2020. The special local regulations would be enforced from 7 a.m. to 1:30 p.m. on September 27, 2020. The regulated area would cover all navigable waters of the Chesapeake Bay, adjacent to the shoreline at Sandy Point State Park and between and adjacent to the spans of the William P. Lane Jr. Memorial Bridges, from shoreline to shoreline, bounded to the north by a line drawn from the western shoreline at latitude 39°01′05.23″ N, longitude 076°23′47.93″ W; thence eastward to latitude 39°01′02.08″ N, longitude 076°22′40.24″ W; thence southeastward to eastern shoreline at latitude 38°59′13.70″ N, longitude 076°19′58.40″ W; and bounded to the south by a line drawn parallel and 500 yards south of the south bridge span that originates from the western shoreline at latitude 39°00′17.08″ N, longitude 076°24′28.36″ W; thence southward to latitude 38°59′38.36″ N, longitude 076°23′59.67″ W; thence eastward to latitude 38°59′26.93″ N, longitude 076°23′25.53″ W; thence eastward to the eastern shoreline at latitude 38°58′40.32″ N, longitude 076°20′10.45″ W, located between Sandy Point and Kent Island, MD.

The proposed special local regulations duration and size of the regulated area are intended to ensure the safety of life on these navigable waters before, during, and after the paddle races, scheduled from 8 a.m. to 12:30 p.m. on September 27, 2020. The COTP and the Coast Guard Patrol Commander (PATCOM) would have the authority to forbid and control the movement of all vessels and persons, including event participants, in the regulated area.

Except for Bay Bridge Paddle participants and vessels already at berth, a vessel or person would be required to get permission from the COTP or PATCOM before entering the regulated area. Vessel operators can request permission to enter and transit through the regulated area by contacting the PATCOM on VHF–FM channel 16. Vessel traffic would be able to safely transit the regulated area once the PATCOM deems it safe to do so. A person or vessel not registered with the event sponsor as a participant or assigned as official patrols would be considered a non-participant. Official Patrols are any vessel assigned or approved by the Commander, Coast Guard Sector Maryland-National Capital Region with a commissioned, warrant, or petty officer on board and displaying a Coast Guard ensign.

If permission is granted by the COTP or PATCOM, a person or vessel would be allowed to enter the regulated area or pass directly through the regulated area as instructed. Vessels would be required to operate at a safe speed that minimizes wake while within the regulated area. Official patrol vessels will direct non-participants while within the regulated area. Vessels would be prohibited from loitering within the navigable channel. Only participant vessels and official patrol vessels would be allowed to enter the paddle races area.

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 size and duration of the regulated area, which would impact a small designated area of the Chesapeake Bay for 6.5 hours. The Coast Guard would issue a Broadcast Notice to Mariners via VHF–FM marine channel 16 about the status of the regulated area. Moreover, the rule would allow vessels to seek permission to enter the regulated area, and vessel traffic would be able to safely transit the regulated area once the PATCOM deems it safe to do so.

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 Directive 023–01, Rev. 1, associated implementing instructions, and Environmental Planning COMDTINST 5090.1 (series), which guide the Coast Guard in complying with the National Environmental Policy Act of 1969 (42 U.S.C. 4321–4370f), and have 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 implementation of regulations within 33 CFR part 100 applicable to organized marine events on the navigable waters of the United States that could negatively impact the safety of waterway users and shore side activities in the event area lasting for 6.5 hours. Normally such actions are categorically excluded from further review under paragraph L[61] of Appendix A, Table 1 of DHS Instruction Manual 023–01–001–01, Rev. 01. 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 submissions in response to this docket, see DHS's Correspondence System of Records notice (84 FR 48645, September 26, 2018).

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 100

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

For the reasons discussed in the preamble, the Coast Guard is proposing to amend 33 CFR part 100 as follows:

PART 100—SAFETY OF LIFE ON NAVIGABLE WATERS

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

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

■ 2. Add § 100.T05–0148 to read as follows:

§ 100.T05–0148 Bay Bridge Paddle, Chesapeake Bay, Between Sandy Point and Kent Island, MD.

(a) *Regulated area.* The regulations in this section apply to the following area: All navigable waters of the Chesapeake Bay, adjacent to the shoreline at Sandy Point State Park and between and adjacent to the spans of the William P. Lane Jr. Memorial Bridges, from shoreline to shoreline, bounded to the north by a line drawn from the western shoreline at latitude 39°01′05.23″ N, longitude 076°23′47.93″ W; thence eastward to latitude 39°01′02.08″ N, longitude 076°22′40.24″ W; thence southeastward to eastern shoreline at latitude 38°59′13.70″ N, longitude 076°19′58.40″ W; and bounded to the south by a line drawn parallel and 500 yards south of the south bridge span that originates from the western shoreline at latitude 39°00′17.08″ N, longitude 076°24′28.36″ W; thence southward to latitude 38°59′38.36″ N, longitude 076°23′59.67″ W; thence eastward to latitude 38°59′26.93″ N, longitude 076°23′25.53″ W; thence eastward to the eastern shoreline at latitude 38°58′40.32″ N, longitude 076°20′10.45″ W, located between Sandy Point and Kent Island, MD. These coordinates are based on datum NAD 1983.

(b) *Definitions.* As used in this section—

Captain of the Port (COTP) Maryland-National Capital Region means the Commander, U.S. Coast Guard Sector Maryland-National Capital Region or any Coast Guard commissioned, warrant or petty officer who has been authorized by the COTP to act on his behalf.

Coast Guard Patrol Commander (PATCOM) means a commissioned, warrant, or petty officer of the U.S. Coast Guard who has been designated by the Commander, Coast Guard Sector Maryland-National Capital Region.

Official Patrol means any vessel assigned or approved by Commander,

Coast Guard Sector Maryland-National Capital Region with a commissioned, warrant, or petty officer on board and displaying a Coast Guard ensign.

Participant means all persons and vessels registered with the event sponsor as participating in the Bay Bridge Paddle or otherwise designated by the event sponsor as having a function tied to the event.

(c) *Regulations.* (1) Except for vessels already at berth, all non-participants are prohibited from entering, transiting through, anchoring in, or remaining within the regulated area described in paragraph (a) of this section unless authorized by the COTP Maryland-National Capital Region or PATCOM.

(2) To seek permission to enter, contact the COTP Maryland-National Capital Region at telephone number 410–576–2693 or on Marine Band Radio, VHF–FM channel 16 (156.8 MHz) or the PATCOM on Marine Band Radio, VHF–FM channel 16 (156.8 MHz). Those in the regulated area must comply with all lawful orders or directions given to them by the COTP Maryland-National Capital Region or PATCOM.

(3) The COTP Maryland-National Capital Region will provide notice of the regulated area through advanced notice via Fifth Coast Guard District Local Notice to Mariners, broadcast notice to mariners, and on-scene official patrols.

(d) *Enforcement officials.* The Coast Guard may be assisted with marine event patrol and enforcement of the regulated area by other Federal, State, and local agencies.

(e) *Enforcement period.* This section will be enforced from 7 a.m. to 1:30 p.m. on September 27, 2020.

Dated: May 18, 2020.

Joseph B. Loring,

Captain, U.S. Coast Guard, Captain of the Port Maryland-National Capital Region.

[FR Doc. 2020–11853 Filed 6–1–20; 8:45 am]

BILLING CODE 9110–04–P

DEPARTMENT OF HEALTH AND HUMAN SERVICES

45 CFR Part 153

[CMS–9913–P]

RIN 0938–AU23

Amendments to the HHS-Operated Risk Adjustment Data Validation Under the Patient Protection and Affordable Care Act's HHS-Operated Risk Adjustment Program

AGENCY: Centers for Medicare & Medicaid Services (CMS), Department of Health and Human Services (HHS).

ACTION: Proposed rule.

SUMMARY: This rule proposes to adopt certain changes to the risk adjustment data validation error estimation methodology starting with the 2019 benefit year and beyond for states where the Department of Health and Human Services (HHS) operates the risk adjustment program. The Patient Protection and Affordable Care Act (PPACA) established a permanent risk adjustment program under which payments are made to health insurance issuers that attract higher-than-average risk populations funded by payments from health insurance issuers that attract lower-than-average risk populations. To ensure the integrity of the HHS-operated risk adjustment program, CMS, on behalf of HHS, performs risk adjustment data validation, also known as HHS–RADV, to validate the accuracy of data submitted by issuers for the purposes of risk adjustment transfer calculations. Based on lessons learned from the first payment year of HHS–RADV, this rule proposes changes to the HHS–RADV error estimation methodology, which is used to calculate adjusted risk scores and risk adjustment transfers, beginning with the 2019 benefit year of HHS–RADV. This rule also proposes to change the benefit year to which HHS–RADV adjustments to risk scores and risk adjustment transfers would be applied starting with 2021 benefit year HHS–RADV. These proposals seek to further the integrity of the HHS–RADV program, address stakeholder feedback, promote fairness, and improve the predictability of HHS–RADV adjustments.

DATES: To be assured consideration, comments must be received at one of the addresses provided below, no later than 5 p.m. on July 2, 2020.

ADDRESSES: In commenting, please refer to file code CMS–9913–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–9913–P, P.O. Box 8010, Baltimore, MD 21244–8010.

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–9913–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: Allison Yadsko, (410) 786–1740; Joshua Paul, (301) 492–4347; Adrianne Patterson, (410) 786–0686; and Jaya Ghildiyal, (301) 492–5149.

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.

I. Background

A. Legislative and Regulatory Overview

The Patient Protection and Affordable Care Act (Pub. L. 111–148) was enacted on March 23, 2010; the Health Care and Education Reconciliation Act of 2010 (Pub. L. 111–152) was enacted on March 30, 2010. These statutes are collectively referred to as ''PPACA'' in this proposed rule. Section 1343 of the PPACA [1] established a permanent risk adjustment program to provide payments to health insurance issuers that attract higher-than-average risk populations, such as those with chronic conditions, funded by payments from those that attract lower-than-average risk populations, thereby reducing incentives for issuers to avoid higher-risk enrollees. The PPACA directs the Secretary, in consultation with the states, to establish criteria and methods to be used in carrying out risk adjustment activities, such as determining the actuarial risk of enrollees in risk adjustment covered plans within a state market risk pool.[2] The statute also provides that the Secretary may utilize criteria and methods similar to the ones utilized

[1] 42 U.S.C. 18063.

[2] 42 U.S.C. 18063(a) and (b).

under Medicare Parts C or D.[3] Consistent with section 1321(c)(1) of the PPACA, the Secretary is responsible for operating the risk adjustment program on behalf of any state that elected not to do so. For the 2014–2016 benefit years, all states and the District of Columbia, except Massachusetts, participated in the HHS-operated risk adjustment program. Since the 2017 benefit year, all states and the District of Columbia have participated in the HHS-operated risk adjustment program.

Data submission requirements for the HHS-operated risk adjustment program are set forth at 45 CFR 153.700 through 153.740. Each issuer is required to establish and maintain an External Data Gathering Environment (EDGE) server on which the issuer submits masked enrollee demographics, claims, and encounter diagnosis-level data in a format specified by HHS. Issuers must also execute software provided by HHS on their respective EDGE servers to generate summary reports, which HHS uses to calculate the enrollee-level risk score to determine the average plan liability risk scores for each state market risk pool, the individual issuers' plan liability risk scores, and the transfer amounts by state market risk pool for the applicable benefit year.

Pursuant to 45 CFR 153.350, HHS performs risk adjustment data validation (also known as HHS–RADV) to validate the accuracy of data submitted by issuers for the purposes of risk adjustment transfer calculations for states where HHS operates the risk adjustment program. This process establishes uniform audit standards to ensure that actuarial risk is accurately and consistently measured, thereby strengthening the integrity of the risk adjustment program.[4] HHS–RADV also ensures that issuers' actual actuarial risk is reflected in risk adjustment transfers and that the HHS-operated program assesses charges to issuers with plans with lower-than-average actuarial risk while making payments to issuers with plans with higher-than-average actuarial risk. Pursuant to 45 CFR 153.350(a), HHS, in states where it operates the program, must ensure proper validation of a statistically valid sample of risk adjustment data from each issuer that offers at least one risk adjustment covered plan [5] in that state. Under 45 CFR 153.350, HHS, in states where it operates the program, may adjust the plan average actuarial risk for a risk adjustment covered plan based on discrepancies discovered as a result of HHS–RADV and use those adjusted risk scores to modify charges and payments to all risk adjustment covered plan issuers in the same state market risk pool.

For the HHS-operated risk adjustment program, 45 CFR 153.630 requires an issuer of a risk adjustment covered plan to have an initial and second validation audit performed on its risk adjustment data for the applicable benefit year. Each issuer must engage one or more independent auditors to perform the initial validation audit of a sample of risk adjustment data selected by HHS.[6] After the initial validation audit entity has validated the HHS-selected sample, a subsample is validated in a second validation audit.[7] The second validation audit is conducted by an entity HHS retains to verify the accuracy of the findings of the initial validation audits.

HHS conducted two pilot years of HHS–RADV for the 2015 and 2016 benefit years [8] to give HHS and issuers experience with HHS–RADV prior to applying HHS–RADV findings to adjust issuers' risk scores, as well as the risk adjustment transfers in the applicable state market risk pool(s). The 2017 benefit year HHS–RADV was the first non-pilot year that resulted in adjustments to issuers' risk scores and the risk adjustment transfers in the applicable state market risk pool(s) as a result of HHS–RADV findings.[9] [10]

When initially developing the HHS–RADV process, HHS sought the input of issuers, consumer advocates, providers, and other stakeholders, and issued the ''Affordable Care Act HHS-Operated Risk Adjustment Data Validation Process White Paper'' on June 22, 2013 (the 2013 RADV White Paper).[11] The 2013 RADV White Paper discussed and sought comment on a number of potential considerations for the development and operation of the HHS–RADV program. Based on the feedback received, HHS promulgated regulations to implement HHS–RADV that we have modified in certain respects based on experience and public comments, as follows.

In the July 15, 2011 **Federal Register** (76 FR 41929), we published a proposed rule outlining the framework for the risk adjustment program, including standards related to HHS–RADV. We implemented the risk adjustment program and adopted standards related to HHS–RADV in a final rule, published in the March 23, 2012 **Federal Register** (77 FR 17219) (Premium Stabilization Rule). The HHS–RADV regulations adopted in the Premium Stabilization Rule provide for adjustments to risk scores and risk adjustment transfers to reflect HHS–RADV errors, including the two-sided nature of such adjustments.

In the December 7, 2012 **Federal Register** (77 FR 73117), we published a proposed rule outlining benefit and payment parameters related to the risk adjustment program, including six steps for error estimation for HHS–RADV in 45 CFR 153.630 (proposed 2014 Payment Notice). We published the 2014 Payment Notice final rule in the March 11, 2013 **Federal Register** (78 FR 15436). In addition to finalizing 45 CFR 153.630, this final rule further clarified HHS–RADV policies, including that adjustments would occur when an issuer under-reported its risk scores.

In the December 2, 2013 **Federal Register** (78 FR 72321), we published a proposed rule outlining the benefit and payment parameters related to the risk adjustment program (proposed 2015 Payment Notice). This rule also included several HHS–RADV proposals. We published the 2015 Payment Notice final rule, which finalized HHS–RADV requirements related to sampling; initial validation audit standards, second validation audit processes, and medical record review as the basis of enrollee risk score validation; the error estimation process and original methodology; and HHS–RADV appeals, oversight, and data security standards in the March 11, 2014 **Federal Register** (79 FR 13743). Under the original methodology adopted in that final rule, almost every failure to validate an Hierarchical Condition Category (HCC) during HHS–RADV would have resulted in an adjustment to the issuer's risk score and an accompanying adjustment to all transfers in the applicable state market risk pool.

[3] 42 U.S.C. 18063(b).

[4] HHS also has general authority to audit issuers of risk adjustment covered plans pursuant to 45 CFR 153.620(c).

[5] See 45 CFR 153.20 for the definition of ''risk adjustment covered plan.''

[6] 45 CFR 153.630(b).

[7] 45 CFR 153.630(c).

[8] HHS–RADV was not conducted for the 2014 benefit year. See FAQ ID 11290a (March 7, 2016), available at: *https://www.regtap.info/faq_viewu.php?id=11290.*

[9] The Summary Report of 2017 Benefit Year HHS–RADV Adjustments to Risk Adjustment Transfers released on August 1, 2019 is available at: *https://www.cms.gov/CCIIO/Programs-and-Initiatives/Premium-Stabilization-Programs/Downloads/BY2017-HHSRADV-Adjustments-to-RA-Transfers-Summary-Report.pdf.*

[10] The one exception is for Massachusetts issuers, who were not able to participate in prior HHS–RADV pilot years because the state operated risk adjustment for the 2014–2016 benefit years. Therefore, HHS made the 2017 benefit year HHS–RADV a pilot year for Massachusetts issuers. See 84 FR 17454 at 17508.

[11] A copy of the Affordable Care Act HHS-Operated Risk Adjustment Data Validation Process White Paper (June 22, 2013) is available at: *https://www.regtap.info/uploads/library/ACA_HHS_OperatedRADVWhitePaper_062213_5CR_050718.pdf.*

In the September 6, 2016 **Federal Register** (81 FR 61455), we published a proposed rule outlining benefit and payment parameters related to the risk adjustment program (proposed 2018 Payment Notice) that included proposals related to HHS–RADV. We published the 2018 Payment Notice final rule in the December 22, 2016 **Federal Register** (81 FR 94058), which included finalizing proposals related to HHS–RADV discrepancy reporting, clarifications related to certain aspects of the HHS–RADV appeals process, and a materiality threshold for HHS–RADV to ease the burden of the annual audit requirements for smaller issuers. Under the materiality threshold, issuers with total annual premiums at or below $15 million are not subject to annual initial validation audit requirements, but would be subject to such audits approximately every 3 years (barring risk-based triggers that would warrant more frequent audits).

In the November 2, 2017 **Federal Register** (82 FR 51042), we published a proposed rule outlining benefit and payment parameters related to the risk adjustment program (proposed 2019 Payment Notice) that included proposed provisions related to HHS–RADV. We published the 2019 Payment Notice final rule in the April 17, 2018 **Federal Register** (83 FR 16930), which included finalizing for 2017 benefit year HHS–RADV and beyond, an amended error estimation methodology to only calculate and adjust issuers' risk scores when an issuer's failure rate is statistically significantly different from other issuers based on three HCC groupings (low, medium, and high), that is, when an issuer is identified as an outlier. We also finalized an exemption for issuers with 500 or fewer billable member months from HHS–RADV; a requirement that initial validation audit samples only include enrollees from state market risk pools with more than one issuer; clarifications regarding civil money penalties for non-compliance with HHS–RADV; and a process to handle demographic or enrollment errors discovered during HHS–RADV. We finalized an exception to the prospective application of HHS–RADV results for exiting issuers,[12] such that exiting outlier issuers' results are used to adjust the benefit year being audited (rather than the following transfer year).

In the July 30, 2018 **Federal Register** (83 FR 36456), we published a final rule that adopted the 2017 benefit year HHS-operated risk adjustment methodology set forth in the final rules published in the March 23, 2012 and March 8, 2016 editions of the **Federal Register** (77 FR 17220 through 17252 and 81 FR 12204 through 12352, respectively). This final rule set forth additional explanation of the rationale supporting use of statewide average premium in the HHS-operated risk adjustment state payment transfer formula for the 2017 benefit year, including why the program is operated in a budget-neutral manner. This final rule permitted HHS to resume 2017 benefit year program operations, including collection of risk adjustment charges and distribution of risk adjustment payments. HHS also provided guidance as to the operation of the HHS-operated risk adjustment program for the 2017 benefit year in light of publication of this final rule.[13]

In the August 10, 2018 **Federal Register** (83 FR 39644), we published a proposed rule concerning the adoption of the 2018 benefit year HHS-operated risk adjustment methodology set forth in the final rules published in the March 23, 2012 and December 22, 2016 editions of the **Federal Register** (77 FR 17220 through 17252 and 81 FR 94058 through 94183, respectively). The proposed rule set forth additional explanation of the rationale supporting use of statewide average premium in the HHS-operated risk adjustment state payment transfer formula for the 2018 benefit year, including why the program is operated in a budget-neutral manner. In the December 10, 2018 **Federal Register** (83 FR 63419), we issued a final rule adopting the 2018 benefit year HHS-operated risk adjustment methodology as established in the final rules published in the March 23, 2012 and the December 22, 2016 (77 FR 17220 through 1752 and 81 FR 94058 through 94183, respectively) editions of the **Federal Register**. This final rule permitted HHS to resume 2018 benefit year program operations, including collection of risk adjustment charges and distribution of risk adjustment payments.

In the January 24, 2019 **Federal Register** (84 FR 227), we published a proposed rule outlining the benefit and payment parameters related to the risk adjustment program, including updates to HHS–RADV requirements (proposed 2020 Payment Notice). We published the 2020 Payment Notice final rule in the April 25, 2019 **Federal Register** (84 FR 17454). The final rule included policies related to incorporating risk adjustment prescription drug categories (RXCs) [14] into HHS–RADV beginning with the 2018 benefit year and extending the Neyman allocation to the 10th stratum for HHS–RADV sampling. We also finalized using precision analysis to determine whether the second validation audit results of the full sample or the subsample (of up to 100 enrollees) results should be used in place of initial validation audit results when an issuer's initial validation audit results have insufficient agreement with SVA results following a pairwise means test. We clarified the application and distribution of default data validation charges under 45 CFR 153.630(b)(10) and how CMS will apply error rates for exiting issuers and sole issuer markets. We codified the previously established materiality threshold and exemption for issuers with 500 or fewer billable member months and established a new exemption from HHS–RADV for issuers in liquidation who met certain conditions. In response to comments, in the final rule, we updated the timeline for collection, distribution, and reporting of HHS–RADV adjustments to transfers; provided that the 2017 benefit year would be a pilot year for HHS–RADV for Massachusetts; and established that the 2018 benefit year would be a pilot year for incorporating RXCs into HHS–RADV.

In the February 6, 2020 **Federal Register** (85 FR 7088), we published a proposed rule outlining the benefit and payment parameters related to the risk adjustment program (proposed 2021 Payment Notice), including several HHS–RADV proposals. Among other things, in this rulemaking, we proposed updates to the diagnostic classifications and risk factors in the HHS risk adjustment models beginning with the 2021 benefit year to reflect more recent claims data, as well as proposed amendments to the outlier identification process for HHS–RADV in cases where an issuer's HCC count is low. We proposed that beginning with 2019 benefit year HHS–RADV, any issuer with fewer than 30 HCCs (diagnostic conditions) within an HCC failure rate

[12] To be an exiting issuer, the issuer has to exit all of the market risk pools in the state (that is, not sell or offer any new plans in the state). If an issuer only exits some market risk pools in the state, but continues to sell or offer plans in others, it is not an exiting issuer. A small group issuer with off-calendar year coverage, who exits the small group market risk pool in a state and only has small group carry-over coverage that ends in the next benefit year, and is not otherwise selling or offering new plans in any market risk pools in the state, would be an exiting issuer. See 83 FR 16965 through 16966 and 84 FR 17503. The exiting issuer exception is discussed in Section II.B.

[13] ''Update on the HHS-operated Risk Adjustment Program for the 2017 Benefit Year.'' July 27, 2018. Available at *https://www.cms.gov/CCIIO/Resources/Regulations-and-Guidance/Downloads/2017-RA-Final-Rule-Resumption-RAOps.pdf.*

[14] An RXC uses a drug to impute a diagnosis (or indicate the severity of diagnosis) otherwise indicated through medical coding in a hybrid diagnoses-and-drugs risk adjustment model.

group would not be determined an outlier. We also proposed to make 2019 benefit year HHS–RADV another pilot year for the incorporation of RXCs to allow additional time for HHS, issuers, and auditors to gain experience with validating RXCs. On May 14, 2020, we published the HHS Notice of Benefit and Payment Parameters for 2021 final rule (85 FR 29164) (2021 Payment Notice) that finalized these HHS–RADV changes as proposed. The proposed updates to the diagnostic classifications and risk factors in the HHS risk adjustment models were also finalized with some modifications.

As explained in prior notice-and-comment rulemaking,[15] while the PPACA did not include an explicit requirement that the risk adjustment program operate in a budget-neutral manner, HHS is constrained by appropriations law to devise and implement its risk adjustment program in a budget-neutral fashion.[16] Although the statutory provisions for many other PPACA programs appropriated funding, authorized amounts to be appropriated, or provided budget authority in advance of appropriations,[17] the PPACA neither authorized nor appropriated additional funding for risk adjustment payments beyond the amount of charges paid in, and did not authorize HHS to obligate itself for risk adjustment payments in excess of charges collected.[18] Indeed, unlike the Medicare Part D statute, which expressly authorized the appropriation of funds and provided budget authority in advance of appropriations to make Part D risk-adjusted payments, the PPACA's risk adjustment statute made no reference to additional appropriations.[19] Congress did not give HHS discretion to implement a risk adjustment program that was not budget neutral. Because Congress omitted from the PPACA any provision appropriating independent funding or creating budget authority in advance of an appropriation for the risk adjustment program, we explained that HHS could not—absent another source of appropriations—have designed the program in a way that required payments in excess of collections consistent with binding appropriations law.

B. Stakeholder Consultation and Input

HHS has consulted with stakeholders on policies related to the HHS-operated risk adjustment program and HHS–RADV. We held a series of stakeholder listening sessions to gather input, and received input from numerous interested groups, including states, health insurance issuers, and trade groups. We also issued a white paper for public comment on December 6, 2019 entitled the HHS Risk Adjustment Data Validation (HHS–RADV) White Paper (2019 RADV White Paper).[20] We considered comments received on the 2019 RADV White Paper and in connection with previous rules as we developed the policies in this proposed rule.

II. Provisions of the Proposed Regulations

HHS conducts HHS–RADV under 45 CFR 153.630 and 153.350 in any state where HHS is operating risk adjustment on a state's behalf. Since the 2017 benefit year, HHS has been operating risk adjustment and HHS–RADV in all 50 states and the District of Columbia. The purpose of HHS–RADV is to ensure issuers are providing accurate and complete risk adjustment data to HHS, which is crucial to the purpose and proper functioning of the HHS-operated risk adjustment program. HHS–RADV ensures that issuers' actual actuarial risk is reflected in risk adjustment transfers and that the HHS-operated risk adjustment program assesses charges to issuers with plans with lower-than-average actuarial risk while making payments to issuers with plans with higher-than-average actuarial risk.

HHS–RADV consists of an initial validation audit and a second validation audit. Under 45 CFR 153.630, each issuer of a risk adjustment covered plan must engage an independent initial validation auditor. The issuer provides demographic, enrollment, claims data and medical record documentation for a sample of enrollees selected by HHS to its initial validation auditor for data validation. Each issuer's initial validation audit is followed by a second validation audit, which is conducted by an entity that HHS retains to verify the accuracy of the findings of the initial validation audit.

This rule proposes changes to two aspects of HHS–RADV: (A) The error rate calculation, and (B) the application of HHS–RADV results. Beginning with the 2019 benefit year of HHS–RADV,[21] we propose to: (1) Modify the HCC grouping methodology used in the error rate calculation; (2) refine the error rate calculation in cases where an outlier issuer is only slightly outside of the confidence interval for one or more HCC groups; and (3) modify the error rate calculation in cases where a negative error rate outlier issuer also has a negative failure rate. We also propose, beginning with the 2021 benefit year of HHS–RADV, to transition from the current prospective application of HHS–RADV results[22] to an approach that would apply HHS–RADV results to the benefit year being audited. We believe these proposals specifically address stakeholder feedback received after the first payment year of HHS–RADV. These proposals seek to further the integrity of the HHS–RADV program, while promoting fairness and improving the predictability of HHS–RADV.

In addition to soliciting comments on the following proposals, we also request feedback on the potential impact of the COVID–19 public health emergency on the proposed timelines for implementation of the proposals in this rulemaking.

A. Error Rate Calculation Methodology

HHS recognizes that variation in provider documentation of enrollees' health status across provider types and groups results in natural variation and validation errors. Therefore, in the 2019 Payment Notice final rule,[23] HHS adopted the current error rate calculation methodology to evaluate material statistical deviation in failure rates. The current methodology was adopted to avoid adjusting issuers' risk scores and transfers due to expected

[15] See, *e.g.,* 78 FR 15441 and 83 FR 16930.

[16] Also see *New Mexico Health Connections* v. *United States Department of Health and Human Services,* 946 F.3d 1138 (10th Cir. 2019).

[17] For examples of PPACA provisions appropriating funds, *see* PPACA secs. 1101(g)(1), 1311(a)(1), 1322(g), and 1323(c). For examples of PPACA provisions authorizing the appropriation of funds, *see* PPACA secs. 1002, 2705(f), 2706(e), 3013(c), 3015, 3504(b), 3505(a)(5), 3505(b), 3506, 3509(a)(1), 3509(b), 3509(e), 3509(f), 3509(g), 3511, 4003(a), 4003(b), 4004(j), 4101(b), 4102(a), 4102(c), 4102(d)(1)(C), 4102(d)(4), 4201(f), 4202(a)(5), 4204(b), 4206, 4302(a), 4304, 4305(a), 4305(c), 5101(h), 5102(e), 5103(a)(3), 5203, 5204, 5206(b), 5207, 5208(b), 5210, 5301, 5302, 5303, 5304, 5305(a), 5306(a), 5307(a), and 5309(b).

[18] *See* 42 U.S.C. 18063.

[19] *Compare* 42 U.S.C. 18063 (failing to specify source of funding other than risk adjustment charges), *with* 42 U.S.C. 1395w–116(c)(3) (authorizing appropriations for Medicare Part D risk adjusted payments); 42 U.S.C. 1395w–115(a) (establishing ''budget authority in advance of appropriations Acts'' for Medicare Part D risk adjusted payments).

[20] The 2019 RADV White Paper is available at: *https://www.cms.gov/files/document/2019-hhs-risk-adjustment-data-validation-hhs-radv-white-paper.*

[21] As part of the Administration's efforts to combat the Coronavirus Disease 2019 (COVID–19), we announced the postponement of the 2019 benefit year RADV process. We intend to provide further guidance by August 2020 on our plans to begin 2019 benefit year RADV in calendar year 2021. See *https://www.cms.gov/files/document/2019-HHS-RADV-Postponement-Memo.pdf.*

[22] The exception to the current prospective application of HHS–RADV results is for exiting issuers, whose HHS–RADV results are applied to the risk scores and transfer amounts for the benefit year being audited. See 83 FR 16930 at 16965.

[23] See 83 FR 16930 at 16961 through 16965.

variation and error. Instead, HHS amends an issuer's risk score only when the issuer's failure rate materially deviates from a statistically meaningful national value. HHS defines the national statistically meaningful value as the weighted mean and standard deviation of the failure rate calculated based on all issuers' HHS–RADV results. Each issuer's results are compared to these national metrics to determine whether the issuer's results are outliers. Based on outlier issuers' failure rate results, error rates are calculated and applied to outlier issuers' plan liability risk scores.[24]

Given comments received on the 2019 RADV White Paper and to help put the methodological changes proposed in this rule in context, this section outlines how the current error rate calculation methodology would apply if no changes were made since the latest policies were finalized in the 2021 Payment Notice.[25] This includes information on how HHS uses outlier issuer group failure rates to adjust enrollee risk scores, calculates an outlier issuer's error rate, and applies that error rate to the outlier issuer's plan liability risk score.

To apply the current error rate calculation methodology, HHS first uses the failure rates for each HCC to categorize all HCCs into three HCC groupings (a high, medium, or low HCC failure rate grouping). These HCC groupings are determined by first ranking all HCC failure rates and then dividing the rankings into three groupings, such that the total observations of HCCs on EDGE in each grouping are relatively equal across all issuers' initial validation audit (IVA) samples (or second validation audit (SVA) samples, if applicable), resulting in high, medium, and low HCC failure rate groupings. An issuer's HCC group failure rate is calculated as follows:

$$GFR_{G,i} = 1 - \frac{freqIVA_{G,i}}{freqEDGE_{G,i}}$$

Where:

$freqEDGE_{G,i}$ is the number of occurrences of HCCs in group *G* that are recorded on EDGE for all enrollees sampled from issuer *i.*

$freqIVA_{G,i}$ is the number of occurrences of HCCs in group *G* that are identified by the IVA audit (or SVA audit, as applicable) for all enrollees sampled from issuer *i.*

$GFR_{G,i}$ is issuer *i*'s group failure rate for the HCC group *G.*

HHS calculates the weighted mean failure rate and the standard deviation of each HCC group as:

$$\mu\{GFR_G\} = 1 - \frac{\sum_i freqIVA_{G,i}}{\sum_i freqEDGE_{G,i}}$$

$$Sd\{GFR_G\} = \sqrt{\frac{\sum_i \left(freqEDGE_{G,i} * \left(GFR_{G,i} - \mu\{GFR_G\}\right)^2\right)}{\sum_i freqEDGE_{G,i}}}$$

Where:

$\mu\{GFR_G\}$ is the weighted mean of $GFR_{G,i}$ of all issuers for the HCC group *G* weighted by all issuers' sample observations in each group.

$Sd\{GFR_G\}$ is the weighted standard deviation of $GFR_{G,i}$ of all issuers for the HCC group *G.*

Each issuer's HCC group failure rates are then compared to the national metrics for each HCC grouping. All enrollee HCCs identified by the IVA (or SVA, as applicable) are used to determine an issuer's failure rate for the applicable HCC group. If an issuer's failure rate for an HCC group falls outside of the 95 percent confidence interval around the weighted mean failure rate for the HCC group, that is, a failure rate further than 1.96 standard deviations from the weighted mean failure rate when assuming all issuers' group failure rates are normally distributed, the failure rate for the issuer's HCCs in that group is considered an outlier (if the issuer meets the minimum number of HCCs for the HCC group). To calculate the outlier status thresholds, HHS calculates the lower and upper limits as:

$LB_G = \mu\{GFR_G\} - sigma\_cutoff * Sd\{GFR_G\}$

$UB_G = \mu\{GFR_G\} - sigma\_cutoff * Sd\{GFR_G\}$

Where:

sigma_cutoff is the parameter used to set the threshold for the outlier detection as the number of standard deviations away from the mean; 1.96 for a two-tailed 95 percent confidence interval as determined by a normal distribution.

LB_G, UB_G are the lower and upper thresholds to classify issuers as outliers or not outliers for group *G.*

Outlier status is determined independently for each issuer's HCC failure rate group such that an issuer may be considered an outlier in one HCC failure rate group but not an outlier in another HCC failure rate group. Beginning with the 2019 benefit year, issuers are also not considered an outlier for an HCC group in which the issuer has fewer than 30 HCCs.[26] [27] If no issuers' HCC group failure rates in a state market risk pool materially deviate from the national mean of failure rates or does not meet the minimum HCC requirements (that is, no issuers are outliers), HHS does not apply any adjustments to issuers' risk scores or to transfers in that state market risk pool.

When an issuer's HCC group failure rate is an outlier, we reduce (or increase) each of the applicable IVA sample (or SVA sample, if applicable) enrollees' HCC risk coefficients for HCCs in that group by the difference between the outlier issuer's failure rate for the HCC group and the weighted mean failure rate for the HCC group. Specifically, this will result in the sample enrollees' applicable HCC risk score components being reduced (or increased) by a partial value, or percentage, calculated as the difference between the outlier failure rate for the HCC group and the weighted mean failure rate for the applicable HCC group. Beginning with the 2019 benefit year, when the issuer meets the minimum HCC frequency requirement per an HCC group ($Freq\_EDGE_{G,i}$ this group adjustment factor $GAF_{G,i}$ amount for outliers is the distance between issuer *i*'s Group Failure Rate $GFR_{G,i}$ and

[24] As detailed further below, these risk score changes are then used to adjust risk adjustment transfers for the applicable state market risk pool.

[25] 85 FR 29164.

[26] See 85 FR 29196–29198.

[27] Data from issuers with fewer than 30 HCCs in an HCC group will be included in the calculation of national metrics for that HCC group, including the national mean failure rate, standard deviation, and upper and lower confidence interval bounds. Ibid.

the weighted mean $\mu\{GFR_G\}$. This is calculated [28] as:

If $GFR_{G,i} > UB_G$ or $GFR_{G,i} < LB_G$,
And if $Freq\_EDGE_{G,i} \leq 30$:
Then $Flag_{G,i}$ = ''*outlier*'' and $GAF_{G,i} - \mu\{GFR_G\}$
If $GFR_{G,i} \leq UB_G$and $GFR_{G,i} \geq, LB_G$,
Or if $Freq\_EDGE_{G,i} < 30$:
Then $Flag_{G,i}$ = ''*not outlier*'' and $GAF_{G,i} = 0$

Where:

$Flag_{G,i}$ is the indicator if the value of issuer *i*'s group failure rate for group *G* is more extreme than a calculated threshold by which we classify issuers into ''outliers'' or ''not outliers'' for group *G*.

$GAF_{G,i}$ is the calculated adjustment factor for issuer *i*'s risk score component for all sampled HCCs in group *G* that are recorded on EDGE.

The enrollee adjustment factor is then calculated by applying the group adjustment factor $GAF_{G,i}$ to individual HCCs. For example, if an issuer has one enrollee with the HIV/AIDS HCC and the issuer's HCC group adjustment rate is 10 percent (the difference between the issuer's group failure rate and the weighted mean failure rate) for the HCC group that contains the HIV/AIDS HCC, the enrollee's HIV/AIDS coefficient would be reduced by 10 percent. This reduction would be aggregated with any reductions to other HCCs for that enrollee to arrive at the overall enrollee adjustment factor. This value is calculated according to the following formula for each enrollee in stratum 1 through 9:

$$Adjustment_{i,e} = \frac{\sum_h \left(RS_{h,G,i,e} * GAF_{G,i}\right)}{\sum_h \left(RS_{h,G,i,e}\right)}$$

Where:

$RS_{h,G,i,e}$ is the risk score component of a single HCC *h* (belonging to HCC group *G*) recorded on EDGE for enrollee *e* of issuer *i*.

$Adjustment_{i,e}$ is the calculated adjustment factor to adjust enrollee *e* of issuer *i*'s EDGE risk scores.

$GAF_{G,i}$ is the calculated adjustment factor for issuer *i*'s risk score components for all sampled HCCs in group *G* that are recorded on EDGE.

The calculation of the enrollee adjustment factor above only considers risk score components related to the HCC and ignores any other risk score components (such as demographic components and RXC components). Newly identified HCCs by the IVA (or SVA as applicable) contribute to the calculation of the issuer's group failure rate but do not contribute to enrollee risk score adjustments for that enrollee and adjusted enrollee risk scores are only computed for sampled enrollees with HCCs in strata 1 through 9.

Next, for each sampled enrollee with HCCs, HHS applies the enrollee adjustment factor to each stratum 1 through 9 enrollee's risk score (including the non-HCC risk adjustment components, such as demographic components and RXC components) as recorded on the EDGE server, calculating the total adjusted enrollee risk score for these enrollees as:

$AdjRS_{i,e} = EdgeRS_{i,.e} * (1 - Adjustments_{i,e})$

Where:

$EdgeRS_{i,e}$ is the risk score as recorded on the EDGE server of enrollee *e* of issuer *i*.

$AdjRS_{i,e}$ is the amended risk score for sampled enrollee *e* of issuer *i*.

$Adjustment_{i,e}$ is the adjustment factor by which we estimate the EDGE risk score exceeds or falls short of the initial or second validation audit projected total risk score for sampled enrollee *e* of issuer *i*.

The calculation of the total adjusted enrollee risk score $AdjRS_{i,e}$ for sample enrollees in strata 1–9 is based on the risk score recorded on EDGE server $EdgeRS_{i,e}$ that includes all risk score components (that is, both HCCs and the non-HCC components). Enrollees with no HCCs do not have enrollee adjustment factors or adjusted risk scores; however, we note that they contribute to the calculation of the outlier issuer's group failure rate in advance of the calculation of adjustments.

After calculating the adjusted EDGE risk scores for outlier issuers' sample enrollees with HCCs, HHS calculates an outlier issuer's error rate by extrapolating the difference between the amended risk score and EDGE risk score for all enrollees (stratum 1 through 10) in the sample. The weight in the extrapolation formula associated with an enrollee's amended risk score and EDGE risk score is determined as the ratio of (1) the stratum size in the issuer's population for the enrollee's stratum, to (2) the number of sampled enrollees in the same stratum as the enrollee. Sample enrollees with no HCCs are included in the extrapolation of the error rate for outlier issuers with unchanged EDGE risk scores where $AdjRSi,e = EdgeRSi,e$ for enrollees with no HCCs. The formulas to compute the error rate using the stratum-weighted risk score before and after the adjustment are:

$$ErrorRate_i = 1 - \frac{\sum_e (w_{i,e} * AdjRS_{i,e})}{\sum_e (w_{i,e} * EdgeRS_{i,e})}$$

Where:

$$w_{i,e} = \frac{stratum\ size\ in\ population}{number\ of\ sample\ enrollees\ of\ the\ stratum}$$

Consistent with 45 CFR 153.350(c), HHS then applies the outlier issuer's error rate to adjust that issuer's applicable benefit year plan liability risk score.[29] This risk score change, which also impacts the state market average

[28] This calculation sequence is printed here as it appears in the 2021 Payment Notice (85 FR 29164 at 29196–29198). In certain later sections of this proposed rule, we revised the order of similar sequences to ensure simplicity when demonstrating how the proposals in this proposed rule would be combined with the current error rate calculation methodology (including the changes finalized in the 2021 Payment Notice). The different display of these sequences does not modify or otherwise change the amendments to the outlier identification process finalized in the 2021 Payment Notice.

[29] Exiting outlier issuer risk score error rates are currently applied to the plan liability risk scores and risk adjustment transfer amounts for the benefit year being audited. For all other outlier issuers, risk score error rates are currently applied to the plan liability risk scores and risk adjustment transfer amounts for the current transfer year. The exiting issuer exception is discussed in Section II.B.

risk score, is then used to adjust the applicable benefit year's risk adjustment transfers for the applicable state market risk pool. Due to the budget-neutral nature of the HHS-operated program, adjustments to one issuer's risk scores and risk adjustment transfers based on HHS–RADV findings will affect other issuers in the state market risk pool (including those who were not identified as outliers) because the state market average risk score is recalculated to reflect the change in the outlier issuer's plan liability risk score. This also means that issuers that are exempt from HHS–RADV for a given benefit year may have their risk adjustment transfers adjusted based on other issuers' HHS–RADV results.

In response to stakeholder concerns, comments to the 2019 RADV White Paper, and our analyses of 2017 benefit year HHS–RADV results, HHS is proposing to modify the HCC grouping methodology used to calculate failure rates by combining certain HCCs with the same risk score coefficient for grouping purposes, and to refine the error estimation methodology to mitigate the impact of the ''payment cliff'' effect, in which some issuers with similar HHS–RADV findings may experience different adjustments to their risk scores and transfers. We also propose changes to mitigate the impact of HHS–RADV adjustments that result from negative error rate outlier issuers with negative failure rates.

The 2019 RADV White Paper discussed several alternatives for potential changes to HHS–RADV, and we considered those alternatives and the comments we received on them when considering which proposals to propose in this rulemaking. This proposed rule addresses only certain policies discussed in the 2019 RADV White Paper. We intend to continue to analyze HHS–RADV results and consider potential further refinements to the HHS–RADV methodology for future benefit years.

1. HCC Grouping for Failure Rate Calculation

HHS groups medical conditions in multiple distinct ways during the risk adjustment and HHS–RADV processes. These grouping processes include:

For risk adjustment model development:

(1) The hierarchies of Hierarchical Condition Categories (HCCs),

(2) HCC coefficient estimation groups,[30]

(3) *A priori* stability constraints, and

(4) Hierarchy violation constraints.

And, for HHS–RADV:

(5) HHS–RADV HCC failure rate groups.

The first four of these grouping processes are related to the development and estimation of coefficients in the HHS risk adjustment models, while the fifth is related to error estimation during HHS–RADV. These grouping processes are not concurrent. The grouping processes related to the risk adjustment models are implemented prior to the benefit year and interact with HHS–RADV HCC failure rate groups that are implemented after the benefit year. Our experience in the initial years of HHS–RADV found that differences among the risk adjustment and HHS–RADV grouping procedures interact in varying ways and may result in greater or lesser HHS–RADV adjustments than may be warranted in certain circumstances. Examples of these interactions are discussed later in this proposed rule.

The first grouping of medical conditions —HCCs—is used to aggregate thousands of standard disease codes into medically meaningful but statistically manageable categories. HCCs in the 2019 benefit year HHS risk adjustment models were derived from ICD–9–CM codes [31] that are aggregated into diagnostic groups (DXGs), which are in turn aggregated into broader condition categories (CCs). Then, clinical hierarchies are applied to the CCs, so that an enrollee receives an increase to their risk score for only the most severe manifestation among related diseases that may appear in their medical claims data on an issuer's EDGE server.[32] Condition categories become Hierarchical Condition Categories (HCCs) once these hierarchies are imposed.

As noted above, for a given hierarchy, if an enrollee has more than one HCC recorded in an issuer's EDGE server, only the most severe of those HCCs will be applied for the purposes of risk adjustment model and plan liability risk score calculation.[33] For example, respiratory distress diagnosis codes are organized in a hierarchy consisting of three HCCs arranged in descending order of clinical severity from (1) HCC 125 *Respirator Dependence/ Tracheostomy Status* to (2) HCC 126 *Respiratory Arrest* to (3) HCC 127 *Cardio-Respiratory Failure and Shock, Including Respiratory Distress Syndromes.* An enrollee may have diagnosis codes in two respiratory distress HCCs, but once hierarchies are imposed, that enrollee would only be assigned the single highest severity HCC in the hierarchy. Thus, an enrollee with diagnosis codes in HCC 126 *Respiratory Arrest* and HCC 127 *Cardio-Respiratory Failure and Shock, Including Respiratory Distress Syndromes* would only be assigned the single highest HCC (in this case, HCC 126 *Respiratory Arrest*). Although HCCs reflect hierarchies among related disease categories, for unrelated diseases, multiple HCCs can accumulate for those enrollees, that is, the model is ''additive.'' For example, an enrollee with both diabetes and asthma would have (at least) two separate HCCs coded and the predicted cost for that enrollee will reflect increments for both conditions.

In the risk adjustment models, estimated coefficients of the various HCCs within a hierarchy will ensure that more severe and expensive HCCs within that hierarchy receive higher risk factors than less severe and less expensive HCCs. Additionally, as a part of the recalibration of the risk adjustment models, HHS has grouped some HCCs so that the coefficients of two or more HCCs are equal in the fitted risk adjustment models and only one model factor is assigned to an enrollee regardless of the number of HCCs from that group present for that enrollee on the issuer's EDGE server,[34] giving rise to the second set of condition groupings used in risk adjustment. We impose these HCC coefficient estimation groups for a number of reasons, including the limitation of diagnostic upcoding by severity within an HCC hierarchy and the reduction of additivity within disease groups (but not across disease

[30] The current HCC coefficient estimation groups for the adult models are identified in Column B of Table 6 in the ''Do It Yourself'' Software. The current HCC coefficient estimation groups for the child models are identified in Column B of Table 7 in the ''Do it Yourself'' Software.

[31] In the 2021 Payment Notice, we finalized several updates to the HHS–HCC clinical classification by using more recent claims data to develop updated risk factors that apply beginning with the 2021 benefit year risk adjustment models. See 85 FR 29164 at 29175 (May 14, 2020). Also see The Potential Updates to HHS–HCCs for the HHS-operated Risk Adjustment Program (June 17, 2019) (2019 HHS–HCC Potential Updates Paper), available at: *https://www.cms.gov/CCIIO/Resources/Regulations-and-Guidance/Downloads/Potential-Updates-to-HHS-HCCs-HHS-operated-Risk-Adjustment-Program.pdf.*

[32] The process for creating hierarchies is an iterative process that considers severity, as well as costs of the HCCs in the hierarchies and clinical input, among other factors. For information on this process, see section 2.3 of the 2019 HHS–HCC Potential Updates Paper.

[33] Once hierarchies are imposed, CC code groups are referred to as HCCs.

[34] As described in the June 17, 2019 document ''Potential Updates to HHS–HCCs for the HHS-operated Risk Adjustment Program'', available at *https://www.cms.gov/CCIIO/Resources/Regulations-and-Guidance/Downloads/Potential-Updates-to-HHS-HCCs-HHS-operated-Risk-Adjustment-Program.pdf#page=11.*

groups) in order to decrease the sensitivity of the models to coding proliferation.

Some of these HCC coefficient estimation groups occur within hierarchies. For example, HCC 126 *Respiratory Arrest* and HCC 127 *Cardio-Respiratory Failure and Shock, Including Respiratory Distress Syndromes* within the respiratory distress hierarchy are grouped into a single HCC coefficient estimation group. However, some HCC coefficient estimation groups include HCCs that do not share a hierarchy. For example, another HCC coefficient estimation group consists of HCC 61 *Osteogenesis Imperfecta and Other Osteodystrophies* and HCC 62 *Congenital/Developmental Skeletal and Connective Tissue Disorders.* Within an HCC coefficient estimation group, each HCC will have the same coefficient in our risk adjustment models. However, as with hierarchies, only one risk marker is triggered by the presence of one or more HCCs in the HCC coefficient estimation groups. These HCC coefficient estimation groups are identified in DIY Software Table 6 for the adult models and DIY Software Table 7 for the child models. The adult model HCC coefficient estimation groups for the V05 risk adjustment models [35] are displayed in Table 1:

TABLE 1—HCC COEFFICIENT ESTIMATION GROUPS FROM ADULT RISK ADJUSTMENT MODELS V05

HHS HCC	V05 HHS–HCC label	Adult model HCC coefficient estimation group
19	Diabetes with Acute Complications	G01
20	Diabetes with Chronic Complications	G01
21	Diabetes without Complication	G01
26	Mucopolysaccharidosis	G02A
27	Lipidoses and Glycogenosis	G02A
29	Amyloidosis, Porphyria, and Other Metabolic Disorders	G02A
30	Adrenal, Pituitary, and Other Significant Endocrine Disorders	G02A
54	Necrotizing Fasciitis	G03
55	Bone/Joint/Muscle Infections/Necrosis	G03
61	Osteogenesis Imperfecta and Other Osteodystrophies	G04
62	Congenital/Developmental Skeletal and Connective Tissue Disorders	G04
67	Myelodysplastic Syndromes and Myelofibrosis	G06
68	Aplastic Anemia	G06
69	Acquired Hemolytic Anemia, Including Hemolytic Disease of Newborn	G07
70	Sickle Cell Anemia (Hb-SS)	G07
71	Thalassemia Major	G07
73	Combined and Other Severe Immunodeficiencies	G08
74	Disorders of the Immune Mechanism	G08
81	Drug Psychosis	G09
82	Drug Dependence	G09
106	Traumatic Complete Lesion Cervical Spinal Cord	G10
107	Quadriplegia	G10
108	Traumatic Complete Lesion Dorsal Spinal Cord	G11
109	Paraplegia	G11
117	Muscular Dystrophy	G12
119	Parkinson's, Huntington's, and Spinocerebellar Disease, and Other Neurodegenerative Disorders	G12
126	Respiratory Arrest	G13
127	Cardio-Respiratory Failure and Shock, Including Respiratory Distress Syndromes	G13
128	Heart Assistive Device/Artificial Heart	G14
129	Heart Transplant	G14
160	Chronic Obstructive Pulmonary Disease, Including Bronchiectasis	G15
161	Asthma	G15
187	Chronic Kidney Disease, Stage 5	G16
188	Chronic Kidney Disease, Severe (Stage 4)	G16
203	Ectopic and Molar Pregnancy, Except with Renal Failure, Shock, or Embolism	G17
204	Miscarriage with Complications	G17
205	Miscarriage with No or Minor Complications	G17
207	Completed Pregnancy With Major Complications	G18
208	Completed Pregnancy With Complications	G18
209	Completed Pregnancy with No or Minor Complications	G18

The HHS–HCC model also incorporates a small number of ''*a priori* stability constraints'' to stabilize estimates that might vary greatly due to small sample size.[36] These *a priori* stability constraints differ from the HCC coefficient estimation groups in how the corresponding estimates are counted. In contrast to HCC coefficient estimation groups, with *a priori* stability constraints, a person can have more than one indicated condition (each with

[35] The shorthand ''V05'' refers to the current HHS–HCC classification for the HHS risk adjustment models, which applies through the 2020 benefit year.

[36] For example, we previously finalized a constraint for six coefficients associated with seven transplant status HCCs (excluding kidney transplants) in the child model, as the sample sizes of transplants are smaller in the child than the adult model. Because the levels and changes in the child transplant relative coefficients appeared to be dominated by random instability at the time, we believed the accuracy of the models were improved by constraining these coefficients. See the HHS Notice of Benefit and Payment Parameters for 2016, Final Rule, 80 FR 10749 at 10761 (February 27, 2015).

the same coefficient value) as long as the HCCs are not in the same hierarchy. As seen in Table 2, prior to the 2021 benefit year recalibration,[37] only one *a priori* stability constraint was applied to the models, and this constraint was only applied to the child models.

TABLE 2—HCCS SUBJECT TO A PRIORI STABILITY CONSTRAINTS IN RISK ADJUSTMENT CHILD MODELS V05

HHS HCC	V05 HHS–HCC label	Child model a Priori stability constraint
18	Pancreas Transplant Status/Complications	S1
34	Liver Transplant Status/Complications	S1
41	Intestine Transplant Status/Complications	S1
128	Heart Assistive Device/Artificial Heart	S1
129	Heart Transplant	S1
158	Lung Transplant Status/Complications	S1
251	Stem Cell, Including Bone Marrow, Transplant Status/Complications	S1

HCC coefficient estimation group constraints and *a priori* stability constraints are both applied in the initial phase of risk adjustment regression modeling. Other constraints may be applied in later stages depending on regression results. For example, HCCs may be constrained equal to each other if there is a hierarchy violation (a lower severity HCC has a higher estimate than a higher severity HCC in the same hierarchy).[38] HCC coefficients may also be constrained to 0 if the estimates fitted by the regression model are negative.

The final set of groupings is imposed during the error estimation stage of the HHS–RADV process. In this process, HCCs are categorized into low, medium, and high HCC failure rate groups. These groupings are designed to balance the need to assess the impact of medical coding errors of individual HCCs on risk scores and risk adjustment transfers and the need to assess failure rates on enough HCCs to provide statistically meaningful HHS–RADV results. Furthermore, these groupings are intended to reflect the fact that some HCCs are more difficult to code accurately than other HCCs and to provide national standards that take into account the level of coding difficulty for a given HCC.

To create the HHS–RADV HCC failure rate groupings, the first step is to calculate the national average failure rate for each HCC individually. The second step involves ranking HCCs in order of their failure rates and then dividing them into three groups—a low, medium, and high failure rate group—such that the total counts of HCCs in each group nationally as recorded in EDGE data across all IVA samples (or SVA samples if applicable) are roughly equal. These HCC failure rate groups form the basis of the failure rate outlier determination process, with each failure rate group receiving an independent assessment of outlier status for each issuer.[39]

Based on our experience with the initial years of HHS–RADV, HHS observed that, in certain situations, the risk adjustment HCC hierarchies and HCC coefficient estimation groups can influence and interact with the HHS–RADV HCC failure rate groupings in varying ways that could result in misalignments.[40] For example:

- *Scenario 1:* HCCs in the same HCC hierarchy with different coefficients are sorted into different HHS–RADV HCC failure rate groupings.

++ If one HCC is commonly miscoded as another HCC in the same hierarchy, but the two HCCs are sorted into different HCC failure rate groupings in HHS–RADV, an issuer may be flagged as an outlier in either of the HCC failure rate groupings where one HCC is missing or the other HCC is newly found.

++ For example, HCC 8 *Metastatic Cancer* and HCC 11 *Colorectal, Breast (Age <50), Kidney, and Other Cancers* are in the same hierarchy in risk adjustment, but for the 2017 benefit year of HHS–RADV, HCC 8 was in the medium HCC failure rate grouping and HCC 11 was in the high HCC failure rate grouping. In validating an enrollee with HCC 8 in HHS–RADV, the IVA or SVA Entity may find that an enrollee with HCC 8 reported in EDGE is not validated as having HCC 8, which is at the top of the HCC hierarchy in risk adjustment, but the enrollee may have been found to have HCC 11 in the issuer's HHS–RADV audit data. In this case, HCC 8 would be considered missing in the medium HCC failure rate grouping, and HCC 11 would be considered found in the high HCC failure rate grouping.

++ This circumstance would influence the failure rate for that issuer, potentially leading to the issuer being classified as an outlier in an HCC failure rate grouping. If the issuer is found to be an outlier in one of the two failure rate groupings, the issuer's HCC failure rate would not represent the actual difference in risk and costs between these two coefficients.

- *Scenario 2:* HCCs in the same HCC hierarchy with different coefficients are sorted into the same HHS–RADV HCC failure rate grouping.

++ If one HCC is commonly miscoded as another HCC in the same hierarchy, and the two HCCs are sorted into the same HCC failure rate grouping, the issuer may not be flagged as an outlier for that HCC grouping. This may occur because the failure to validate an HCC and the discovery of a new HCC in that same HCC failure rate grouping have a net impact of zero on the total final value of the issuer's failure rate. For purposes of the calculation of the failure rate, there would appear to be no difference between the two HCCs, even though they have different coefficients in risk adjustment.

[37] In the 2021 Payment Notice (85 FR 29164 at 29178), we introduced an additional *a priori* stability constraint to the child risk adjustment models, constraining HCC 218 *Extensive Third Degree Burns* and HCC 223 *Severe Head Injury* to have the same risk adjustment coefficient due to small sample size. We also revised the current single transplant stability constraint in the child models (shown in Table 2) into two stability constraints to better distinguish transplant cost differences.

[38] For example, in the 2019 benefit year of risk adjustment adult models, HCC 88 (Major Depression and Bipolar Disorders) and HCC 89 (Reactive and Unspecified Psychosis, Delusional Disorders) were constrained to be equal due to a hierarchy violation occurring. Therefore, these HCCs in the 2019 benefit year final adult models have the same risk scores; however, these two HCCs are not grouped (as shown in Table 6, Column B of 2019 benefit year DIY Software).

[39] For a table of the HCC failure rate groupings for 2017 benefit year HHS–RADV, see the 2019 RADV White Paper, Appendix E.

[40] See Section 3.3 of the 2019 RADV White Paper.

++ For example, HCC 35 *End-Stage Liver Disease* and HCC 34 *Liver Transplant Status/Complications* are in the same hierarchy in risk adjustment and were both sorted into the medium HCC failure rate grouping in the 2017 benefit year HHS–RADV results. In validating an enrollee with HCC 35 in HHS–RADV, the IVA or SVA Entity may find that an enrollee with HCC 35 reported in EDGE is not validated as having HCC 35, but the enrollee may have been found to have HCC 34 in issuer's HHS–RADV audit data. In this case, not validating HCC 35 and finding HCC 34 in the same HCC grouping in HHS–RADV would, when taken together, have no net impact on the issuer's HCC group failure rate.

++ This situation would influence the failure rate for that issuer, potentially leading to the issuer not being classified as an outlier in an HCC failure rate grouping even though the two HCCs have different risk and costs. If the issuer is not found to be an outlier in the applicable failure rate grouping, the issuer's HHS–RADV adjustment would not represent the actual difference in risk and costs between these two coefficients.

• *Scenario 3:* HCCs in the same HCC coefficient estimation group are sorted into different HCC failure rate groupings.

++ In this situation, a miscoding of one HCC for the other may lead to the issuer being identified as a positive outlier in one HCC failure rate grouping or a negative outlier in another, despite there being no difference in risk score due to the coding error.

++ For example, HCC 54 *Necrotizing Fasciitis* and HCC 55 *Bone/Joint/Muscle Infections/Necrosis* share a hierarchy and an HCC coefficient estimation group in risk adjustment, resulting in risk score coefficients constrained to be equal, but for 2017 benefit year HHS–RADV, HCC 54 was in the high failure rate HCC grouping, while HCC 55 was in the medium failure rate HCC grouping. In validating an enrollee with HCC 54 in HHS–RADV, the IVA or SVA Entity may find that an enrollee with HCC 54 reported in EDGE is not validated as having HCC 54, but the enrollee may have been found to have HCC 55 in issuer's HHS–RADV audit data.

++ In this case, when taken together with the issuer's other HHS–RADV results, HCCs in the same HCC coefficient estimation group could contribute to an issuer's failure rate in a HCC failure rate grouping, even though the HCCs do not have different risk scores and an adjustment to risk scores is not conceptually warranted. If the issuer is found to be an outlier in one of the two failure rate groupings, the issuer's HCC failure rate would not represent actual differences in risk or costs between these two coefficients.

Based on HHS's initial analysis of the occurrence of these scenarios in the 2017 benefit year HHS–RADV results,[41] and in response to comments to the 2019 RADV White Paper, HHS is considering an option in this proposed rule to address the influence of the HCC hierarchies and HCC coefficient estimation groups on the HCC failure rate groupings in HHS–RADV. Our intention is to address this issue on an interim basis while we continue to assess different longer-term options, including potential significant changes to the outlier determination process, which require additional analysis and consideration before proposing.

To address Scenario 3, we propose to modify the creation of HHS–RADV HCC failure rate groupings and place all HCCs that share an HCC coefficient estimation group in the adult risk adjustment models (see Table 1 for the list of the HCC coefficient estimation groups in the V05 classification) into the same HCC failure rate grouping. Specifically, we propose that when HHS calculates EDGE and IVA frequencies for each individual HCC and prior to sorting the HCCs into low, medium, and high failure rate groups for HHS–RADV, HCCs that are in the same HCC coefficient estimation group in the adult risk adjustment models (and, therefore, have coefficients constrained to be equal to one another) would be aggregated into one HCC. These new frequencies, including the aggregated frequencies of HCC coefficient estimation groups and the frequencies of all other unconstrained HCCs, treated separately, would be considered frequencies of ''Super HCCs''.

In the current process,[42] before sorting into the three HCC failure rate groups, failure rates for each HCC are calculated individually as:

$$FR_h = 1 - \frac{freqIVA_h}{freqEDGE_h}$$

Where:

h is the index of the h^{th} HCC code;

$freqEDGE_h$ is the frequency of an HCC h occurring in EDGE data; that is, the number of sampled enrollees recording HCC h in EDGE data across all issuers participating in HHS–RADV;

$freqIVA_h$ is the frequency of an HCC h occurring in IVA results (or SVA results, as applicable); that is, the number of sampled enrollees recording HCC h in IVA (or SVA, as applicable) results across all issuers participating in HHS–RADV; and

FR_h is the national overall (average) failure rate of HCC h across all issuers participating in HHS–RADV.

In the proposed methodology, this step would be modified as:

$$FR_c = 1 - \frac{freqIVA_c}{freqEDGE_c}$$

Where:

c is the index of the c^{th} Super HCC;

$freqEDGE_c$ is the frequency of a Super HCC c occurring in EDGE data across all issuers participating in HHS–RADV; that is, the sum of $freqEDGE_h$ for all HCCs that share an HCC coefficient estimation group in the adult models:

$$freqEDGE_c = \sum_h freqEDGE_{h,c}$$

When an HCC is not in an HCC coefficient estimation group in the adult risk adjustment models, the $freqEDGE_c$ for that HCC will be equivalent to $freqEDGE_h$;

$freqIVA_c$ is the frequency of a Super HCC c occurring in IVA results (or SVA results, as applicable) across all issuers participating in HHS–RADV; that is, the sum of $freqIVA_h$ for all HCCs that share an HCC coefficient estimation group in the adult risk adjustment models:

$$freqIVA_c = \sum_h freqIVA_{h,c}$$

And;

FR_c is the national overall (average) failure rate of Super HCC c across all issuers participating in HHS–RADV.

Then, the failure rates for all Super HCCs, both those composed of a single

[41] As discussed in the 2019 RADV White Paper, we performed an initial review of the occurrence of these scenarios in the 2017 benefit year HHS–RADV results. Of all the HCCs in EDGE that were not validated in the audit data, about 1/8th represented HCCs that IVA or SVA auditors coded as different HCCs within the same hierarchy. Of the HCCs that were newly found in the audit data—that is, they were not recorded in the original EDGE data—around 1/3rd represented HCCs that were newly found because they were originally reported on EDGE as a different HCC in the same hierarchy. However, we note that these occurrences reflect both HCCs sorted into different HCC failure rate groups and HCCs sorted into the same HCC failure rate groups, including a scenario, discussed in the whitepaper wherein HCCs in the same hierarchy and the same HCC coefficient estimation group are sorted into the same HCC failure rate group, which would have no impact on failure rate and would not warrant any adjustment to risk score. Therefore, for many issuers, these occurrences would be unlikely to impact whether they were an outlier in an HCC failure rate grouping. However, we note that the initial review discussed in the white paper did not consider HCCs that share an HCC coefficient estimation group, but do not share a hierarchy.

[42] See the 2018 HHS–RADV protocols, section 11.3.1, available at: *https://www.regtap.info/uploads/library/HRADV_2018Protocols_070319_5CR_070519.pdf.*

HCC and those composed of the aggregate frequencies of HCCs that share an HCC coefficient estimation group in the adult risk adjustment models, would be grouped according to the current HHS–RADV failure rate grouping methodology.

As an illustrative example, this proposal would mean that, for purposes of HHS–RADV groupings, two of the three current respiratory distress HCCs in the adult risk adjustment models, HCC 126 *Respiratory Arrest* and HCC 127 *Cardio-Respiratory Failure and Shock, Including Respiratory Distress Syndromes,* would be aggregated into one Super HCC because they have the same estimated costs and share an HCC coefficient estimation group. That Super HCC would then be sorted into a failure rate group according to its overall national failure rate. As such, all validations or failures to validate either of the two HCCs composing the Super HCC would contribute to the failure rate for the same HCC failure rate grouping. However, if an enrollee with one of the two HCCs in the Super HCC reported on EDGE was not validated as having the EDGE reported HCC but is found to have the other HCC in the Super HCC (*e.g.,* an enrollee with HCC 126 reported on EDGE is not validated as having HCC 126 but is found to have HCC 127), the issuer's failure rate would not be affected. This approach would ensure that HCCs with the same estimated costs in the adult risk adjustment models that share an HCC coefficient estimation group do not contribute to an issuer's failure rate in a HCC failure rate grouping. To promote fairness and ensure the integrity of the program, we do not believe that issuers should be considered to have an HHS–RADV error for similar conditions from the same HCC coefficient estimation group and, as a result, were estimated as having the same risk in the adult risk adjustment models. This proposal to aggregate the frequencies of HCCs in the same HCC coefficient estimation group in the adult risk adjustment models would refine the HHS–RADV methodology to better identify and focus outlier determinations on actual differences in risk and costs. Based on our testing of this proposed policy on 2017 benefit year HHS–RADV results, we estimate that by creating the proposed Super HCCs, approximately 98.1 percent of the occurrences of HCCs on EDGE belong to HCCs that would be assigned to the same failure rate groups under the proposed methodology as they have been under the current methodology as seen in Table 3. Although the impact on individual issuer results may vary depending upon the accuracy of their initial data submissions and the rate of occurrence of various HCCs in their enrollee population, the national metrics used for HHS–RADV would only be slightly affected, as seen in Table 4. The stability of these metrics and high proportion of EDGE frequencies of HCCs that would be assigned to the same failure rate group under the proposed and current sorting methodologies reflects that the most common conditions will have similar failure rates if this proposal is adopted. However, the failure rate estimates of less common conditions may be stabilized with the proposed creation of Super HCCs by ensuring these conditions are grouped alongside more common, related conditions.

In testing this proposal to create the Super HCCs in HHS–RADV, we grouped HCCs in the same HCC coefficient estimation group in the adult risk adjustment models. To do this, we used variables in Column B in Table 6 of the HHS-Developed Risk Adjustment Model Algorithm ''Do It Yourself'' software [43] to determine the candidate HCCs that should be incorporated into Super HCCs under this policy proposal. If a set of candidate HCCs are all from the same HCC coefficient estimation group, they would be grouped into one Super HCC in HHS–RADV. Each remaining HCC that does not meet these criteria would be assigned to its own Super HCC prior to determining the HCC failure rate grouping. We chose to use the adult risk adjustment models for testing because the majority of the population with HCCs in the HHS–RADV samples are subject to the adult models (88.3 percent for the 2017 benefit year).[44] As such, the adult models' HCC coefficient estimation groups will be applicable to the vast majority of enrollees and we believe that the use of HCC coefficient estimation groups present in the adult risk adjustment models sufficiently balances the representativeness and precision of HCC failure rate estimates across the entire population in aggregate and may be used as the source for the proposed creation of Super HCCs for all RADV sample enrollees, regardless of the risk adjustment model to which they are subject.

In developing this policy, we limited the grouping of risk adjustment HCCs into Super HCCs for HHS–RADV to HCC coefficient estimation groups alone and have not considered including *a priori* stability constraints or hierarchy violation constraints in the aggregation of Super HCCs. *A priori* stability constraints currently are only applied to a limited number of HCCs in the child models and are applied differently than HCC hierarchies and HCC coefficient estimation groups. Whereas enrollees can only receive one HCC from a hierarchy or one model factor from a coefficient estimation group (for example, one factor for the presence of either HCC 61 *Osteogenesis Imperfecta and Other Osteodystrophies* or HCC 62 *Congenital/Developmental Skeletal and Connective Tissue Disorders*), enrollees may receive more than one HCC when there is an *a priori* stability constraint (for example, HCC 129 *Heart Transplant* and HCC 158 *Lung Transplant Status/ Complications* in the child model). Although HCCs subject to *a priori* stability constraints will have the same coefficient value, the possible additive nature of these HCCs suggests that a failure to validate one HCC subject to an *a priori* stability constraint paired with the IVA or SVA entity identifying a different HCC subject to the same *a priori* stability constraint does not constitute a swapping of HCCs in the same way that a similar scenario among HCCs in a common HCC coefficient estimation group would. As such, we do not find it necessary or appropriate to include *a priori* stability constraints in the aggregation of Super HCCs.

We also did not consider hierarchy violation constraints as a part of the sorting algorithm in order to balance complexity and consistency, as hierarchy violation constraints in the risk adjustment models can change from year-to-year as a natural result of risk adjustment model coefficient annual recalibration updates. These year-to-year changes would make HCC groupings for these HCCs less stable and transparent, and would reduce predictability for issuers.

For the above mentioned reasons, we propose to combine HCCs in HCC coefficient estimation groups in the adult risk adjustment models into Super HCCs prior to sorting the HCCs into low, medium and high failure rate groups for HHS–RADV, starting with the 2019 benefit year of HHS–RADV. If finalized as proposed, these Super HCC groupings would apply to all RADV sample enrollees, regardless of the risk adjustment models to which they are subject. Once sorted into failure rate groups, the failure rates for all Super

[43] 2017 Benefit Year Risk Adjustment: HHS-Developed Risk Adjustment Model Algorithm ''Do It Yourself (DIY)'' Software. Technical Details. July 21, 2017. Assessed at: *https://www.cms.gov/CCIIO/Resources/Regulations-and-Guidance/Downloads/DIY-Tables-7-12-2017.xlsx.*

[44] This was calculated after removing issuers in Massachusetts and incorporating cases where issuers failed pairwise and the SVA sub-sample was used.

HCCs, both those composed of a single HCC and those composed of the aggregate frequencies of HCCs that share an HCC coefficient estimation group in the adult risk adjustment models, would be grouped according to the current HHS–RADV failure rate grouping methodology.

We solicit comment on all aspects of this proposal. In particular, we solicit comments on the proposed use of the HCC coefficient estimation groups to identify the HCCs that would be aggregated into Super HCCs in HHS–RADV and whether we should also consider incorporating *a priori* stability constraints from the child models, or hierarchy violation constraints from the adult risk adjustment models as part of HHS–RADV Super HCCs. We also solicit comment on whether, in addition to the Super HCCs based on the adult risk adjustment models, CMS should create separate infant Super HCCs for each severity type in the infant risk adjustment models. As we considered with the adult risk adjustment model-based Super HCCs, if we were to adopt separate infant model-based Super HCCs, we solicit comments on whether we should incorporate only the HCC coefficient groupings inherent in the infant severity level determination process, or both these groupings and any hierarchy violation constraints that may occur in the infant models. The latter option may make the composition of HCC groups less stable year-to-year, but may more comprehensively address Scenario 3 when it occurs and reflect the full risk structure of HCC hierarchies as expressed in infant risk adjustment models.

Additionally, we solicit comment regarding the impact of COVID–19 on the proposed changes to the HCC grouping methodology for error rate calculation. In particular, we solicit comment on whether the need for providers to focus on caring for patients during the COVID–19 pandemic could impact the completeness of the data that would be used to implement the new HCC grouping methodology for HHS–RADV, such that we should consider a later applicability date if we finalize this proposal.

TABLE 3—ESTIMATED PROPOSED CHANGES IN THE HCC GROUPINGS USING SUPER HCCS BASED ON ADULT MODEL HCC COEFFICIENT ESTIMATION GROUPS

[Using the 2017 benefit year HHS–RADV results]

Count of HCC categories in each failure rate group	Super HCCs using HCC coefficient estimation groups (proposed option)		
	Low	Medium	High
Current Methodology:			
Low	31	1	1
Medium	2	29	4
High	1	5	53
Frequency of HCC occurrence on EDGE	**Super HCCs using HCC coefficient estimation groups (proposed option)**		
	Low (percent)	Medium (percent)	High (percent)
Current Methodology:			
Low	32.2	0.0	0.0
Medium	0.1	33.0	1.0
High	0.3	0.3	32.9

TABLE 4—ESTIMATED PROPOSED NATIONAL METRICS IN THE HCC GROUPINGS USING SUPER HCCS BASED ON ADULT MODEL HCC COEFFICIENT ESTIMATION GROUPS

[Using the 2017 benefit year HHS–RADV results]

HCC grouping options	Group	Weighted mean failure rate	Weighted std. dev	Lower threshold	Upper threshold
Current	Low	0.0476	0.0973	−0.1431	0.2382
	Med	0.1549	0.0992	−0.0395	0.3493
	High	0.2621	0.1064	0.0536	0.4706
Super HCCs using HCC Coefficient Estimation Groups (Proposed Option).	Low	0.0496	0.0959	−0.1384	0.2376
	Med	0.1557	0.0994	−0.0392	0.3506
	High	0.2595	0.1065	0.0508	0.4682

2. ''Payment cliff'' Effect

The HHS–RADV error rate calculation methodology is based on the identification of outliers, as determined using certain national thresholds. In the case of the current error rate calculation methodology, those thresholds are used to determine whether an issuer is an outlier, and to determine the error rate that will be used to adjust risk scores. As previously discussed, under the current methodology, 1.96 standard deviations on both sides of the confidence interval around the weighted HCC group means are the thresholds currently used to determine whether an issuer is an outlier. In practice, these thresholds mean that an issuer with failure rates outside the 1.96 standard deviations range for any of the HCC failure groups is deemed an outlier and

receives an adjustment to its risk score, while an issuer with failure rates inside the 1.96 standard deviations range for all groups receives no adjustment to its risk score.[45]

As stated in the 2021 Payment Notice, beginning with the 2019 benefit year, when the issuers meets the minimum HCC requirement per an HCC group ($Freq\_EDGE_{G,i}$, the group adjustment factor for outliers is the distance between issuer *i*'s Group Failure Rate $GFR_{G,i}$ and the weighted mean $\mu\{GFR_G\}$ calculated [46] as:

If $GFR_{G,i} > UB_G$ or $GFR_{G,i} < LB_G$:
And if $Freq\_EDGE_{G,i} \geq 30$:
Then $Flag_{G,i}$ = ''*outlier*'' and $GAF_{G,i} = GFR_{G,i} - \mu\{GFR_G\}$
If $GFR_{G,i} \leq UB_G$ amd $GFR_{G,i} \geq LB_G$,
Or if $Freq\_EDGE_{G,i} < 30$:
Then $Flag_{G,i}$ = ''*not outlier*'' and $GAF_{G,i} = 0$

Where:

$Flag_{G,i}$ is the indicator if issuer *i*'s group failure rate for group *G* is located beyond a calculated threshold that we use to classify issuers into ''outliers'' or ''not outliers'' for group *G*.

$GAF_{G,i}$ is the calculated adjustment factor to adjust issuer *i*'s EDGE risk score components for all sampled HCCs in group *G*.

For each sampled enrollee with HCCs, the group adjustment factor (GAF) is applied at the individual HCC level to all EDGE HCCs in the HCC grouping in which the issuer is an outlier. For example, if an issuer's sample has one enrollee with the HIV/AIDS HCC and the issuer's HCC GAF [47] is 10 percent (the difference between the outlier issuer's group failure rate and the weighted mean group failure rate) for the HCC group that contains the HIV/AIDS HCC, the enrollee's HIV/AIDS HCC risk score coefficient would be reduced by 10 percent. This reduction would be aggregated with any reductions to other HCCs for that enrollee to arrive at the overall enrollee adjustment factor for each sample enrollee in stratum 1 through 9. Next, each stratum 1 through 9 sample enrollee's enrollee adjustment factor is applied to that enrollee's entire EDGE risk score (including the non-HCC risk adjustment components) to calculate an adjusted risk score for that sample enrollee. These adjusted risk scores are extrapolated to the issuer's population strata and aggregated with the unadjusted risk scores of stratum 10 enrollees in the calculation of the issuer's error rate.

Some stakeholders have expressed concern that the failure rates of issuers that are just outside of the confidence intervals receive an adjustment, even though they may not be significantly different from the failure rates of issuers just inside the confidence intervals who receive no adjustment, creating a ''payment cliff'' or ''leap frog'' effect. For example, an issuer with a low HCC group failure rate of 23.9 percent would be considered a positive error rate outlier for that HCC group based on the 2017 benefit year national failure rate statistics, because the upper bound confidence interval for the low HCC group is 23.8 percent. That issuer's GAF would be calculated based on the difference between the weighted low HCC group mean of 4.8 percent and the issuer's 23.9 percent failure rate for that HCC group. Under this example, the issuer's GAF would be 19.1 percent, and that GAF would be applied to the enrollee-level risk score coefficients for enrollees in the issuer's sample who have HCCs in the HCC failure rate group for which the issuer was determined to be an outlier. At the same time, another issuer with a low HCC group failure rate of 23.7 percent would receive no adjustment to its risk score as a result of HHS–RADV. While this result is due to the nature of establishing and using a threshold, some stakeholders have recommended mitigating this effect by calculating error rates based on the position of the bounds of the confidence interval for the HCC group and not on the position of the weighted mean for the HCC group. Others have recommended not adjusting issuers' risk scores in the case of negative error rate issuers to limit the impact of these adjustments on issuers who are not determined to be outliers.[48]

As we have previously discussed,[49] we have concerns about only adjusting issuers' risk scores for positive error rate outliers. However, we recognize that changing the calculation and application of an outlier issuer's error rate may be appropriate if the outlier issuer is not statistically different from the issuers within the confidence intervals. Therefore, to promote fairness, HHS's focus in considering potential changes to mitigate the payment cliff in the calculation of error rates is on situations where issuers with failure rates that are close to the bounds of the confidence intervals are not substantially different from issuers with failure rates inside the confidence intervals. To address this issue, we are considering potential modifications to the error rate calculation that maintain the two-sided approach of HHS–RADV through which both positive and negative error rate outliers would continue to receive risk score adjustments.

While HHS considered several possible methods to address the payment cliff in the 2019 RADV White Paper, we are proposing to address the payment cliff by adding a sliding scale adjustment to the current error rate calculation, such that different adjustments would be applied to issuers based on their distance from the mean and the farthest outlier threshold. This proposed approach would employ additional thresholds to create a smoothing of the error rate calculation beyond what the current methodology allows and to help reduce the disparity of risk score adjustments using a linear adjustment.[50] We are proposing to make this modification beginning with 2019 benefit year HHS–RADV.

To apply the sliding scale adjustment, we propose to modify the calculation of the GAF by providing a linear sliding scale adjustment, for issuers whose failure rates are near the point at which the payment cliff occurs. For those issuers, we propose to add an additional step to the calculation of their GAFs to take into consideration these issuers' distance from the confidence interval. The present formula for an issuers' GAF, $GAF_{G,i} = GFR_{G,i} - \mu\{GFR_G\}$, would be modified by replacing the $GFR_{G,i}$ with a decomposition of this value that uses the national weighted mean and national weighted standard deviation for the HCC failure rate group, as well as $z_{G,i,}$ the z-score associated with the $GFR_{G,i}$, where:

$$z_{G,i} = \frac{GFR_{G,i} - \mu\{GFR_G\}}{Sd\{GFR_G\}}$$

[45] An issuer with no error rate would not have its risk score adjusted due to HHS–RADV, but that issuer may have its risk adjustment transfer impacted if there is another issuer(s) in the state market risk pool that is an outlier.

[46] This calculation sequence is printed here as it appears in the 2021 Payment Notice (85 FR 29164 at 29196–29198). In later sections of this rule, we revised the order of similar sequences for simplicity when demonstrating how this sequence would be combined with proposals in this proposed rule. The different display does not modify or otherwise change the amendments to the outlier identification process finalized in the 2021 Payment Notice.

[47] To more clearly distinguish between the enrollee adjustment factor and the group adjustment factor, for the purposes of this proposed rule, we use GAF instead of ''adjustment''.

[48] See Section II.A.3 for proposals intended to mitigate the impact of HHS–RADV adjustments for negative error rate issuers with negative failure rates.

[49] See, for example, Section 4.4.3 of the 2019 RADV White Paper. Also see 84 FR 17504 through 17508.

[50] In the 2020 Payment Notice final rule, we stated that we may consider alternative options for error rate adjustments, such as using multiple or smoothed confidence intervals for outlier identification and risk score adjustments. See 84 FR at 17507.

And therefore:

$GFR_{G,i} = z_{G,i} * Sd\{GFR_G\} + \mu\{GFR_G\}$

So:

$GAF_{G,i} = [z_{G,i} * Sd\{GFR_G\} + \mu\{GFR_G\}] - \mu\{GFR_G\}$

The z-score would then be discounted using the general formula:, where $disZ_{G,i,r} = a * z_{G,i} + b_r$, Where $disZ_{G,i,r}$ is the confidence-level discounted z-score for that value of $z_{G,i}$ according to the parameters of the positive or negative sliding scale range, *r.* This $disZ_{G,i,r}$ value would replace the $z_{G,i}$ value in the $GAF_{G,i}$ formula to provide the value of the sliding scale adjustment for the positive or negative side of the confidence interval:

$GAF_{G,i,r} = [disZ_{G,i,r} * Sd\{GFR_G\} + \mu\{GFR_G\}] - \mu\{GFR_G\}$

In the calculation of $disZ_{G,i,r,}$ the coefficient *a* would be the slope of the linear adjustment, which shows the adjustment increase rate per unit increase of $GFR_{G,i}$, and b_r is the intercept of the linear adjustment for either the negative or positive sliding scale range. The coefficients would be determined based on the standard deviation thresholds of the range selected for the application of the sliding scale adjustment. Specifically, coefficient *a* would be defined as:

$$a = \frac{outerZ_r}{outerZ_r - innerZ_r}$$

Where:

- *a* is the slope of the sliding scale adjustment
- *r* indicates whether the *GAF* is being calculated for a negative or positive outlier
- $outerZ_r$ is the greater magnitude z-score selected to define the edge of a given sliding scale range *r* (3.00 for positive outliers; and −3.00 for negative outliers)
- $innerZ_r$ is the lower magnitude z-score selected to define the edge of a given sliding scale range *r* (1.645 for positive outliers; and −1.645 for negative outliers)

The value of intercept b_r would differ based on whether the sliding scale were being calculated for a positive or negative outlier and would be defined as:

$b_r = outerZ_r - a * (outerZ_r) = outerZ_r * (1 - a)$

In the absence of the constraints on negative failure rates described later in this proposed rule, the final formula for the group adjustment when an outlier issuer is subject to the sliding scale ($GAF_{G,i,r,}$ above) could be simplified to:

$GAF_{G,i,r} = disZ_{G,i,r} * Sd\{GFR_G\}$

However, for the purposes of aligning formulas between the multiple proposals in this proposed rule, we feel that it is helpful to provide both the above expanded and simplified versions of the sliding scale $GAF_{G,i,r}$ formula in this section.

This sliding scale $GAF_{G,i,r}$ would be applied to the HCC coefficients in the applicable HCC failure rate group when calculating each enrollee with an HCCs' risk score adjustment factor for an issuer that had a failure rate with a z-score within the range of values selected for the sliding scale adjustment ($innerZ_r$ and $outerZ_r$). All other enrollee adjustment factors would be calculated using the current formula for the $GAF_{G,i}$. Using this linear sliding scale adjustment would provide a smoothing effect in the error rate calculation for issuers with failure rates just outside of the confidence interval of an HCC group.

To implement this proposed option, we would need to select the thresholds of the range ($innerZ_r$ *and* $outerZ_r$) to calculate and apply the sliding scale adjustment.[51] Commenters to the 2019 RADV White Paper supported a sliding scale option that would calculate and apply the sliding scale adjustment from +/−1.96 to 3 standard deviations. This option would retain the confidence interval at 1.96 standard deviations under the current methodology, meaning that issuers within the 95 percent confidence interval would not have their respective risk scores adjusted. This option would also retain the full adjustment to the mean failure rate for issuers outside of the 99.7 percent confidence interval (beyond 3 standard deviations). While some of these stakeholders would prefer that the error rate be calculated to the edge of the confidence intervals for all outliers, rather than applying a sliding scale, some of these same commenters expressed support for this option because it would not increase the number of outliers compared to the current methodology, promoting stability for issuers. Specifically, this option would provide stability by maintaining the current thresholds used in the error rate calculation and without changing the number of issuers that would be impacted. While we recognize that this option would mitigate the payment cliff, we have concerns that it would weaken the HHS–RADV program by reducing its overall impact and the magnitude of HHS–RADV adjustments to the risk scores of outlier issuers.

Instead, in this proposed rule, we propose to calculate and apply a sliding scale adjustment between the 90 and 99.7 percent confidence interval bounds (from +/−1.645 to 3 standard deviations). Under this proposal, the determination of outliers in HHS–RADV for each HCC grouping would no longer have a 95 percent confidence interval or 1.96 standard deviations, and would instead have a 90 percent confidence interval or 1.645 standard deviations. Specifically, this approach would adjust the upper and lower bounds of the confidence interval to be at 1.645 standard deviations, meaning that issuers outside of the 90 percent confidence interval would have their risk scores adjusted, instead of beginning adjustments for issuers at the 95 percent confidence interval under the current methodology. This would mean that more issuers would be considered outliers under this proposal than the current methodology.

Under this proposed approach, the above formulas would be implemented[52] as follows:

If $Freq\_EDGE_{G,i} \geq 30$, then:

If $z_{G,i} < -3.00$ or $z_{G,i} > 3.00$

Then $Flag_{G,i}$ = ''*outlier*'' and $GAF_{G,i} = GFR_{G,i} - \mu\{GFR_G\}$

Or if $-3 < z_{G,i} < -1.645$ or $3 > z_{G,i} > 1.645$

Then $Flag_{G,i}$ = ''*outlier*'' and $GAF_{G,i} = disZ_{G,i,r} * Sd\{GFR_G\}$

If $Freq\_EDGE_{G,i} < 30$ or if $-1.645 \leq z_{G,i} \leq 1.645$.

Then $Flag_{G,i}$ = ''*not outlier*'' and $GAF_{G,i} = 0$

Where $disZ_{G,i,r}$ is calculated using 3.00 (or −3.00, for negative outliers) as the value of *outerZr* and 1.645 (or −1.645, for negative outliers) as the value of *innerZr.*

This proposed approach would retain the current significant adjustment to the HCC group weighted mean for issuers beyond three standard deviations to ensure that the mitigation of the payment cliff for those issuers close to the confidence intervals does not impact situations where outlier issuers' failure rates are not close to the confidence intervals and a larger adjustment is warranted.

As discussed in the 2019 RADV White Paper, we tested a sliding scale adjustment between the 90 and 99 percent confidence interval bounds using 2017 HHS–RADV results.[53] We found that even though it would

[51] In the 2019 RADV White Paper, we considered four different options on how to calculate and apply additional thresholds for the sliding scale adjustment to the error rate calculation. See section 4.4.4 and 4.4.5 of the 2019 RADV White Paper.

[52] This calculation sequence is expressed here in a revised order compared to how the sequence is published in the 2021 Payment Notice (85 FR 29164 at 29196–29198). This change was made for simplicity to demonstrate how the current sequence would be combined with this proposed approach. The different display does not modify or otherwise change the amendments to the outlier identification process finalized in the 2021 Payment Notice.

[53] See section 4.4.5 and Appendix C of the 2019 RADV White Paper.

increase the number of outliers by including issuers whose failure rates fell between 1.645 and 1.96 standard deviations from the mean, it would lower the overall impact of HHS–RADV adjustments to transfers and result in the distribution of issuers' error rates moving closer to zero compared to the current methodology.[54] Therefore, this proposal preserves a strong incentive for issuers to submit accurate EDGE data that can be validated in HHS–RADV because it increases the range in which issuers can be flagged as outliers, while lowering the calculation of that adjustment amount for those outlier issuers close to the confidence intervals and maintaining a larger adjustment for those who are not close to the confidence intervals. For these reasons, we believe that this proposal for calculating and applying the sliding scale adjustment provides a balanced approach to addressing the payment cliff. We seek comment on this proposal, including the proposed calculation of the sliding scale adjustment and the thresholds used to calculate and apply it.

3. Negative Error Rate Issuers With Negative Failure Rates

HHS–RADV is intended to promote confidence and stability in the budget neutral HHS-operated risk adjustment program by ensuring the integrity and quality of data provided by issuers. HHS–RADV also serves to ensure that, consistent with the statute, charges are collected from issuers with lower-than-average actuarial risk and payments are made to issuers with higher-than-average actuarial risk. It uses a two-sided outlier identification approach because the long-standing intent of HHS–RADV has been to account for identified material risk differences between what issuers submitted to their EDGE servers and what was validated in medical records through HHS–RADV, regardless of the direction of those differences.[55] In addition, the two-sided adjustment policy penalizes issuers who validate HCCs in HHS–RADV at much lower rates than the national average and rewards issuers in HHS–RADV who validate HCCs in HHS–RADV at rates that are much higher than the national average, encouraging issuers to ensure that their EDGE-reported risk scores reflect the true actuarial risk of their enrollees. Positive and negative error rate outliers represent these two types of adjustments, respectively.

If an issuer is a positive error rate outlier, its risk score will be adjusted downward. Assuming no changes to risk scores for the other issuers in the same state market risk pool, this downward adjustment increases the issuer's charge or decreases its payment for the applicable benefit year, leading to a decrease in charges or an increase in payments for the other issuers in the state market risk pool. If an issuer is a negative error rate outlier, its risk score will be adjusted upward. Assuming no changes to risk scores for the other issuers in the same state market risk pool, this upward adjustment reduces the issuer's charge or increases its payment for the applicable benefit year, leading to an increase in charges or a decrease in payments for the other issuers in the state market risk pool. The increase to risk score(s) for negative error rate outliers is consistent with the upward and downward risk score adjustments finalized as part of the original HHS–RADV methodology in the 2015 Payment Notice[56] and the HCC failure rate approach to error estimation finalized in the 2019 Payment Notice.[57] As noted above, some stakeholders have recommended HHS not adjust issuers' risk scores in the case of negative error rate issuers to limit the impact of these adjustments on issuers who are not outliers.

An issuer can be identified as a negative error rate outlier for a number of reasons. However, the current error rate methodology does not distinguish between low failure rates due to accurate data submission and failure rates that have been depressed through the presence of found HCCs (that is, HCCs in the audit data that were not present in the EDGE data). If a negative failure rate is due to a large number of found HCCs, it does not reflect accurate reporting through the EDGE server for risk adjustment. While we believe that any issuer with a negative failure rate is likely to review their internal processes to better capture missing HCCs in their future EDGE data submissions, we are proposing to refine the current error rate calculation to mitigate the impact of adjustments that result from negative error rate outliers whose low failure rates are driven by newly found HCCs rather than by high validation rates. We believe that a constraint in the GAF calculation in the current error rate calculation would mitigate potential incentives for issuers to use HHS–RADV to identify more HCCs than were reported to their EDGE servers. It also would mitigate the impact of HHS–RADV adjustments to transfers in the case of negative error rate issuers with negative failure rates and improve predictability.

Currently, an outlier issuer's error rate is calculated based on the difference between the weighted mean failure rate for the HCC group and the issuer's failure rate for that HCC grouping, which may be a negative failure rate. Beginning with 2019 benefit year HHS–RADV, we propose to adopt an approach that constrains negative error rate outlier issuers' error rate calculations in cases when an issuer's failure rate is negative. The proposed constraint would be to the GAF whereby the error rates of a negative error rate outlier issuer with a negative failure rate would be calculated as the difference between the weighted mean failure rate for the HCC grouping (if positive) and zero (0). This would be calculated by substituting the following ‖double bars‖ terms into the error rate calculation[58] process:

If $Freq\_EDGE_{G,i} \geq 30$, then:
If $GFR_{G,i} > UB_G$ or $GFR_{G,i} < LB_G$:
Then $Flag_{G,i}$ = ''*outlier*'' and $GAF_{G,i} = \|GFR_{G,i,constr} - \mu\{GFR_G\}_{constr}\|$
If $Freq\_EDGE_{G,i} < 30$ or if $GFR_{G,i} \leq UB_G$ and $GFR_{G,i} \geq LB_G$:
Then $Flag_{G,i}$ = ''*not outlier*'' and $GAF_{G,i} = 0$

Where:

$GFR_{G,i}$ is an issuer's failure rate for the HCC failure rate grouping

$\|GFR_{G,i,constr}$ is an issuer's failure rate for the HCC failure rate grouping, constrained to 0 if is less than 0. Also expressed as: $GFR_{G,i,constr} = max\{0, GFR_{G,i}\}\|$

$\mu\{GFR_G\}$ is the weighted national mean failure rate for the HCC failure rate grouping

$\|\mu\{GFR_G\}_{constr}$ is the weighted national mean failure rate for the HCC failure rate grouping, constrained to 0 if $\mu\{GFR_G\}$ is less than 0. Also expressed as: $\mu\{GFR_G\}_{constr} = max\{0,\mu\{GFR_G\}\}\|$

UB_G and LB_G are the upper and lower bounds of the HCC failure rate grouping confidence interval, respectively.

[54] Ibid.

[55] An exception to this approach was established, beginning with the 2018 benefit year of HHS–RADV, for exiting issuers who are negative error rate outliers. See 84 FR at 17503–17504.

[56] For example, we stated that ''the effect of an issuer's risk score error adjustment will depend upon its magnitude and direction compared to the average risk score error adjustment and direction for the entire market.'' See 79 FR 13743 at 13769.

[57] See 83 FR 16930 at 16962. The shorthand ''positive error rate outlier'' captures those issuers whose HCC coefficients are reduced as a result of being identified as an outlier, while ''negative error rate outlier'' captures those issuers whose HCC coefficients are increased as a result of being identified as an outlier.

[58] This calculation sequence is expressed here in a revised order compared to how the sequence is published in the 2021 Payment Notice (85 FR 29164 at 29196–29198). This change was made for simplicity when demonstrating how this sequence would be combined with this proposal. The different display does not modify or otherwise change the amendments to the outlier identification process finalized in the 2021 Payment Notice.

$Flag_{G,i}$ is the indicator if issuer *i*'s group failure rate for group G locates beyond a calculated threshold that we are using to classify issuers into ''outliers'' or ''not outliers'' for group *G*.

$GAF_{G,i}$ is the calculated adjustment amount to adjust issuer i's EDGE risk score components for all sampled HCCs in group *G*.

We would then compute total adjustments and error rates for each outlier issuer based on the weighted aggregates of the $GAF_{G,i}$.[59]

This approach would limit the financial impact that negative error rate outliers with negative failure rates would have on other issuers in the same state market risk pool, and would help provide stability to issuers in predicting the impact of HHS–RADV adjustments. For example, under the current error rate methodology using the 2017 benefit year HHS–RADV metrics, a negative outlier issuer with a −15 percent failure rate for the low HCC grouping would receive a GAF of the difference between −15 percent and the weighted mean for the low HCC grouping of 4.8 percent of −19.8 percent. However, under the proposal in this rulemaking to constrain the negative failure rates for negative outlier issuers to zero, the GAF in this example would be the difference between 0 percent and the weighted mean for the low HCC grouping of 4.8 percent, resulting in a −4.8 percent GAF.

If this proposal is finalized, the constrained values in the calculation of the GAF would only impact issuers with negative failure rates; therefore, issuers who have been extremely accurate in reporting their data to their EDGE server will not be affected. Issuers who report accurately to their EDGE servers are likely to have failure rates very close to zero, and may have negative error rates, but not negative failure rates. As such, these issuers would not have their GAF values constrained. In contrast, the issuers found to have negative failure rates, indicating that diagnosis data to their EDGE server was underreported for a particular benefit year, would have their GAF values constrained. As such, the proposed constraints on the GAF calculation will not apply or impact adjustments for issuers who are extremely accurate in reporting their diagnosis data to their EDGE servers.

We are proposing this option because it could be easily implemented under the current error rate methodology, would address stakeholders' concerns about the impact of adjustments due to negative error rate issuers with negative failure rates, and would reduce incentives that may exist for issuers to use HHS–RADV to identify more HCCs than existed in EDGE. We seek comment on this proposal.

a. Combining the HCC Grouping Constraint, Negative Failure Rate Constraint and the Sliding Scale Proposals

To help commenters understand the interaction of the above proposals to create Super HCCs for grouping purposes, apply a sliding scale option, and constrain negative failure rates for negative error rate outliers, this section outlines the complete proposed revised error rate calculation methodology formulas, integrating all the changes proposed to apply beginning with 2019 HHS–RADV in this proposed rule.

First, HHS would use the failure rates for Super HCCs to group each HCC into three HCC groupings (a high, medium, or low HCC failure rate grouping). Under the above proposed approach, Super HCCs would be defined as HCCs that have been aggregated such that HCCs that are in the same HCC coefficient estimation group are aggregated together and all other HCCs each compose an individual Super HCC. Using the Super HCCs, we would calculate the HCC failure rate as follows:

$$FR_c = 1 - \frac{freqIVA_c}{freqEDGE_c}$$

Where:

c is the index of the *c*th Super HCC;

$freqEDGE_c$ is the frequency of a Super HCC *c* occurring in EDGE data; that is, the sum of $freqEDGE_h$ for all HCCs that share an HCC coefficient estimation group in the adult risk adjustment models:

$$freqEDGE_c = \sum_h freqEDGE_{h,c}$$

When an HCC is not in an HCC coefficient estimation group in the adult risk adjustment models, the $freqEDGE_c$ for that HCC will be equivalent to $freqEDGE_h$;

$freqIVA_c$ is the frequency of a Super HCC *c* occurring in IVA results (or SVA results, as applicable); that is, the sum of $freqIVA_h$ for all HCCs that share an HCC coefficient estimation group in the adult risk adjustment models:

$$freqIVA_c = \sum_h freqIVA_{h,c}$$

And;

FR_c is the national overall (average) failure rate of Super HCC *c* across all issuers.

Then, the failure rates for all Super HCCs, both those composed of a single HCC and those composed of the aggregate frequencies of HCCs that share an HCC coefficient estimation group in the adult models, would be grouped according to the current HHS–RADV failure rate grouping methodology. These HCC groupings would be determined by first ranking all Super HCC failure rates and then dividing the rankings into the three groupings weighted by total observations of that Super HCC across all issuers' IVA samples, assigning each Super HCC into a high, medium, or low HCC grouping. This process ensures that all HCCs in a Super HCC are grouped into the same HCC grouping in HHS–RADV.

Next, an issuer's HCC group failure rate would be calculated as follows:

$$GFR_{G,i} = 1 - \frac{freqIVA_{G,i}}{freqEDGE_{G,i}}$$

Where:

$freqEDGE_{G,i}$ is the number of occurrences of HCCs in group *G* that are recorded on EDGE for all enrollees sampled from issuer *i*.

$freqIVA_{G,i}$ is the number of occurrences of HCCs in group *G* that are identified by the IVA audit (or SVA audit, as applicable) for all enrollees sampled from issuer *i*.

$GFR_{G,i}$ is issuer *i*'s group failure rate for the HCC group *G*.

HHS calculates the weighted mean failure rate and the standard deviation of each HCC group as:

[59] See, for example, the 2018 Benefit Year Protocols: PPACA HHS Risk Adjustment Data Validation, Version 7.0 (June 24, 2019), available at: *https://www.regtap.info/uploads/library/HRADV_2018Protocols_070319_5CR_070519.pdf*.

$$\mu\{GFR_G\} = 1 - \frac{\sum_i freqIVA_{G,i}}{\sum_i freqEDGE_{G,i}}$$

$$Sd\{GFR_G\} = \sqrt{\frac{\sum_i \left(freqEDGE_{G,i} * \left(GFR_{G,i} - \mu\{GFR_G\}\right)^2\right)}{\sum_i freqEDGE_{G,i}}}$$

Where:

$\mu\{GFR_G\}$ is the weighted mean of $GFR_{G,i}$ of all issuers for the HCC group G weighted by all issuers' sample observations in each group.

$Sd\{GFR_G\}$ is the weighted standard deviation of $GFR_{G,i}$ of all issuers for the HCC group G.

Each issuer's HCC group failure rates would then be compared to the national metrics for each HCC grouping. If an issuer's failure rate for an HCC group falls outside of the two-tailed 90 percent confidence interval with a 1.645 standard deviation cutoff based on the weighted mean failure rate for the HCC group, the failure rate for the issuer's HCCs in that group would be considered an outlier (if the issuer meets the minimum number of HCCs for the HCC group). Based on issuers' failure rates for each HCC group, outlier status would be determined for each issuer independently for each issuer's HCC failure rate group such that an issuer may be considered an outlier in one HCC failure rate group but not an outlier in another HCC failure rate group. Beginning with the 2019 benefit year, issuers will not be considered an outlier for an HCC group in which the issuer has fewer than 30 HCCs. If no issuers' HCC group failure rates in a state market risk pool materially deviate from the national mean of failure rates (that is, no issuers are outliers), HHS does not apply any adjustments to issuers' risk scores or to transfers in that state market risk pool.

Then, once the outlier issuers are determined, we would calculate the group adjustment factor taking into consideration the outlier issuer's distance from the confidence interval and limiting calculation of the group adjustment factor when the issuer has a negative failure rate. The formula [60] would apply as follows:

If $Freq\_EDGE_{G,i} \geq 30$, then:

If $z_{G,i} < -3.00$ or $z_{G,i} > 3.00$

Then $Flag_{G,i}$ = ''*outlier*'' and

$GAF_{G,i} = \max\{0, GFR_{G,i}\} - \max\{0, \mu\{GFR_G\}\}$

Or if $-3 < z_{G,i} < -1.645$ or $3 > z_{G,i} > 1.645$

Then $Flag_{G,i}$ = ''*outlier*'' and

$GAF_{G,i} = \max\{0, (disZ_{G,i,r} * Sd\{GFR_G\} + \mu\{GFR_G\})\} - \max\{0, \mu\{GFR_G\}\}$

If $Freq\_EDGE_{G,i} < 30$ or if $-1.645 \leq z_{G,i} \leq 1.645$

Then $Flag_{G,i}$ = ''*not outlier*'' and $GAF_{G,i} = 0$

Where:

- r indicates whether the GAF is being calculated for a negative or positive outlier;
- a is the slope of the sliding scale adjustment, calculated as:

$$a = \frac{outerZ_r}{outerZ_r - innerZ_r}$$

With $outerZ_r$ defined as the greater magnitude z-score selected to define the edge of the sliding scale range r (3.00 for positive outliers; and -3.00 for negative outliers) and $innerZ_r$ defined as the lower magnitude z-score selected to define the edge of the range r (1.645 for positive outliers; and -1.645 for negative outliers);

- b_r is the intercept of the sliding scale adjustment for a given sliding scale range r, calculated as:

$b_r = outerZ_r - a * (outerZ_r = outerZ_r * (1 - a)$

- $disZ_{G,i,r}$ is the z-score of issuer i's $GFR_{G,i,}$ for HCC failure rate group G discounted according to the sliding scale for range r, calculated as:

$disZ_{G,i,r} = a * z_{G,i} + b_r$

With $z_{G,i}$ defined as the z-score of i issuers' $GFR_{G,i}$:

$$z_{G,i} = \frac{GFR_{G,i} - \mu\{GFR_G\}}{Sd\{GFR_G\}}$$

- $GAF_{G,i}$ is the group adjustment factor for HCC failure rate group G for an issuer i;
- $Sd\{GFR_G\}$ is the weighted national standard deviation of all issuers' GFRs for HCC failure rate group G;
- $\mu\{GFR_G\}$ is the weighted national mean of all issuers' GFRs for HCC failure rate group G.

Once an outlier issuer's group adjustment factor is calculated, the enrollee adjustment would be calculated by applying the group adjustment factor to an enrollee's individual HCCs. For example, if an issuer has one enrollee with the HIV/AIDS HCC and the issuer's HCC group adjustment rate is 10 percent for the HCC group that contains the HIV/AIDS HCC, the enrollee's HIV/AIDS coefficient would be reduced by 10 percent. This reduction would be aggregated with any reductions to other HCCs for that enrollee to arrive at the overall enrollee adjustment factor. This value would be calculated according to the following formula for each sample enrollee in stratum 1 through 9:

$$Adjustment_{i,e} = \frac{\sum_h \left(RS_{h,G,i,e} * GAF_{G,i}\right)}{\sum_h \left(RS_{h,G,i,e}\right)}$$

Where:

$RS_{h,G,i,e}$ is the risk score component of a single HCC h (belonging to HCC group G) recorded on EDGE for enrollee e of issuer i.

$GAF_{G,i}$ is the group adjustment factor for HCC failure rate group G for an issuer i;

$Adjustment_{i,e}$ is the calculated adjustment amount to adjust enrollee e of issuer i's EDGE risk scores.

The calculation of the enrollee adjustment factor only considers risk score factors related to the HCCs and ignores any other risk score factors (such as demographic factors and RXC factors). Furthermore, because this formula is concerned exclusively with EDGE HCCs, HCCs newly identified by the IVA (or SVA as applicable) would not contribute to enrollee risk score

[60] This calculation sequence is expressed here in a revised order compared to how the sequence is published in the 2021 Payment Notice (85 FR 29164 at 29196–29198). This change was made for simplicity to demonstrate how this sequence would be combined with proposals in this proposed rule. The different display does not modify or otherwise change the amendments to the outlier identification process finalized in the 2021 Payment Notice.

adjustments for that enrollee and adjusted enrollee risk scores are only computed for sampled enrollees with HCCs in strata 1 through 9.

Next, for each sampled enrollee with HCCs, HHS would calculate the total adjusted enrollee risk score as:

$$AdjRS_{i,e} = EdgeRS_{i,e} * (1 - Adjustment_{i,e})$$

Where:

$EdgeRS_{i,e}$ is the risk score as recorded on the EDGE server of enrollee *e* of issuer *i*.

$AdjRS_{i,e}$ is the amended risk score for sampled enrollee *e* of issuer *i*.

$Adjustment_{i,e}$ is the adjustment factor by which we estimate whether the EDGE risk score exceeds or falls short of the initial or second validation audit projected total risk score for sampled enrollee *e* of issuer *i*.

The calculation of the sample enrollee's adjusted risk score includes all EDGE server components for sample enrollees in strata 1 through 9.

After calculating the outlier issuers' sample enrollees with HCCs' adjusted EDGE risk scores, HHS would calculate an outlier issuer's error rate by extrapolating the difference between the amended risk score and EDGE risk score for all enrollees (stratum 1 through 10) in the sample. The extrapolation formula would be weighted by determining the ratio of an enrollee's stratum size in the issuer's population to the number of sample enrollees in the same stratum as the enrollee. Sample enrollees with no HCCs would be included in the extrapolation of the error rate for outlier issuers with the EDGE risk score unchanged for these sample enrollees. The formulas to compute the error rate using the stratum-weighted risk score before and after the adjustment would be:

$$ErrorRate_i = 1 - \frac{\sum_e (w_{i,e} * AdjRS_{i,e})}{\sum_e (w_{i,e} * EdgeRS_{i,e})}$$

Where:

$$w_{i,e} = \frac{stratum\ size\ in\ population}{number\ of\ sample\ enrollees\ of\ the\ stratum}$$

Consistent with 45 CFR 153.350(b), HHS then would apply the outlier issuer's error rate to adjust that issuer's applicable benefit year's plan liability risk score.[61] This risk score change, which also would impact the state market average risk score, would then be used to adjust the applicable benefit year's risk adjustment transfers for the applicable state market risk pool.[62] Due to the budget-neutral nature of the HHS-operated program, adjustments to one issuer's risk scores and risk adjustment transfers based on HHS–RADV findings affects other issuers in the state market risk pool (including those who were not identified as outliers) because the state market average risk score changes to reflect the outlier issuer's change in its plan liability risk score. This also means that issuers that are exempt from HHS–RADV for a given benefit year will have their risk adjustment transfers adjusted based on other issuers' HHS–RADV results if any issuers in the applicable state market risk pool are identified as outliers. We seek comments on our modified error rate calculation methodology proposed to be applicable starting for the 2019 benefit year of HHS–RADV.

In drafting this proposed rule, as requested by commenters on the 2019 RADV White Paper, we estimated the combined impact of applying the proposed sliding scale adjustment, the proposed negative failure rate constraint and the proposed Super HCC aggregation using 2017 benefit year HHS–RADV results. Table 5 provides a comparison of the estimated change in error rates between the current methodology for sorting HCCs for HHS–RADV grouping and the proposed Super HCC aggregation for sorting of HCCs for HHS–RADV grouping, the proposed negative failure rate constraint and the proposed sliding scale option in this proposed rule. In addition, in response to comments on the 2019 RADV White Paper that supported the adoption of a sliding scale adjustment from +/−1.96 to 3 standard deviations, Table 5 also includes information on the estimated change(s) if option 1 from the 2019 RADV White Paper was adopted as the sliding scale adjustment.

As shown in Table 5, we also found through testing the 2017 benefit year HHS–RADV results that, although the proposed sliding scale adjustment (adjusting from +/−1.645 to 3 standard deviations) increases the number of outliers, the mean error rates among positive outliers under this proposal are smaller than the mean error rates among positive outliers for the 2019 RADV White Paper sliding scale option 1 (adjusting from +/−1.96 to 3 standard deviations), even when tested in combination with the proposed negative failure rate constraint and/or the current and proposed sorting methodologies. This suggests that the proposed sliding scale option would result in reduced HHS–RADV adjustments to risk adjustment transfers relative to both the current methodology and the 2019 RADV White Paper sliding scale option 1, and reflects the smoother transition between a GAF of zero and a full-value GAF that is provided by the proposed sliding scale option when compared to 2019 RADV White Paper sliding scale option 1.

[61] Exiting outlier issuer risk score error rates are currently applied to the plan liability risk scores and risk adjustment transfer amounts for the benefit year being audited if they are a positive error rate outlier. For all other outlier issuers, risk score error rates are currently applied to the plan liability risk scores and risk adjustment transfer amounts for the current transfer year. The exiting issuer exception is discussed in Section II.B.

[62] See 45 CFR 153.350(c).

TABLE 5—A COMPARISON OF HHS–RADV ERROR RATE (ER) ESTIMATED CHANGES BASED ON 2017 BENEFIT YEAR [63]
HHS–RADV DATA

Scenario	Current sorting method		Super HCCs using HCC coefficient estimation groups	
	Mean Neg ER (%)	Mean Pos ER (%)	Mean Neg ER (%)	Mean Pos ER (%)
Sorting Method Only	−5.68	9.96	−5.98	9.91
Sorting Method with Proposed Negative Constraint	−3.11	9.96	−3.38	9.91
Sorting Method with Proposed Sliding Scale Option [64]	−2.27	5.28	−2.49	5.32
Sorting Method, Proposed Sliding Scale Option & Proposed Negative Constraint	−1.50	5.28	−1.66	5.32
Sorting Method with 2019 RADV White Paper Sliding Scale Option 1 [65]	−2.16	6.46	−2.48	6.51
Sorting Method with 2019 RADV White Paper Sliding Scale Option 1 & Proposed Negative Constraint	−1.12	6.46	−1.26	6.51

B. Application of HHS–RADV Results

In the 2014 Payment Notice, HHS finalized a prospective approach for making adjustments to risk adjustment transfers based on findings from the HHS–RADV process.[66] Specifically, we finalized using an issuer's HHS–RADV error rates from the prior year to adjust the issuer's average risk score in the current benefit year. As such, we used the 2017 benefit year HHS–RADV results to adjust 2018 benefit year risk adjustment plan liability risk scores for non-exiting issuers, resulting in adjustments to 2018 benefit year risk adjustment transfer amounts.[67] [68]

When we finalized the prospective HHS–RADV results application policy in the 2014 Payment Notice, we did not anticipate the extent of the changes that could occur in the risk profile of enrollees or market participation in the individual and small group markets from benefit year to benefit year. As a result of experience with these changes over the early years of the program, and in light of the changes finalized in the 2020 Payment Notice to the timeline for the reporting, collection, and disbursement of risk adjustment transfer adjustments for HHS–RADV [69] and the changes to the risk adjustment holdback policy,[70] both of which will lead to reopening of prior year risk adjustment transfers, we are now proposing changes to this prospective approach for non-exiting issuers.

Starting with the 2021 benefit year of HHS–RADV, we propose applying HHS–RADV results to the benefit year being audited for all issuers. This proposal is intended to address stakeholder concerns about maintaining actuarial soundness in the application of an issuer's HHS–RADV error rate if an issuer's risk profile, enrollment, or market participation changes substantially from benefit year to benefit year. This proposed change has the potential to provide more stability for issuers of risk adjustment covered plans and help them better predict the impact of HHS–RADV results. It would also prevent situations where an issuer who newly enters a state market risk pool is subject to HHS–RADV adjustments from the prior benefit year for which they did not participate. We seek comment on this proposal.

If we finalize and implement the policy to adjust the benefit year being audited beginning with the 2021 benefit year HHS–RADV, we would need to adopt transitional measures to move from the current prospective approach to one that applies the HHS–RADV results to the benefit year being audited. More specifically, 2021 benefit year risk adjustment plan liability risk scores and transfers would need to be adjusted first to reflect 2020 benefit year HHS–RADV results, and adjusted again based on 2021 benefit year HHS–RADV results. For the 2022 benefit year of HHS–RADV and beyond, risk adjustment plan liability risk scores and transfers would only be adjusted once based on the same benefit year's HHS–RADV results (that is, 2022 benefit year HHS–RADV results would adjust 2022 benefit year risk adjustment plan liability risk scores and transfers).[71]

In order to effectuate this transition, we considered and are proposing an ''average error rate approach,'' as set forth in the 2019 RADV White Paper, under which HHS would calculate an average value for the 2021 and 2020 benefit years' HHS–RADV error rates and apply this average error rate to 2021 risk adjustment plan liability risk scores and transfers. This approach would result in one final HHS–RADV adjustment to 2021 benefit year risk adjustment plan liability risk scores and transfers, reflecting the average value for the 2021 and 2020 benefit years' HHS–RADV error rates. The adjustments to transfers would be collected and paid in accordance with the 2021 benefit year HHS–RADV timeline, in 2025.[72]

However, in an effort to be consistent with our current risk score error rate application and calculation and ensure

[63] These estimates include the exclusion from outlier status of issuers with fewer than 30 HCCs in an HCC group, consistent with the policy finalized in the 2021 Payment Notice (85 FR 29164), which was not in effect for 2017 Benefit Year HHS–RADV. We included the fewer than 30 HCC exclusion from outlier status in these estimates to provide a sense of the impact of the proposed changes when compared to the methodology presently in effect for 2019 benefit year HHS–RADV and beyond.

[64] The Proposed Sliding Scale Option outlined in Section II.A.2. of this rule would create a sliding scale adjustment from +/−1.645 to 3 standard deviations.

[65] The 2019 RADV White Paper Sliding Scale Option 1 would create a sliding scale adjustment from +/−1.96 to 3 standard deviations.

[66] See 78 FR 15409 at 15438.

[67] See the Summary Report of 2017 Benefit Year HHS–RADV Adjustments to Risk Adjustment Transfers released on August 1, 2019, available at: *https://www.cms.gov/CCIIO/Programs-and-Initiatives/Premium-Stabilization-Programs/Downloads/BY2017-HHSRADV-Adjustments-to-RA-Transfers-Summary-Report.pdf.*

[68] In the 2019 Payment Notice, we adopted an exception to the prospective application of HHS–RADV results for exiting issuers, whereby risk score error rates for outlier exiting issuers are applied to the plan liability risk scores and transfer amounts for the benefit year being audited. Therefore, for exiting issuers, we used the 2017 benefit year's HHS–RADV results to adjust 2017 benefit year risk adjustment plan liability risk scores, resulting in adjustments to 2017 benefit year risk adjustment transfer amounts. See 83 FR at 16965 through 16966.

[69] See 84 FR at 17504 through 17508.

[70] See the Change to Risk Adjustment Holdback Policy for the 2018 Benefit Year and Beyond Bulletin (May 31, 2019) (May 2019 Holdback Guidance), available at: *https://www.cms.gov/CCIIO/Resources/Regulations-and-Guidance/Downloads/Change-to-Risk-Adjustment-Holdback-Policy-for-the-2018-Benefit-Year-and-Beyond.pdf.*

[71] As discussed in the May 2019 Holdback Guidance, a successful HHS–RADV appeal may require additional adjustments to transfers for the applicable benefit year in the impacted state market risk pool.

[72] For a general description of the current timeline for reporting, collection, and disbursement of HHS–RADV adjustments to transfers, see 84 FR at 17506 through 17507.

that both years of HHS–RADV results are taken into consideration in calculating risk adjustment plan liability risk scores, we also propose as an alternative transition strategy from the prospective application of HHS–RADV results to a concurrent application approach the ''combined plan liability risk score option,'' also set forth in the 2019 RADV White Paper. Under the combined plan liability risk score option, we would apply 2020 benefit year HHS–RADV risk score adjustments to 2021 benefit year plan liability risk scores, and then apply 2021 benefit year HHS–RADV risk score adjustments to the adjusted 2021 plan liability risk scores. We would then use the final adjusted plan liability risk scores (reflecting both the 2020 and 2021 HHS–RADV adjustments to risk scores) to adjust 2021 benefit year transfers. Under this proposal, HHS would calculate risk score adjustments for 2020 and 2021 benefit year HHS–RADV sequentially and incorporate 2020 and 2021 benefit year HHS–RADV results in one final adjustment amount to 2021 benefit year transfers that would be collected and paid in accordance with the 2021 benefit year HHS–RADV timeline, in 2025. We seek comment on both of these approaches to transition from the current prospective approach to one that applies the HHS–RADV results to the benefit year being audited.

Additionally, the transition to a policy to apply HHS–RADV results to the benefit year being audited would remove the need to continue the current policy on issuers entering sole issuer markets that was finalized in the 2020 Payment Notice.[73] As finalized in the 2020 Payment Notice, new issuer(s) that enter a new market or a previously sole issuer market have their risk adjustment transfers in the current benefit year adjusted if there was an outlier issuer in the applicable state market risk pool in the prior benefit year's HHS–RADV.[74] If the proposal to apply HHS–RADV results to the benefit year being audited for all issuers is finalized, new issuers, including new issuers in previously sole issuer markets, would no longer be prospectively impacted by HHS–RADV results from a previous benefit year; rather, the new issuer would only have their current benefit year risk scores (and subsequently, risk adjustment transfers) impacted. The exception would be for the proposed transition benefit years, 2020 and 2021. If a new issuer enters a market in 2021, its risk adjustment plan liability risk score and transfers could be impacted by the new issuer's own 2021 HHS–RADV results and the combined 2020 and 2021 HHS–RADV results of other issuers in the same state market risk pool(s). In addition, since the current prospective approach would continue to apply to the 2019 benefit year HHS–RADV, if a new issuer enters a sole issuer market in 2020, this new issuer would see its 2020 risk adjustment plan liability risk scores and transfers impacted if there was an outlier issuer as a result of 2019 benefit year HHS–RADV in the applicable state market risk pool.

We solicit comment on all of these proposals. In addition, in light of the postponement of the 2019 HHS–RADV process as part of the Administration's efforts to combat COVID–19,[75] we are additionally seeking comment on an alternative timeline for the proposed transition from the prospective application of HHS–RADV results for non-exiting issuers.

Under this alternative timeline, we would apply HHS–RADV results to the benefit year being audited for all issuers starting with the 2020 benefit year of HHS–RADV, rather than the 2021 benefit year. If we finalize and implement either of the above transition options using the alterative timeline, 2020 benefit year risk adjustment plan liability risk scores and transfers would need to be adjusted twice—first to reflect 2019 benefit year HHS–RADV results and again based on 2020 benefit year HHS–RADV results.[76] To accomplish this, we would either (1) implement the ''combined plan liability risk score option,'' whereby we would apply 2019 benefit year HHS–RADV risk score adjustments to 2020 benefit year plan liability risk scores, and then apply 2020 benefit year HHS–RADV risk score adjustments to the already adjusted 2020 plan liability risk scores, or (2) implement the ''average error rate approach,'' whereby we would calculate an average value for the 2019 and 2020 benefit years' HHS–RADV error rates and apply the averaged error rate to 2020 benefit year plan liability risk scores. We would then use the final adjusted plan liability risk scores from either of these approaches to adjust 2020 benefit year transfers. The adjustments to transfers would be collected and paid in accordance with the 2020 benefit year HHS–RADV timeline, in 2024. We also seek comment on whether, if we finalize and implement either of the above transition options using the alterative timeline, we should also pilot RXCs for the 2020 benefit year HHS–RADV to increase consistency between the operations of 2019 and 2020 HHS–RADV. We solicit comment on all of these proposals.

III. Collection of Information Requirements

This document does not impose information collection requirements, that is, reporting, recordkeeping, or third-party disclosure requirements. Consequently, there is no need for review by the Office of Management and Budget under the authority of the Paperwork Reduction Act of 1995 (44 U.S.C. 3501 *et seq.*).

Under this proposed rule, we propose to amend the calculation of error rates to modify the sorting methodology for HCCs that share an HCC coefficient estimation group in the adult risk adjustment models; to amend the error rate calculation for cases where outlier issuers are near the confidence intervals; to constrain the error rate calculation for issuers with negative failure rates; and to transition to the application of HHS–RADV results to the benefit year being audited. These proposed changes are methodological changes to the error estimation methodology used in calculating error rates and changes to the application of HHS–RADV results to risk scores and transfers. Since HHS calculates error rates and applies HHS–RADV results to risk scores and transfers, we do not estimate a burden change on issuers to conduct and complete HHS–RADV in states where HHS operates the risk adjustment program for a given benefit year.[77]

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 will consider all comments we receive by the date and time specified in the **DATES** section of this proposed rule, and, when we proceed with a subsequent document, we will respond to the comments in the preamble to that document.

[73] 84 FR at 17504.

[74] Ibid.

[75] Available at *https://www.cms.gov/files/document/2019-HHS-RADV-Postponement-Memo.pdf*. As discussed in the memo, our intention is to provide guidance by August 2020 on the updated timeline for 2019 benefit year HHS–RADV activities that we plan to begin in 2021.

[76] If no changes are made to the timeline for 2020 benefit year HHS–RADV activities, they would begin with the release of enrollee samples in late May 2021. Given the postponement of 2019 benefit year HHS–RADV activities in response to the COVID–19 pandemic, it is possible HHS–RADV activities for the 2019 and 2020 benefit years would be conducted at the same time.

[77] Since the 2017 benefit year, HHS has been responsible for operating risk adjustment in all 50 states and the District of Columbia.

V. Regulatory Impact Statement

A. Statement of Need

This rule proposes standards related to the HHS–RADV program, including certain refinements to the calculation of error rates and a transition from the prospective application of HHS–RADV results. The Premium Stabilization Rule and other rulemakings noted above provided detail on the implementation of the HHS–RADV program.

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 Social Security Act (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 major rules with economically significant effects ($100 million or more in any 1 year). This rule does not reach the economic significance threshold, and thus is not considered a major rule. For the same reason, it is not a major rule under the Congressional Review Act.

C. Regulatory Alternatives Considered

In developing the policies contained in this proposed rule, we considered numerous alternatives to the presented proposals. Below we discuss the key regulatory alternatives considered.

We considered an alternative approach to the proposed sorting of all HCCs that share an HCC coefficient estimation group in the adult models into the same ''Super HCC'' for HHS–RADV HCC grouping purposes. This alternative approach would have combined all HCCs in the same hierarchy into the same Super HCC for HHS–RADV HCC grouping purposes even if those HCCs had different coefficients in the risk adjustment models. While we did analyze this option, we were concerned that it would not account for risk differences within the HCC hierarchies, and that the proposed approach that focuses on HCCs with the same risk scores in the adult models would better ensure that HHS–RADV results account for risk differences within HCC hierarchies. Additionally, by forcing all HCCs that share a hierarchy into the same HHS–RADV failure rate grouping regardless of whether they have different coefficients, we would not only diminish our ability to allow for differences among various diseases within an HCC hierarchy but would also reduce our ability to recognize differences in the difficulty of providing medical documentation for them.[78]

We considered several other options for addressing the payment cliff effect besides the specific sliding scale approach that we proposed. One option was returning to the original methodology finalized in the 2015 Payment Notice, which would have adjusted almost all issuers' risk scores for every error identified as a result of HHS–RADV.[79] The adjustments under the original methodology would have used the issuer's corrected average risk score to compute an adjustment factor, which would have been based on the ratio between the corrected and original average risk scores. However, our analysis indicated that the original methodology generally resulted in a more severe payment cliff effect, since the majority of outlier issuers had their original failure rates applied without the benefit of subtracting the weighted mean difference.[80]

The second option we considered was to modify the error rate calculation by calculating the issuer's GAF using the HCC group confidence interval rather than the distance to the weighted HCC group mean. As described in the 2019 RADV White Paper and in previous rulemaking,[81] we have concerns that this option would result in under-adjustments based on HHS–RADV results for issuers farthest from the confidence intervals. Thus, although this option could address the payment cliff effect for issuers just outside of the confidence interval, it also could create the unintended consequence of mitigating the payment impact for situations where issuers are not close to the confidence intervals, potentially reducing incentives for issuers to submit accurate risk adjustment data to their EDGE servers.

An additional option suggested by some stakeholders that could address, at least in part, the payment cliff effect that we considered would be to modify the current two-sided approach to HHS–RADV and only adjust issuers who are positive error rate outliers. However, moving to a one-sided outlier identification methodology would not have addressed the payment cliff effect because it would still exist on the positive error rate side of the methodology.[82] In addition, the two-sided outlier identification, and the resulting adjustments to outlier issuer risk scores that have significantly better-than-average or poorer-than-average data validation results, ensures that HHS–RADV adjusts for identified, material risk differences between what issuers submitted to their EDGE servers and what was validated by the issuers' medical records. The two-sided outlier identification approach ensures that an issuer who is coding well is able to recoup funds that might have been lost through risk adjustment because its competitors are coding badly.

We also considered various other options for the thresholds under the sliding scale option that we are proposing to address the payment cliff effect. For example, we considered as an alternative the adoption of a sliding scale option that would adjust outlier issuers' error rates on a sliding scale between the 95 and 99 percent confidence interval bounds (from +/−1.96 to 3 standard deviations). This alternative sliding scale option would retain the current methodology's confidence interval at 1.96 standard deviations, the full adjustment to the mean failure rate for issuers outside of the 99 percent confidence interval (beyond three standard deviations), and the current significant adjustment to the HCC group weighted mean after three standard deviations. In comments on the 2019 RADV White Paper, stakeholders expressed support for this sliding-scale option because it addressed the payment cliff issue without increasing the number of issuers identified as outliers. However, while we recognize that this alternative also would address the payment cliff effect, we are concerned it would not

[78] See 83 FR 16961 and 16965.

[79] See 79 FR 13755–13770.

[80] See the 2019 RADV White Paper at pages 78–79 and Appendix B.

[81] See 84 FR 17507–17508. See also the 2019 RADV White Paper at page 80.

[82] It is important to note the purpose of HHS–RADV approach is fundamentally different from the Medicare Advantage risk adjustment data validation (MA–RADV) approach. MA–RADV only adjusts for positive error rate outliers, as the program's intent is to recoup Federal funding that was the result of improper payments under the Medicare Part C program.

provide the same balanced approach as the proposed sliding scale option and would instead weaken the HHS–RADV program by reducing its overall impact and the magnitude of HHS–RADV adjustments to outlier issuer's risk scores.

When developing a process for implementing the transition from the prospective application of HHS–RADV results to a concurrent application approach, we considered three options for the transition year. In previous sections of the proposed rule, we described two of those options. The third option is the ''RA transfer option.'' The RA transfer option would separately calculate 2020 benefit year HHS–RADV adjustments to 2021 benefit year transfers and 2021 benefit year HHS–RADV adjustments to 2021 benefit year transfers.[83] Under this option, we would then calculate the difference between each of these values and the unadjusted 2021 benefit year transfers before any HHS–RADV adjustments were applied, and add these differences together to arrive at the total HHS–RADV adjustment that would be applied to the 2021 benefit year transfers. That is, HHS would separately calculate adjustments for the 2020 and 2021 benefit year HHS–RADV results and incorporate 2020 and 2021 benefit year HHS–RADV results in one final adjustment to 2021 benefit year transfers that would be collected and paid in accordance with the 2021 benefit year HHS–RADV timeline, in 2025.[84] However, we believe this alternative is not as consistent with our current risk score error rate application and calculation as the combined plan liability risk score option, or as simple as the average error rate approach discussed above.

VI. Regulatory Flexibility Act

The Regulatory Flexibility Act (5 U.S.C. 601, *et seq.*) (RFA), requires agencies to prepare an initial regulatory flexibility analysis to describe the impact of a proposed rule on small entities, unless the head of the agency can certify that the rule will not have a significant economic impact on a substantial number of small entities. The RFA generally defines a ''small entity'' as (1) a proprietary firm meeting the size standards of the Small Business Administration (SBA), (2) a not-for-profit organization that is not dominant in its field, or (3) a small government jurisdiction with a population of less than 50,000. States and individuals are not included in the definition of ''small entity.'' HHS uses a change in revenues of more than 3 to 5 percent as its measure of significant economic impact on a substantial number of small entities.

In this proposed rule, we propose standards for the HHS–RADV program. This program is generally intended to ensure the integrity of the HHS-operated risk adjustment program, which stabilizes premiums and reduces the incentives for issuers to avoid higher-risk enrollees. Because we believe that insurance firms offering comprehensive health insurance policies generally exceed the size thresholds for ''small entities'' established by the SBA, we do not believe that an initial regulatory flexibility analysis is required for such firms.

We believe that health insurance issuers would be classified under the North American Industry Classification System code 524114 (Direct Health and Medical Insurance Carriers). According to SBA size standards, entities with average annual receipts of $41.5 million or less would be considered small entities for these North American Industry Classification System codes. Issuers could possibly be classified in 621491 (HMO Medical Centers) and, if this is the case, the SBA size standard would be $35.0 million or less.[85] We believe that few, if any, insurance companies underwriting comprehensive health insurance policies (in contrast, for example, to travel insurance policies or dental discount policies) fall below these size thresholds. Based on data from MLR annual report [86] submissions for the 2017 MLR reporting year, approximately 90 out of 500 issuers of health insurance coverage nationwide had total premium revenue of $41.5 million or less. This estimate may overstate the actual number of small health insurance companies that may be affected, since over 72 percent of these small companies belong to larger holding groups, and many, if not all, of these small companies are likely to have non-health lines of business that will result in their revenues exceeding $41.5 million.

In addition, section 1102(b) of the Act requires us 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 of a metropolitan statistical area and has fewer than 100 beds. This proposed rule would not affect small rural hospitals. Therefore, the Secretary has determined that this proposed rule will not have a significant impact on the operations of a substantial number of small rural hospitals.

VII. Unfunded Mandates

Section 202 of the Unfunded Mandates Reform Act of 1995 (UMRA) requires that agencies assess anticipated costs and benefits and take certain other actions before issuing a proposed rule that includes any Federal mandate that may result in expenditures in any 1 year by state, local, or Tribal governments, in the aggregate, or by the private sector, of $100 million in 1995 dollars, updated annually for inflation. In 2019, that threshold is approximately $154 million. Although we have not been able to quantify all costs, we expect the combined impact on state, local, or Tribal governments and the private sector to be below the threshold.

VIII. Federalism

Executive Order 13132 establishes certain requirements that an agency must meet when it issues a proposed rule that imposes substantial direct costs on state and local governments, preempts state law, or otherwise has federalism implications.

In compliance with the requirement of Executive Order 13132 that agencies examine closely any policies that may have federalism implications or limit the policymaking discretion of the states, we have engaged in efforts to consult with and work cooperatively with affected states, including participating in conference calls with and attending conferences of the National Association of Insurance Commissioners, and consulting with state insurance officials on an individual basis.

While developing this proposed rule, we attempted to balance the states' interests in regulating health insurance issuers with the need to ensure market stability. By doing so, it is our view that we have complied with the requirements of Executive Order 13132.

Because states have flexibility in designing their Exchange and Exchange-related programs, state decisions will ultimately influence both administrative expenses and overall premiums. States are not required to establish an Exchange or risk adjustment program. HHS operates risk adjustment on behalf of any state that does not elect to do so. Beginning with the 2017 benefit year,

[83] See section 5.2 of the 2019 RADV White Paper.

[84] For a general description of the current timeline for publication, collection, and distribution of HHS–RADV adjustments to transfers, see 84 FR at 17506–17507.

[85] *https://www.sba.gov/document/support--table-size-standards.*

[86] Available at *https://www.cms.gov/CCIIO/Resources/Data-Resources/mlr.html.*

HHS has operated risk adjustment for all 50 states and the District of Columbia.

In our view, while this proposed rule would not impose substantial direct requirement costs on state and local governments, it has federalism implications due to direct effects on the distribution of power and responsibilities among the state and Federal Governments relating to determining standards about health insurance that is offered in the individual and small group markets.

IX. Reducing Regulation and Controlling Regulatory Costs

Executive Order 13771 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.'' This proposed rule is not subject to the requirements of Executive Order 13771 because it is expected to result in no more than de minimis costs.

X. Conclusion

In accordance with the provisions of Executive Order 12866, this regulation was reviewed by the Office of Management and Budget.

Dated: February 19, 2020.

Seema Verma,

Administrator, Centers for Medicare & Medicaid Services.

Dated: May 20, 2020.

Alex M. Azar II,

Secretary, Department of Health and Human Services.

[FR Doc. 2020–11703 Filed 5–29–20; 4:15 pm]

BILLING CODE 4120–01–P

DEPARTMENT OF TRANSPORTATION

National Highway Traffic Safety Administration

49 CFR Part 572

[Docket No. NHTSA–2019–0023]

RIN 2127–AM13

Anthropomorphic Test Devices, HIII 5th Percentile Female Test Dummy; Incorporation by Reference

AGENCY: National Highway Traffic Safety Administration (NHTSA), Department of Transportation (DOT).

ACTION: Re-opening of comment period; availability of technical document.

SUMMARY: In response to a request from the public, NHTSA is re-opening the comment period on a Notice of Proposed Rulemaking (NPRM) issued in December 2019 for an additional 60 days. With this extension, the comment period will re-open today and close on August 3, 2020. NHTSA is also docketing a document describing procedures it has developed to measure SAE chest jackets already in use in the field in order to assess the uniformity of the jackets and to determine jacket dimensions and tolerances to be specified in the Final Rule.

DATES: You should submit your comments early enough to be received not later than August 3, 2020.

ADDRESSES: You may submit comments to the docket number identified in the heading of this document by any of the following methods:

- *Federal eRulemaking Portal:* Go to *http://www.regulations.gov.* Follow the online instructions for submitting comments.
- *Mail:* Docket Management Facility, M–30, U.S. Department of Transportation, West Building, Ground Floor, Rm. W12–140, 1200 New Jersey Avenue SE, Washington, DC 20590.
- *Hand Delivery or Courier:* West Building, Ground Floor, Room W12–140, 1200 New Jersey Avenue, SE, between 9 a.m. and 5 p.m. Eastern Time, Monday through Friday, except Federal holidays. To be sure someone is there to help you, please call (202) 366–9322 before coming.
- You may also call the Docket at 202–366–9826.

Regardless of how you submit your comments, please mention the docket number of this document.

Instructions: For detailed instructions on submitting comments and additional information on the rulemaking process, see the Public Participation heading of the **SUPPLEMENTARY INFORMATION** section of this document. *Note:* all comments received, including any personal information provided, will be posted without change to *http://www.regulations.gov.*

Privacy Act: Anyone is able to search the electronic form of all comments received in any of our dockets by the name of the individual submitting the comment (or signing the comment, if submitted on behalf of an association, business, labor union, etc.). You may review DOT's complete Privacy Act Statement in the **Federal Register** published on April 11, 2000 (65 FR 19477–78).

Confidential Business Information: If you wish to submit any information under a claim of confidentiality, you should submit three copies of your complete submission, including the information you claim to be confidential business information, to the Chief Counsel, NHTSA, at the address given under **FOR FURTHER INFORMATION CONTACT**. In addition, you should submit two copies, from which you have deleted the claimed confidential business information, to the Docket at the address given above. When you send a comment containing information claimed to be confidential business information, you should include a cover letter setting forth the information specified in our confidential business information regulation (49 CFR part 512).

FOR FURTHER INFORMATION CONTACT: For technical issues, you may contact Mr. Peter G. Martin, Office of Crashworthiness Standards (telephone: 202–366–5668). For legal issues, you may contact Mr. John Piazza, Office of Chief Counsel (telephone: 202–366–2992) (fax: 202–366–3820). *Address:* National Highway Traffic Safety Administration, U.S. Department of Transportation, 1200 New Jersey Avenue SE, West Building, Washington, DC 20590.

SUPPLEMENTARY INFORMATION:

I. Re-Opening of the Comment Period

On December 26, 2019, NHTSA published a NPRM (84 FR 70916) to revise the chest jacket and spine box specifications for the Hybrid III 5th Percentile Female Test Dummy (HIII–5F) set forth in Part 572, *Anthropomorphic Test Devices.* NHTSA proposed to adopt the jacket specifications described in SAE J2921, as well as several additional specifications for the jacket's contour that are not contained in SAE J2921. The NPRM comment period closed on February 24, 2020. Humanetics has requested a ninety-day extension to the NPRM comment period in order to collect data regarding the proposed additional chest jacket specifications while also ensuring a sufficient sample size. This request can be found in the docket for this rulemaking.[1]

NHTSA has considered Humanetics' request and believes that re-opening the comment period for 60 days appropriately balances NHTSA's interest in providing the public with sufficient time to comment on the notice with its interest in completing this rulemaking in a timely manner. Accordingly, we are re-opening the comment period on the NPRM for an additional 60 days.

II. Availability of Technical Document

The NPRM proposed chest jacket dimensions and tolerances. Separate

[1] NHTSA–2019–0023–0004.

sets of dimensions and tolerances were proposed for the unworn jacket (on a table top) and the jacket as worn by an actual HIII–5F dummy. The nominal dimensions and tolerances proposed in the NPRM were derived from a sample of eight SAE jackets measured by NHTSA. The ''as worn'' measurements were taken in combination with various HIII–5F dummies, including older units (4 built by FTSS, 1 built by Denton) and newer units (2 built by Humanetics). Measurements were carried out at two different test labs.

In the NPRM, we stated that we would continue to collect measurement data on newly purchased jackets to check whether the proposed dimensions and tolerances (including those derived from the drawings in SAE J2921 and the new section dimensions added by NHTSA) were being met by SAE jackets already in the field. We also stated that we would examine all measurement data provided to us, and explained that in the final rule we may adjust the dimensions and tolerances to assure that jackets in the field achieve an acceptable degree of conformity while still assuring a high level of uniformity.

NHTSA has developed the procedure described in the docketed document, *Measurement Procedure: Chest Jacket Dimensions, Hybrid III 5th Female Test Dummy,* for NHTSA staff and contractors to use in measuring SAE chest jackets, both unworn and as fitted to HIII–5F units, including new units built by Humanetics and older units built by FTSS and Denton. NHTSA will use these measurements to assess the uniformity of SAE jackets and to determine the jacket dimensions and tolerances to be specified in the Final Rule. The purpose of the procedures described in the docketed document is to ensure that these measurements are taken in a consistent manner. This measurement procedure should not be construed as a proposed requirement for conformity with Part 572 Subpart O, nor should it be construed as a configuration requirement for use of the dummy in NCAP or any FMVSS. NHTSA is docketing a copy of this document for the information of others who may wish to make similar measurements of the SAE jacket.

Public Participation

How do I prepare and submit comments?

- To ensure that your comments are correctly filed in the Docket, please include the Docket Number found in the heading of this document in your comments.
- Your comments must not be more than 15 pages long.[2] NHTSA established this limit to encourage you to write your primary comments in a concise fashion. However, you may attach necessary additional documents to your comments, and there is no limit on the length of the attachments.
- If you are submitting comments electronically as a PDF (Adobe) file, NHTSA asks that the documents be submitted using the Optical Character Recognition (OCR) process, thus allowing NHTSA to search and copy certain portions of your submissions.
- Please note that pursuant to the Data Quality Act, in order for substantive data to be relied on and used by NHTSA, it must meet the information quality standards set forth in the OMB and DOT Data Quality Act guidelines. Accordingly, NHTSA encourages you to consult the guidelines in preparing your comments. DOT's guidelines may be accessed at *https://www.transportation.gov/regulations/dot-information-dissemination-quality-guidelines.*

Tips for Preparing Your Comments

When submitting comments, please remember to:

- Identify the rulemaking by docket number and other identifying information (subject heading, **Federal Register** date and page number).
- Explain why you agree or disagree, suggest alternatives, and substitute language for your requested changes.
- Describe any assumptions you make and provide any technical information and/or data that you used.
- If you estimate potential costs or burdens, explain how you arrived at your estimate in sufficient detail to allow for it to be reproduced.
- Provide specific examples to illustrate your concerns, and suggest alternatives.
- Explain your views as clearly as possible, avoiding the use of profanity or personal threats.
- To ensure that your comments are considered by the agency, make sure to submit them by the comment period deadline identified in the **DATES** section above.

For additional guidance on submitting effective comments, visit: *https://www.regulations.gov/docs/Tips_For_Submitting_Effective_Comments.pdf.*

How can I be sure that my comments were received?

If you wish Docket Management to notify you upon its receipt of your comments, enclose a self-addressed, stamped postcard in the envelope containing your comments. Upon receiving your comments, Docket Management will return the postcard by mail.

How do I submit confidential business information?

If you wish to submit any information under a claim of confidentiality, you should submit three copies of your complete submission, including the information you claim to be confidential business information, to the Chief Counsel, NHTSA, at the address given above under **FOR FURTHER INFORMATION CONTACT**. In addition, you should submit a copy, from which you have deleted the claimed confidential business information, to the docket at the address given above under **ADDRESSES**. When you send a comment containing information claimed to be confidential business information, you should include a cover letter setting forth the information specified in our confidential business information regulation. (49 CFR part 512)

Will the agency consider late comments?

We will consider all comments received before the close of business on the comment closing date indicated above under **DATES**. To the extent possible, we will also consider comments that the docket receives after that date. If the docket receives a comment too late for us to consider in developing a final rule (assuming that one is issued), we will consider that comment as an informal suggestion for future rulemaking action.

How can I read the comments submitted by other people?

You may read the comments received by the docket at the address given above under **ADDRESSES**. The hours of the docket are indicated above in the same location. To be sure someone is there to help you, please call (202) 366–9322 before coming. You may also see the comments on the internet. To read the comments on the internet, go to *http://www.regulations.gov.* Follow the online instructions for accessing the dockets.

Please note that even after the comment closing date, we will continue to file relevant information in the docket as it becomes available. Further, some people may submit late comments. Accordingly, we recommend that you periodically check the Docket for new material. You can arrange with the docket to be notified when others file comments in the docket. See *www.regulations.gov* for more information.

[2] 49 CFR 553.21.

Issued in Washington, DC, under authority delegated in 49 CFR 1.95 and 501.4.

James Clayton Owens,

Deputy Administrator.

[FR Doc. 2020–11689 Filed 6–1–20; 8:45 am]

BILLING CODE 4910–59–P

Notices

Federal Register
Vol. 85, No. 106
Tuesday, June 2, 2020

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

DEPARTMENT OF AGRICULTURE

Submission for OMB Review; Comment Request

May 27, 2020.

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

Comments regarding this information collection received by July 2, 2020 will be considered. Written comments and recommendations for the proposed information collection should be submitted within 30 days of the publication of this notice on the following website *www.reginfo.gov/public/do/PRAMain.* Find this particular information collection by selecting ''Currently under 30-day Review—Open for Public Comments'' or by using the search function.

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

Office of Partnerships and Public Engagement

Title: Community of Faith and Opportunity Initiative.

OMB Control Number: 0503–NEW.

Summary of Collection: The Office of Partnerships and Public Engagement (OPPE) (previously known as the Office of Advocacy and Outreach) was established pursuant to section 226B of the Department of Agriculture Reorganization Act of 1994 (7 U.S.C. 6934), as added by section 14013 of the Food, Conservation, and Energy Act of 2008, Public Law 110–246. The OPPE was established to improve access to USDA programs and services by small farms and ranches, beginning farmers and ranchers, and socially disadvantaged farmers and ranchers. Delegations from the Assistant Secretary for Administration to the Director, OPPE are reflected in 7 CFR 2.94 and include certain outreach functions previously carried out by other elements within USDA.

Need and Use of the Information: The Communities of Faith and Opportunity initiative seeks to better understand the challenges facing rural and underserved communities across the country, while also providing outreach and assistance to build the local capacity needed to address community challenges. Communities are invited to participate in outreach summits, capacity building workshops, as well as provide additional information to become a Community of Faith and Opportunity.

Respondents will be required to submit a mailing address, telephone, and email address for themselves, the name and email address for any partners and/or potential stakeholders. They will also be required to identify at least 5 community challenges or projects in which they wish USDA assistance to address. Submitted information will be used by USDA agencies, grant recipients and Land Grant University Extension Staff on an as needs basis to provide technical assistance, services and recommendations to communities to address the self-identified challenges and community projects on an as needs basis. The information will also be used by the OPPE to evaluate the effectiveness and efficiency of the initiative.

Description of Respondents: Not-for-profit institutions; Small businesses.

Number of Respondents: 200.

Frequency of Responses: Reporting: On occasion.

Total Burden Hours: 150.

Ruth Brown,

Departmental Information Collection Clearance Officer.

[FR Doc. 2020–11766 Filed 6–1–20; 8:45 am]

BILLING CODE 3412–88–P

COMMISSION ON CIVIL RIGHTS

Notice of Public Meeting of the Texas Advisory Committee

AGENCY: U.S. Commission on Civil Rights.

ACTION: Announcement of meeting.

SUMMARY: Notice is hereby given, pursuant to the provisions of the rules and regulations of the U.S. Commission on Civil Rights (Commission) and the Federal Advisory Committee Act (FACA) that a teleconference meeting of the Texas Advisory Committee (Committee) to the Commission will be held at 1:00 p.m. (Central) Thursday, June 18, 2020. The purpose of the meeting is for the Committee to discuss potential project prompts.

DATES: The meeting will be held on Thursday, June 18, 2020 at 1:00 p.m. CDT.

Public Call Information:
Dial: 800–367–2403.
Conference ID: 5260316.

FOR FURTHER INFORMATION CONTACT: Brooke Peery, Designated Federal Officer (DFO) at *bpeery@usccr.gov* or (202) 701–1376.

SUPPLEMENTARY INFORMATION: This meeting is available to the public through the following toll-free call-in number: 800–367–2403, conference ID number: 5260316. Any interested member of the public may call this number and listen to the meeting. Callers can expect to incur charges for calls they initiate over wireless lines, and the Commission will not refund any incurred charges. Callers will incur no charge for calls they initiate over land-line connections to the toll-free telephone number. Persons with hearing impairments may also follow the proceedings by first calling the Federal Relay Service at 1–800–877–8339 and providing the Service with the

conference call number and conference ID number.

Members of the public are entitled to make comments during the open period at the end of the meeting. Members of the public may also submit written comments; the comments must be received in the Regional Programs Unit within 30 days following the meeting. Written comments may be mailed to the Western Regional Office, U.S. Commission on Civil Rights, 300 North Los Angeles Street, Suite 2010, Los Angeles, CA 90012 or emailed to Brooke Peery (DFO) at *bpeery@usccr.gov.*

Records and documents discussed during the meeting will be available for public viewing prior to and after the meeting at *https://www.facadatabase.gov/FACA/FACAPublicViewCommitteeDetails?id=a10t0000001gzkoAAA.*

Please click on the ''Meeting Details'' and ''Documents'' links. Records generated from this meeting may also be inspected and reproduced at the Regional Programs Unit, as they become available, both before and after the meeting. Persons interested in the work of this Committee are directed to the Commission's website, *https://www.usccr.gov,* or may contact the Regional Programs Unit at the above email or street address.

Agenda

Welcome & Roll Call
Approval of Minutes
Discussion on Potential Project Prompts
Public Comment
Adjournment

Dated: May 27, 2020.

David Mussatt,

Supervisory Chief, Regional Programs Unit.

[FR Doc. 2020–11825 Filed 6–1–20; 8:45 am]

BILLING CODE P

DEPARTMENT OF COMMERCE

Bureau of the Census

Census Scientific Advisory Committee

AGENCY: Bureau of the Census, Department of Commerce.

ACTION: Notice of Renewal of the Census Scientific Advisory Committee.

SUMMARY: The Secretary of the U.S. Department of Commerce renewed and filed the charter for the Census Scientific Advisory Committee (CSAC). The purpose of the CSAC is to provide advice to the Director of the Bureau of the Census (Census Bureau) on the full range of Census Bureau programs and activities including communications, decennial, demographic, economic, field operations, geographic, information technology, and statistics. The Secretary has determined that the work of the CSAC is in the public interest and relevant to the duties of the Census Bureau. Additional information concerning the CSAC can be found by visiting the CSAC's website at: *https://www.census.gov/about/cac/sac.html.*

FOR FURTHER INFORMATION CONTACT: Kimberly L. Leonard, External Stakeholder Program Manager, Office of Program, Performance and Stakeholder Integration (PPSI), Room 2K137, U.S. Census Bureau, 4600 Silver Hill Road, Washington, DC 20233, by telephone on 301–763–7281 or by email at *Kimberly.L.Leonard@census.gov.* Individuals who use telecommunication devices for the deaf (TDD) may call the Federal Information Relay Service (FIRS) at 1–800–877–8339 between 8:00 a.m. and 8:00 p.m., Eastern Standard Time, Monday through Friday.

SUPPLEMENTARY INFORMATION:

Background

In accordance with the Federal Advisory Committee Act (FACA), the Secretary of the Department of Commerce renewed and filed the charter for the CSAC. The CSAC will operate under the provisions of FACA and will report to the Secretary of the Department of Commerce through the Director of the Census Bureau. The CSAC will advise the Director of the Census Bureau on the full range of Census Bureau programs and activities.

Objectives and Duties

1. The CSAC will address census policies, research and methodology, tests, operations, communications/messaging, and other activities to ascertain needs and best practices to improve censuses, surveys, operations, and programs.

2. The CSAC will provide formal review and feedback on internal and external working papers, reports, and other documents related to the design and implementation of census programs and surveys.

3. The CSAC will provide scientific and technical expertise from the following disciplines: demographics, economics, geography, psychology, statistics, survey methodology, social and behavorial sciences, information technology and computing, marketing and other fields of expertise, as appropriate, to address Census Bureau program needs and objectives.

The function of the CSAC will be a ''Scientific Technical Program Advisory Board''.

4. The CSAC functions solely as an advisory body under the FACA.

Membership

1. The CSAC consists of up to 21 members who serve at the discretion of the Director of the Census Bureau (the Director). The Census Bureau is seeking three qualified candidates to be considered for appointment.

2. The CSAC aims to have a balanced representation among its members, considering such factors as geography, age, sex, race, ethnicity, scientific expertise, community involvement, and knowledge of census programs and/or activities.

3. The CSAC aims to include members from diverse backgrounds, including state, local and tribal governments; academia; research, national and community-based organizations; and, the private sector.

4. Members will serve as Special Government Employees (SGEs). SGEs will be subject to the ethics rules applicable to SGEs. Members will be individually advised of the capacity in which they will serve through their appointment letters.

5. SGEs and representatives will be selected from academia, public and private enterprise, and nonprofit organizations, which are further diversified by business type or industry, geography, and other factors.

6. Membership is open to persons who are not seated on other Census Bureau stakeholder entities (*i.e.,* State Data Centers, Census Information Centers, Federal State Cooperative on Populations Estimates Program, other Census Advisory Committees, etc.). People who have already served one full-term on a Census Bureau Advisory Committee may not serve on any other Census Bureau Advisory Committee for three years from the termination of previous service. No employee of the federal government can serve as a member of the CSAC.

7. Members will serve for a three-year term. All members will be reevaluated at the conclusion of each term with the prospect of renewal, pending CSAC needs. Active attendance and participation in meetings and activities (*e.g.,* conference calls and assignments) will be factors considered when determining term renewal or membership continuance. Members may be appointed for a second three-year term at the discretion of the Director.

8. Members will be selected on a standardized basis, in accordance with applicable U.S. Department of Commerce guidance.

Miscellaneous

1. Members of the CSAC serve without compensation but receive

reimbursement for CSAC-related travel and lodging expenses.

2. The CSAC meets once or twice a year, budget permitting, but additional meetings may be held as deemed necessary by the Director or Designated Federal Officer. CSAC meetings are open to the public in accordance with FACA.

3. Members must be able to actively participate in the tasks of the CSAC, including, but not limited to, regular meeting attendance, CSAC meeting discussant responsibilities, review of materials, as well as participation in conference calls, webinars, working groups, and/or special committee activities.

4. The Department of Commerce is committed to equal opportunity in the workplace and seeks diverse CSAC membership.

Steven D. Dillingham, Director, Bureau of the Census approved the publication of this notice in the **Federal Register**.

Dated: May 28, 2020.

Sheleen Dumas,

Department PRA Clearance Officer, Office of the Chief Information Officer, Commerce Department.

[FR Doc. 2020–11881 Filed 6–1–20; 8:45 am]

BILLING CODE 3510–07–P

DEPARTMENT OF COMMERCE

Foreign-Trade Zones Board

[B–33–2020]

Foreign-Trade Zone (FTZ) 137—Washington Dulles International Airport, Virginia; Notification of Proposed Production Activity; FN America, LLC (Disassembly of Machine Guns), Dulles, Virginia

CDS Air Freight Inc., an operator within FTZ 137 in Dulles, Virginia, submitted a notification of proposed production activity to the FTZ Board on behalf of FN America, LLC (FNA). The notification conforming to the requirements of the regulations of the FTZ Board (15 CFR 400.22) was received on May 22, 2020.

The FNA facility is located within FTZ 137. The facility is currently used for the storage of firearms, but the company is requesting authority to remove parts from firearms stored at the facility. 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 FNA 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, FNA would be able to choose the duty rates during customs entry procedures that apply to: Moving parts assemblies consisting of non-reciprocating sled and charging handle assemblies, non-reciprocating sled assemblies, charging handle assemblies, bolt assemblies, bolt carriers, bolt cam pins, firing pin retaining pin assemblies, return spring assemblies and firing pins; buttstock assemblies consisting of cap screw hexagonal socket heads, buttstock interface plates, buttstock rails, buttstock guide plates, large screw hexagonal countersunk heads, buttstock paddles, screw slotted pan heads, lock guide springs, lock springs, buttstock cheekrests, slotted spring type straight pins, buttstock plungers, buttstock interface pads and buttstock pads; takedown pin retaining clips; takedown pins; takedown hammers; automatic sears; automatic sear springs; cover plates; slotted spring type pins; magazine release buttons; magazine release springs; hammer spring guides; hammer springs; selector lever detents; selector lever spring detents; trigger module frames; locking plates; slotted spring type pins; bolt catch supports; bolt catch springs; bolt catches; magazine catch assemblies; magazine catches; magazine catch levers; trigger pins; hammer spring supports; and, drive rod indexes (duty-free). FNA 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 are machine guns (duty-free). The request indicates that the machine guns are subject to duties under Section 301 of the Trade Act of 1974 (Section 301), depending on the country of origin. The applicable Section 301 decisions require subject merchandise to be admitted to FTZs in privileged foreign status (19 CFR 146.41).

Public comment is invited from interested parties. Submissions shall be addressed to the Board's Executive Secretary and sent to: *ftz@trade.gov.* The closing period for their receipt is July 13, 2020.

A copy of the notification will be available for public inspection in the ''Reading Room'' section of the Board's website, which is accessible via *www.trade.gov/ftz.*

For further information, contact Elizabeth Whiteman at *Elizabeth.Whiteman@trade.gov* or (202) 482–0473.

Dated: May 28, 2020.

Andrew McGilvray,

Executive Secretary.

[FR Doc. 2020–11885 Filed 6–1–20; 8:45 am]

BILLING CODE 3510–DS–P

DEPARTMENT OF COMMERCE

International Trade Administration

[A–570–119]

Certain Vertical Shaft Engines Between 225cc and 999cc, and Parts Thereof From the People's Republic of China: Postponement of Preliminary Determination in the Antidumping Duty Investigation

AGENCY: Enforcement and Compliance, International Trade Administration, Department of Commerce.

DATES: Applicable June 2, 2020.

FOR FURTHER INFORMATION CONTACT: Leo Ayala, AD/CVD Operations, Enforcement and Compliance, International Trade Administration, Department of Commerce, 1401 Constitution Avenue NW, Washington, DC 20230; telephone: (202) 482–3945.

SUPPLEMENTARY INFORMATION:

Background

On February 4, 2020, the Department of Commerce initiated the antidumping duty investigation on certain vertical shaft engines between 225cc and 999cc, and parts thereof from the People's Republic of China, covering the period of investigation (POI) July 1, 2019 through December 31, 2019.[1] Currently, the preliminary determination is due no later than June 23, 2020.

Postponement of the Preliminary Determination

Section 733(b)(1)(A) of the Tariff Act of 1930, as amended (the Act), requires Commerce to issue the preliminary determination in an antidumping investigation within 140 days after the date on which Commerce initiated the investigation. However, section 733(c)(1) of the Act permits Commerce to postpone the preliminary determination until no later than 190 days after the date on which Commerce initiated the investigation if: (A) The petitioner makes a timely request for a

[1] *See Certain Vertical Shaft Engines between 225cc and 999cc, and Parts Thereof from the People's Republic of China: Initiation of Less-Than-Fair-Value Investigation,* 85 FR 8809 (February 18, 2020).

postponement; or (B) Commerce concludes that the parties concerned are cooperating, that the investigation is extraordinarily complicated, and that additional time is necessary to make a preliminary determination. Under 19 CFR 351.205(e), a petitioner must submit a request for postponement 25 days or more before the scheduled date of the preliminary determination and must state the reason for the request. Commerce will grant the request unless it finds compelling reasons to deny the request.[2]

On May 20, 2020, Briggs & Stratton Corporation, the petitioner in this investigation, submitted a timely request pursuant to section 733(c)(1) of the Act and 19 CFR 351.205(e) to postpone fully the preliminary determination. The petitioner stated that the purpose of its request was to provide Commerce with sufficient time to receive and analyze the questionnaire responses of the mandatory respondents, issue any supplemental questionnaires, and prepare an accurate preliminary dumping margin calculation.[3]

Consistent with 19 CFR 351.205(e), the petitioner stated the reasons for its request, and Commerce finds no compelling reason to deny the request. Therefore, in accordance with section 733(c)(1)(A) of the Act, Commerce is postponing the deadline for the preliminary determination to August 12, 2020.[4] Pursuant to section 735(a)(l) of the Act and 19 CFR 351.210(b)(1), the deadline for the final determination will continue to be 75 days after the date of the preliminary determination, unless postponed at a later date.

This notice is issued and published pursuant to section 733(c)(2) of the Act and 19 CFR 351.205(f)(l).

Dated: May 27, 2020.

Jeffrey I. Kessler,

Assistant Secretary for Enforcement and Compliance.

[FR Doc. 2020–11886 Filed 6–1–20; 8:45 am]

BILLING CODE 3510–DS–P

[2] *See* 19 CFR 351.205(e).

[3] *See* Petitioner's Letter, ''Certain Vertical Shaft Engines Between 225cc and 999cc, and Parts Thereof, From the People's Republic of China: Petitioner's Request for Postponement Of The Preliminary Determination,'' dated May 20, 2020.

[4] In this case, 190 days after initiation falls on August 12, 2020.

DEPARTMENT OF COMMERCE

International Trade Administration

[A–570–112]

Certain Collated Steel Staples From the People's Republic of China: Final Affirmative Determination of Sales at Less Than Fair Value and Final Affirmative Critical Circumstances Determination

AGENCY: Enforcement and Compliance, International Trade Administration, U.S. Department of Commerce.

SUMMARY: The Department of Commerce (Commerce) determines that imports of certain collated steel staples (collated staples) 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 June 2, 2020.

FOR FURTHER INFORMATION CONTACT: Sergio Balbontin or William Horn, AD/CVD Operations, Office VIII, Enforcement and Compliance, International Trade Administration, U.S. Department of Commerce, 1401 Constitution Avenue NW, Washington, DC 20230; telephone: (202) 482–6478 or (202) 482–4868, respectively.

SUPPLEMENTARY INFORMATION:

Background

Commerce published the *Preliminary Determination* in the LTFV investigation of collated staples from China on January 8, 2020.[1] For a complete description of the events that followed the *Preliminary Determination, see* the Issues and Decision Memorandum.[2]

Period of Investigation

The period of investigation is October 1, 2018 through March 31, 2019.

Scope of the Investigation

The products covered by this investigation are collated staples from China. For a complete description of the scope of this investigation, *see* Appendix I.

Scope Comments

On November 4, 2019, we issued a Preliminary Scope Memorandum making no changes to the scope of this and the companion countervailing duty (CVD) investigation.[3] For a summary of the product coverage comments and rebuttal comments submitted to the record for this final determination, and accompanying discussion and analysis of all comments timely received, *see* the Final Scope Decision Memorandum.[4] Based on the comments received from interested parties, we are revising the scope of this investigation to exclude ''hog rings.'' The scope in Appendix I reflects this change.

Verification

Commerce normally verifies information relied upon in making its final determination, pursuant to section 782(i) of the Tariff Act of 1930, as amended (the Act). However, on March 16, 2020, Commerce cancelled verification of the questionnaire responses submitted by Tianjin Hweschun Fasteners Manufacturing Co., Ltd. (Tianjin Hweschun).[5] During the course of this investigation, a Level 4 travel advisory was imposed for all of China, preventing Commerce personnel from traveling to China to conduct verification. Due to this, as well as the impending statutory deadline for the completion of the final determination, Commerce was unable to conduct verification in this case.

Pursuant to section 776(a)(2)(D) of the Act, in situations where information has been provided but the information cannot be verified, Commerce may use ''facts otherwise available'' in reaching the applicable determination. Accordingly, as Commerce was unable to proceed to verification in this investigation, we have relied on the information submitted on the record that we used in making the *Preliminary Determination,* as facts available in making our final determination.

Final Affirmative Determination of Critical Circumstances

Commerce preliminarily determined in this investigation that critical circumstances exist with respect to imports of collated staples from China shipped by Tianjin Hweschun, Tianjin Jin Xin Sheng Long Metal Products Co.,

[1] *See Certain Collated Steel Staples from the People's Republic of China: Preliminary Affirmative Determination of Sales at Less Than Fair Value, Preliminary Affirmative Determination of Critical Circumstances, Postponement of Final Determination and Extension of Provisional Measures,* 85 FR 882 (January 8, 2020) (*Preliminary Determination*), and accompanying Preliminary Decision Memorandum (PDM).

[2] *See* Memorandum, ''Certain Collated Steel Staples from the People's Republic of China: Issues and Decision Memorandum for the Final Affirmative Determination of Sales at Less Than Fair Value,'' dated concurrently with, and hereby adopted by, this notice (Issues and Decision Memorandum).

[3] *See* Memorandum, ''Less-Than-Fair-Value and Countervailing Duty Investigations of Certain Collated Steel Staples from the People's Republic of China: Preliminary Scope Decision Memorandum,'' dated November 4, 2019 (Preliminary Scope Decision Memorandum).

[4] *See* Memorandum, ''Certain Collated Steel Staples from the People's Republic of China: Final Scope Determination Decision Memorandum,'' dated concurrently with, and hereby adopted by, this notice (Final Scope Decision Memorandum).

[5] *See* Memorandum, ''Cancellation of Verification,'' dated March 16, 2020.

Ltd. (Tianjin JXSL), the non-individually examined respondents, and the China-wide entity.[6] That determination remains unchanged and a discussion of our final critical circumstances determination can be found in the Issues and Decision Memorandum.

Analysis of Comments Received

All issues raised in the case and rebuttal briefs that were submitted by parties in this investigation are addressed in the Issues and Decision Memorandum. For a list of the issues raised by interested parties and addressed in the Issues and Decision Memorandum, *see* Appendix II to this notice. The Issues and Decision Memorandum is a public document and is made available to the public 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.* In addition, a complete version of the Issues and Decision Memorandum can be accessed directly at *https://enforcement.trade.gov/frn/index.html.* The signed and electronic versions of the Issues and Decision Memorandum are identical in content.

China-Wide Entity and Use of Adverse Facts Available

We continue to find that the use of facts available is warranted in determining the rate of the China-wide entity pursuant to sections 776(a)(1) and (a)(2)(A)-(C) of the Act. Further, use of adverse facts available (AFA) is warranted because the China-wide entity did not cooperate to the best of its ability to comply with our requests for information and, accordingly, we applied adverse inferences in selecting from the facts available, pursuant to section 776(b) of the Act and 19 CFR 351.308(a). For the final determination, we are assigning the China-wide entity, as AFA, the rate of 122.55 percent, which is the highest petition rate.[7]

Separate Rates

As discussed in the Issues and Decision Memorandum, we granted Tianjin Hweschun, Tianjin JXSL, and six non-individually examined respondents [8] a separate rate in the *Preliminary Determination* based on their eligibility.[9] No parties commented on this preliminary finding and the facts have not changed with respect to these companies' separate rate eligibility. Therefore, we continue to grant separate rates to these companies in this final determination. As discussed in the Issues and Decision Memorandum, we assigned Tianjin JXSL, as AFA, the highest petition rate.

In accordance with section 735(c)(5)(A) of the Act, Commerce shall determine an estimated separate rate for companies not individually examined. Generally, under section 735(c)(5)(A) of the Act, this rate shall be an amount equal to the weighted average of the estimated antidumping duty (AD) rates established for those companies individually examined, excluding any zero and *de minimis* rates and any rates based entirely under section 776 of the Act. However, section 735(c)(5)(B) of the Act provides that if the AD duty rates established for all companies individually examined are zero or *de minimis* rates, or are determined entirely under section 776 of the Act, then Commerce may use ''any reasonable method'' to establish a separate rate, ''including averaging the weighted-average anti-dumping duty rates determined for the exporters and producers individually investigated.''

The sole calculated AD rate for this final determination is based on facts otherwise available. As explained above, the sole cooperative mandatory respondent in this investigation, Tianjin Hweschun, is receiving a rate based entirely on the facts available. In the specific circumstances of this case, because we were unable to verify Tianjin Hweschun, we find that a reasonable method to determine the all-others rate under section 735(c)(5)(B) of the Act here is to apply Tianjin Hweschun's individual estimated AD rate as the separate rate for companies not individually examined.

Changes From the Preliminary Determination

Based on our analysis of the comments received, we made certain changes to the dumping margin calculations for Tianjin Hweschun.[10] For a discussion of these changes, *see* the Issues and Decision Memorandum. In light of our method in this investigation for determining the separate rate for companies not individually examined, we have also modified the separate rate.

Combination Rates

Consistent with the *Preliminary Determination*[11] and Policy Bulletin 05.1,[12] Commerce calculated combination rates for the respondents that are eligible for a separate rate in this investigation.

Final Determination

Commerce determines that the following weighted-average dumping margins exist:

Producer	Exporter	Estimated weighted-average dumping margin (percent)	Cash deposit rate (adjusted for subsidy offsets) (percent)
Tianjin Hweschun Fasteners Manufacturing Co., Ltd.	Tianjin Hweschun Fasteners Manufacturing Co., Ltd.	96.15	85.61
Tianjin Jin Xin Sheng Long Metal Products Co., Ltd. ..	Tianjin Jin Xin Sheng Long Metal Products Co., Ltd. ..	122.55	112.01
China Staple (Tianjin) Co., Ltd.	China Staple (Tianjin) Co., Ltd.	96.15	85.61
Shanghai Yueda Nails Co., Ltd.	Shanghai Yueda Nails Co., Ltd.	96.15	85.61
Shijiazhuang Shuangming Trade Co., Ltd.	Shijiazhuang Shuangming Trade Co., Ltd.	96.15	85.61
Tianjin Jinyifeng Hardware Co., Ltd.	Tianjin Jinyifeng Hardware Co., Ltd.	96.15	85.61
Unicorn Fasteners Co., Ltd.	Unicorn Fasteners Co., Ltd.	96.15	85.61
Zhejiang Best Nail Industrial Co., Ltd.	Zhejiang Best Nail Industrial Co., Ltd.	96.15	85.61
China-Wide Entity		122.55	112.01

[6] *See Preliminary Determination* PDM at 30.

[7] *See* Issues and Decision Memorandum at 3–5 for a full discussion of this issue; *see also Preliminary Determination* PDM at 16–18.

[8] These companies are China Staple (Tianjin) Co., Ltd., Shanghai Yueda Nails Co., Ltd., Shijiazhuang Shuangming Trade Co., Ltd., Tianjin Jinyifeng Hardware Co., Ltd., Unicorn Fasteners Co., Ltd., and Zhejiang Best Nail Industrial Co., Ltd.

[9] *See Preliminary Determination* PDM at 10—14.

[10] *See* Issues and Decision Memorandum.

[11] *See Preliminary Determination.*

[12] *See* Enforcement and Compliance's Policy Bulletin No. 05.1, regarding, ''Separate-Rates Practice and Application of Combination Rates in Antidumping Investigations involving Non-Market Economy Countries,'' dated April 5, 2005 (Policy Bulletin 05.1), available on Commerce's website at *http://enforcement.trade.gov/policy/bull05–1.pdf.*

Disclosure

We intend to disclose to parties in this proceeding the calculations performed for this final determination within five days of the date of publication of this notice, in accordance with 19 CFR 351.224(b).

Continuation of Suspension of Liquidation

As a result of our *Preliminary Determination* and pursuant to section 733(e)(2)(A) of the Act, we will instruct U.S. Customs and Border Protection (CBP) to continue to suspend liquidation of all entries of collated staples from China, except for hog rings, as described in Appendix I of this notice, entered or withdrawn from warehouse, for consumption on October 10, 2019, which is 90 days before the date of publication of the *Preliminary Determination* in the **Federal Register**.

With respect to hog rings, we will instruct CBP to discontinue suspension of liquidation of such merchandise effective the date of publication of this determination. In addition, we will direct CBP to liquidate any suspended entries of this merchandise without regard to AD duties and to refund any cash deposits with respect to these entries.

Pursuant to section 735(c)(1)(B)(ii) of the Act, upon the publication of this notice, Commerce will instruct CBP to require a cash deposit equal to the weighted-average amount by which the normal value exceeds U.S. price as follows: (1) The cash deposit rate for the exporter/producer combinations listed in the table above will be the rate identified in the table; (2) for all combinations of Chinese exporters/producers of subject merchandise that have not received their own separate rate above, the cash deposit rate will be the cash deposit rate established for the China-wide entity; and (3) for all non-Chinese exporters of subject merchandise which have not received their own separate rate above, the cash deposit rate will be the cash deposit rate applicable to the Chinese exporter/producer combination that supplied that non-Chinese exporter. These suspension of liquidation instructions will remain in effect until further notice.

To determine the cash deposit rate, Commerce normally adjusts the estimated weighted-average dumping margin by the amount of domestic subsidy pass-through and export subsidies determined in a companion CVD proceeding when CVD provisional measures are in effect. Accordingly, where Commerce makes an affirmative determination for domestic subsidy pass-through or export subsidies, Commerce offsets the calculated estimated weighted-average dumping margin by the appropriate rate(s). In this case, we made a negative finding for domestic subsidy pass-through for all respondents in the *Preliminary Determination,* which remains unchanged for the final determination.[13] However, with respect to export subsidies for all respondents, Commerce issued the final determination of the concurrent CVD investigation of collated staples from China, in which it found export-contingent subsidies of 10.54 percent for Best Nail and 10.54 percent for all others.[14] Therefore, we have deducted export subsidies from the final margins and adjusted the cash deposit rates in the chart above. However, suspension of liquidation for provisional measures in the companion CVD case has been discontinued; therefore, we are not instructing CBP to collect cash deposits based upon the adjusted estimated weighted-average dumping margin for those subsidies at this time.

International Trade Commission Notification

In accordance with section 735(d) of the Act, we will notify the International Trade Commission (ITC) of our final affirmative determination of sales at LTFV. 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 the final determination in this proceeding 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 of subject merchandise from China no later than 45 days after our 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 AD 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.

Notification Regarding Administrative Protective Order

This notice will serve as a reminder to the parties subject to administrative protective order (APO) of their responsibility concerning the disposition 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 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 in accordance with sections 735(d) and 777(i)(1) of the Act, and 19 CFR 351.210(c).

Dated: May 22, 2020.

Jeffrey I. Kessler,

Assistant Secretary for Enforcement and Compliance.

Appendix I

Scope of the Investigation

The merchandise covered by the scope of this investigation is certain collated steel staples. Certain collated steel staples subject to this investigation are made from steel wire having a nominal diameter from 0.0355 inch to 0.0830 inch, inclusive, and have a nominal leg length from 0.25 inch to 3.0 inches, inclusive, and a nominal crown width from 0.187 inch to 1.125 inch, inclusive. Certain collated steel staples may be manufactured from any type of steel, and are included in the scope of this investigation regardless of whether they are uncoated or coated, and regardless of the type or number of coatings, including but not limited to coatings to inhibit corrosion.

Certain collated steel staples may be collated using any material or combination of materials, including but not limited to adhesive, glue, and adhesive film or adhesive or paper tape.

Certain collated steel staples are generally made to American Society for Testing and Materials (ASTM) specification ASTM F1667–18a, but can also be made to other specifications.

Excluded from the scope of this investigation are any carton-closing staples covered by the scope of the existing antidumping duty order on Carton-Closing Staples from the People's Republic of China. *See Carton-Closing Staples from the People's Republic of China: Antidumping Duty Order,* 83 FR 20792 (May 8, 2018).

[13] *See* sections ''Adjustment Under Section 777A(F) of the Act'' and ''Adjustment to Cash Deposit Rate for Export Subsidies'' in the Preliminary Decision Memorandum; *see also* Memorandum, ''Certain Collated Steel Staples from the People's Republic of China: Final Affirmative Countervailing Duty Determination, Issues and Decisions Memorandum'' dated concurrently with this notice (Collated Staples from China CVD IDM).

[14] *See* Collated Staples from China CVD IDM at 6.

Also excluded are collated fasteners commonly referred to as ''C-ring hog rings'' and ''D-ring hog rings'' produced from stainless or carbon steel wire having a nominal diameter of 0.050 to 0.081 inches, inclusive. C-ring hog rings are fasteners whose legs are not perpendicular to the crown, but are curved inward resulting in the fastener forming the shape of the letter ''C''. D-ring hog rings are fasteners whose legs are straight but not perpendicular to the crown, instead intersecting with the crown at an angle ranging from 30 degrees to 75 degrees. The hog rings subject to the exclusion are collated using glue, adhesive, or tape. The hog rings subject to this exclusion have either a 90 degree blunt point or 15–75 degree divergent point.

Certain collated steel staples subject to this investigation are currently classifiable under subheading 8305.20.0000 of the Harmonized Tariff Schedule of the United States (HTSUS). While the HTSUS subheading and ASTM specification are provided for convenience and for customs purposes, the written description of the subject merchandise is dispositive.

Appendix II

List of Topics Discussed in the Issues and Decision Memorandum

[FR Doc. 2020–11891 Filed 6–1–20; 8:45 am]

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DEPARTMENT OF COMMERCE

International Trade Administration

[C–570–113]

Certain Collated Steel Staples From the People's Republic of China: Final Affirmative Countervailing Duty Determination and Final Affirmative Critical Circumstances 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 and exporters of certain collated steel staples (collated staples) from the People's Republic of China (China).

DATES: Applicable June 2, 2020.

FOR FURTHER INFORMATION CONTACT: Joshua Simonidis or Robert Palmer, AD/CVD Operations, Office VIII, Enforcement and Compliance, International Trade Administration, U.S. Department of Commerce, 1401 Constitution Avenue NW, Washington, DC 20230; telephone: (202) 482–0608 or (202) 482–9068, respectively.

SUPPLEMENTARY INFORMATION:

Background

Commerce published the *Preliminary Determination* in the countervailing duty (CVD) investigation of collated staples from China on November 12, 2019.[1] For a complete description of the events that followed the *Preliminary Determination, see* the Issues and Decision Memorandum.[2]

Period of Investigation

The period of investigation (POI) is January 1, 2018 through December 31, 2018.

Scope of the Investigation

The products covered by this investigation are collated staples from China. For a complete description of the scope of this investigation, *see* Appendix I.

Scope Comments

On November 4, 2019, we issued a Preliminary Scope Memorandum making no changes to the scope of this and the companion antidumping duty (AD) investigation.[3] For a summary of the product coverage comments and rebuttal comments submitted to the record for this final determination, and accompanying discussion and analysis of all comments timely received, *see* the Final Scope Decision Memorandum.[4] Based on the comments received from interested parties, we are revising the scope of this investigation to exclude ''hog rings.'' The scope in Appendix I reflects this change.

Verification

Commerce normally verifies information relied upon in making its final determination, pursuant to section 782(i) of the Tariff Act of 1930, as amended (the Act). However, on March 16, 2020, Commerce cancelled verification of the questionnaire responses submitted by Zhejiang Best Nail Industrial Co., Ltd. (Best Nail) and the Government of China.[5] During the course of this investigation, a Level 4 travel advisory was imposed for all of China, preventing Commerce personnel from traveling to China to conduct verification. Due to this, as well as the impending statutory deadline for the completion of the final determination, Commerce was unable to conduct verification in this case.

Pursuant to section 776(a)(2)(D) of the Act, in situations where information has been provided but the information cannot be verified, Commerce may use ''facts otherwise available'' in reaching the applicable determination. Accordingly, as Commerce was unable to proceed to verification in this investigation for reasons beyond its control, we have relied on the information submitted on the record that we used in making the *Preliminary Determination,* as facts available in making our final determination.

[1] *See Certain Collated Steel Staples from the People's Republic of China: Preliminary Affirmative Countervailing Duty Determination, and Alignment of Final Determination with Final Antidumping Duty Determination,* 84 FR 61021 (November 12, 2019) (*Preliminary Determination*).

[2] *See* Memorandum, ''Issues and Decision Memorandum for the Final Affirmative Determination of the Countervailing Duty Investigation of Certain Collated Steel Staples from the People's Republic of China,'' dated concurrently with this determination, and hereby adopted by, this notice (Issues and Decision Memorandum).

[3] *See* Memorandum, ''Less-Than-Fair-Value and Countervailing Duty Investigations of Certain Collated Steel Staples from the People's Republic of China: Preliminary Scope Decision Memorandum,'' dated November 4, 2019 (Preliminary Scope Memorandum).

[4] *See* Memorandum, ''Certain Collated Steel Staples from the People's Republic of China: Final Scope Determination Decision Memorandum,'' dated concurrently with, and hereby adopted by, this notice (Final Scope Decision Memorandum).

[5] *See* Memorandum, ''Cancellation of Verification and Deferment of Upstream Subsidy Investigation,'' dated March 16, 2020.

Final Affirmative Determination of Critical Circumstances

Commerce preliminarily determined in this investigation that critical circumstances exist with respect to imports of collated staples from China shipped by Best Nail and all other producers and exporters.[6] That determination remains unchanged and a discussion of our final critical circumstances determination can be found in the Issues and Decision Memorandum.

Analysis of Subsidy Programs and Comments Received

All issues raised in the case and rebuttal briefs that were submitted by parties in this investigation are addressed in the Issues and Decision Memorandum. For a list of the issues raised by interested parties and addressed in the Issues and Decision Memorandum, *see* Appendix II to this notice. The Issues and Decision Memorandum is a public document and is made available to the public 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.* In addition, a complete version of the Issues and Decision Memorandum can be accessed directly at *https://enforcement.trade.gov/frn/index.html.* The signed and electronic versions of the Issues and Decision Memorandum are identical in content.

Methodology

Commerce conducted this investigation in accordance with section 701 of the Act. For each of the subsidy programs found countervailable, Commerce determines that there is a countervailable subsidy, *i.e.,* a financial contribution by an ''authority'' that gives rise to a benefit to the recipient, and that the subsidy is specific.[7] For a full description of the methodology underlying our final determination, *see* the Issues and Decision Memorandum.

As discussed above, in making this final determination, Commerce relied on facts available pursuant to section 776(a) of the Act. Additionally, as discussed in the Issues and Decision Memorandum, because one or more respondents did not act to the best of their ability in responding to our requests for information, we drew adverse inferences, where appropriate, in selecting from among the facts otherwise available, pursuant to section 776(b) of the Act. Specifically, Commerce assigned rates based entirely on facts otherwise available with adverse inferences, pursuant to section 776(b) of the Act, to Hai Sheng Xin Group Co., Ltd. and Ningbo Deli Stationery. For further information, *see* the section ''Use of Facts Otherwise Available and Adverse Inferences'' in the Issues and Decision Memorandum.

All-Others Rate

In accordance with section 705(c)(5)(A) of the Act, Commerce shall determine an estimated all-others rate for companies not individually examined. Generally, under section 705(c)(5)(A)(i) of the Act, this rate shall be an amount equal to the weighted average of the estimated subsidy rates established for those companies individually examined, excluding any zero and *de minimis* rates and any rates based entirely under section 776 of the Act. However, section 705(c)(5)(A)(ii) of the Act provides that if the countervailable subsidy rates established for all companies individually examined are zero or *de minimis* rates, or are determined entirely under section 776 of the Act, then Commerce may use ''any reasonable method'' to establish an all-others rate, ''including averaging the weighted-average countervailable subsidy rates determined for the exporters and producers individually investigated.''

The sole calculated countervailable subsidy rate for this final determination is based on facts otherwise available. As explained above, the sole cooperative mandatory respondent in this investigation, Best Nail, is receiving a rate based entirely on the facts available. In the specific circumstances of this case, because we were unable to verify Best Nail, we find that a reasonable method to determine the all-others rate under section 705(c)(5)(A)(ii) of the Act here is to apply Best Nail's individual estimated subsidy rate as the all-others rate for companies not individually examined.

Changes Since the Preliminary Determination

Based on our analysis of the comments received, we made certain changes to Best Nail's subsidy rate calculations set forth in the *Preliminary Determination.* For a discussion of these changes, *see* the Issues and Decision Memorandum. In light of our method in this investigation for determining the all-others rate for companies not individually examined, we have also modified the all-others rate.

Final Determination

Commerce determines that the following estimated countervailable subsidy rates exist:

Company	Subsidy rate (percent)
Zhejiang Best Nail Industrial Co., Ltd.	12.32
Hai Sheng Xin Group Co., Ltd.	192.64
Ningbo Deli Stationery	192.64
All Others	12.32

Disclosure

We intend to disclose to parties in this proceeding the calculations performed for this final determination within five days of the date of publication of this notice, in accordance with 19 CFR 351.224(b).

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, we instructed U.S. Customs and Border Protection (CBP) to suspend liquidation of entries of subject merchandise entered, or withdrawn from warehouse, for consumption on August 14, 2019, which is 90 days before the date of publication of the *Preliminary Determination* 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 March 11, 2020, but to continue the suspension of liquidation of all entries from August 14, 2019 through March 10, 2020. As discussed above in the ''Scope Comments'' section, for the final determination we have excluded hog rings from the scope of the investigation. Accordingly, with respect to hog rings, we will instruct CBP to discontinue suspension of liquidation of such merchandise effective the date of publication of this determination. In addition, we will direct CBP to liquidate any suspended entries of this merchandise without regard to countervailing duties and to refund any cash deposits with respect to these entries.

If the U.S. International Trade Commission (ITC) issues a final affirmative injury determination, we will issue a CVD order, reinstate the

[6] *See Certain Collated Steel Staples From the People's Republic of China: Preliminary Affirmative Determinations of Critical Circumstances in the Antidumping and Countervailing Duty Investigations,* 84 FR 59353 (November 4, 2019).

[7] *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.

suspension of liquidation under section 706(a) of the Act, and 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.

International Trade Commission Notification

In accordance with section 705(d) of the Act, we will notify the ITC of our 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. Because the final determination in this proceeding is affirmative, in accordance with section 705(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 of subject merchandise from China no later than 45 days after our 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 a CVD order directing CBP to assess, upon further instruction by Commerce, countervailing 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.

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: May 22, 2020.

Jeffrey I. Kessler,

Assistant Secretary for Enforcement and Compliance.

Appendix I

Scope of the Investigation

The merchandise covered by the scope of this investigation is certain collated steel staples. Certain collated steel staples subject to these investigations are made from steel wire having a nominal diameter from 0.0355 inch to 0.0830 inch, inclusive, and have a nominal leg length from 0.25 inch to 3.0 inches, inclusive, and a nominal crown width from 0.187 inch to 1.125 inch, inclusive. Certain collated steel staples may be manufactured from any type of steel, and are included in the scope of this investigation regardless of whether they are uncoated or coated, and regardless of the type or number of coatings, including but not limited to coatings to inhibit corrosion.

Certain collated steel staples may be collated using any material or combination of materials, including but not limited to adhesive, glue, and adhesive film or adhesive or paper tape.

Certain collated steel staples are generally made to American Society for Testing and Materials (ASTM) specification ASTM F1667–18a, but can also be made to other specifications.

Excluded from the scope of this investigation are any carton-closing staples covered by the scope of the existing antidumping duty order on Carton-Closing Staples from the People's Republic of China. See Carton-Closing Staples from the People's Republic of China: Antidumping Duty Order, 83 FR 20792 (May 8, 2018).

Also excluded are collated fasteners commonly referred to as ''C-ring hog rings'' and ''D-ring hog rings'' produced from stainless or carbon steel wire having a nominal diameter of 0.050 to 0.081 inches, inclusive. C-ring hog rings are fasteners whose legs are not perpendicular to the crown, but are curved inward resulting in the fastener forming the shape of the letter ''C''. D-ring hog rings are fasteners whose legs are straight but not perpendicular to the crown, instead intersecting with the crown at an angle ranging from 30 degrees to 75 degrees. The hog rings subject to the exclusion are collated using glue, adhesive, or tape. The hog rings subject to this exclusion have either a 90 degree blunt point or 15–75 degree divergent point.

Certain collated steel staples subject to this investigation are currently classifiable under subheading 8305.20.0000 of the Harmonized Tariff Schedule of the United States (HTSUS). While the HTSUS subheading and ASTM specification are provided for convenience and for customs purposes, the written description of the subject merchandise is dispositive.

Appendix II

List of Topics Discussed in the Issues and Decision Memorandum

[FR Doc. 2020–11892 Filed 6–1–20; 8:45 am]

BILLING CODE 3510–DS–P

DEPARTMENT OF COMMERCE

International Trade Administration

Antidumping or Countervailing Duty Order, Finding, or Suspended Investigation; 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:

Background

Each year during the anniversary month of the publication of an antidumping or countervailing duty order, finding, or suspended investigation, an interested party, as defined in section 771(9) of the Tariff

Act of 1930, as amended (the Act), may request, in accordance with 19 CFR 351.213, that the Department of Commerce (Commerce) conduct an administrative review of that antidumping or countervailing duty order, finding, or suspended investigation.

All deadlines for the submission of comments or actions by Commerce discussed below refer to the number of calendar days from the applicable starting date.

Respondent Selection

In the event Commerce limits the number of respondents for individual examination for administrative reviews initiated pursuant to requests made for the orders identified below,

Commerce intends to select respondents based on U.S. Customs and Border Protection (CBP) data for U.S. imports during the period of review. We intend to release the CBP data under Administrative Protective Order (APO) to all parties having an APO within five days of publication of the initiation notice and to make our decision regarding respondent selection within 21 days of publication of the initiation **Federal Register** notice. Therefore, we encourage all parties interested in commenting on respondent selection to submit their APO applications on the date of publication of the initiation notice, or as soon thereafter as possible. Commerce invites comments regarding the CBP data and respondent selection within five days of placement of the CBP data on the record of the review.

In the event Commerce decides it is necessary to limit individual examination of respondents and conduct respondent selection under section 777A(c)(2) of the Act:

In general, Commerce finds that determinations concerning whether particular companies should be ''collapsed'' (*i.e.,* treated as a single entity for purposes of calculating antidumping duty rates) require a substantial amount of detailed information and analysis, which often require follow-up questions and analysis. Accordingly, Commerce will not conduct collapsing analyses at the respondent selection phase of a review and will not collapse companies at the respondent selection phase unless there has been a determination to collapse certain companies in a previous segment of this antidumping proceeding (*i.e.,* investigation, administrative review, new shipper review or changed circumstances review). For any company subject to a review, if Commerce determined, or continued to treat, that company as collapsed with others, Commerce will assume that such companies continue to operate in the same manner and will collapse them for respondent selection purposes. Otherwise, Commerce will not collapse companies for purposes of respondent selection. Parties are requested to (a) identify which companies subject to review previously were collapsed, and (b) provide a citation to the proceeding in which they were collapsed. Further, if companies are requested to complete a Quantity and Value Questionnaire for purposes of respondent selection, in general each company must report volume and value data separately for itself. Parties should not include data for any other party, even if they believe they should be treated as a single entity with that other party. If a company was collapsed with another company or companies in the most recently completed segment of a proceeding where Commerce considered collapsing that entity, complete quantity and value data for that collapsed entity must be submitted.

Deadline for Withdrawal of Request for Administrative Review

Pursuant to 19 CFR 351.213(d)(1), a party that requests a review may withdraw that request within 90 days of the date of publication of the notice of initiation of the requested review. The regulation provides that Commerce may extend this time if it is reasonable to do so. Determinations by Commerce to extend the 90-day deadline will be made on a case-by-case basis.

Deadline for Particular Market Situation Allegation

Section 504 of the Trade Preferences Extension Act of 2015 amended the Act by adding the concept of particular market situation (PMS) for purposes of constructed value under section 773(e) of the Act.[1] Section 773(e) of the Act states that ''if a particular market situation exists such that the cost of materials and fabrication or other processing of any kind does not accurately reflect the cost of production in the ordinary course of trade, the administering authority may use another calculation methodology under this subtitle or any other calculation methodology.'' When an interested party submits a PMS allegation pursuant to section 773(e) of the Act, Commerce will respond to such a submission consistent with 19 CFR 351.301(c)(2)(v). If Commerce finds that a PMS exists under section 773(e) of the Act, then it will modify its dumping calculations appropriately.

Neither section 773(e) of the Act nor 19 CFR 351.301(c)(2)(v) set a deadline for the submission of PMS allegations and supporting factual information. However, in order to administer section 773(e) of the Act, Commerce must receive PMS allegations and supporting factual information with enough time to consider the submission. Thus, should an interested party wish to submit a PMS allegation and supporting new factual information pursuant to section 773(e) of the Act, it must do so no later than 20 days after submission of initial Section D responses.

Opportunity To Request a Review: Not later than the last day of June 2020,[2] interested parties may request administrative review of the following orders, findings, or suspended investigations, with anniversary dates in June for the following periods:

Antidumping Duty Proceedings	
GERMANY: Certain Cold-Drawn Mechanical Tubing of Carbon and Alloy Steel, A–428–845	6/1/19–5/31/20
INDIA:	
Certain Cold-Drawn Mechanical Tubing of Carbon and Alloy Steel, A–533–873	6/1/19–5/31/20
Glycine, A–533–883	10/31/18–5/31/20
ITALY: Certain Cold-Drawn Mechanical Tubing of Carbon and Alloy Steel, A–475–838	6/1/19–5/31/20
JAPAN:	
Carbon and Alloy Seamless Standard, Line, and Pressure (over 4½ inches), A–588–850	6/1/19–5/31/20
Carbon and Alloy Seamless Standard, Line, and Pressure (under 4½ inches), A–588–851	6/1/19–5/31/20
Glycine, A–588–878	10/31/18–5/31/20
MEXICO: Prestressed Concrete Steel Rail Tie Wire, A–201–843	6/1/19–6/23/19
REPUBLIC OF KOREA: Certain Cold-Drawn Mechanical Tubing of Carbon and Alloy Steel, A–580–892	6/1/19–5/31/20

[1] *See* Trade Preferences Extension Act of 2015, Public Law 114–27, 129 Stat. 362 (2015).

[2] Or the next business day, if the deadline falls on a weekend, federal holiday or any other day when Commerce is closed.

SOCIALIST REPUBLIC OF VIETNAM:	
Certain Tool Chests and Cabinets, A–552–821	6/1/19–5/31/20
Laminated Woven Sacks, A–552–823	10/11/18–5/31/20
SPAIN:	
Chlorinated Isocyanurates, A–469–814	6/1/19–5/31/20
Finished Carbon Steel Flanges, A–469–815	6/1/19–5/31/20
SWITZERLAND: Certain Cold-Drawn Mechanical Tubing of Carbon and Alloy Steel, A–441–801	6/1/19–5/31/20
TAIWAN: Helical Spring Lock Washers, A–583–820	6/1/19–5/31/20
THE PEOPLE'S REPUBLIC OF CHINA:	
Artist Canvas, A–570–899	6/1/19–5/31/20
Certain Cold-Drawn Mechanical Tubing of Carbon and Alloy Steel, A–570–058	6/1/19–5/31/20
Certain Tool Chests and Cabinets, A–570–056	6/1/19–5/31/20
Chlorinated Isocyanurates, A–570–898	6/1/19–5/31/20
Furfuryl Alcohol, A–570–835	6/1/19–5/31/20
High Pressure Steel Cylinders, A–570–977	6/1/19–5/31/20
Certain Polyester Staple Fiber, A–570–905	6/1/19–5/31/20
Prestressed Concrete Steel Rail Tie Wire, A–570–990	6/1/19–6/23/19
Prestressed Concrete Steel Wire Strand, A–570–945	6/1/19–5/31/20
Silicon Metal, A–570–806	6/1/19–5/31/20
Tapered Roller Bearings, A–570–601	6/1/19–5/31/20
Countervailing Duty Proceedings	
INDIA: Glycine, C–533–884	9/4/18–12/31/19
SOCIALIST REPUBLIC OF VIETNAM: Laminated Woven Sacks, C–552–824	8/13/18–12/31/19
THE PEOPLE'S REPUBLIC OF CHINA:	
Glycine, C–570–081	9/4/18–12/31/19
High Pressure Steel Cylinders, C–570–978	1/1/19–12/31/19
Stainless Steel Flanges, C–570–065	1/1/19–12/31/19
Suspension Agreements	
None.	

In accordance with 19 CFR 351.213(b), an interested party as defined by section 771(9) of the Act may request in writing that the Secretary conduct an administrative review. For both antidumping and countervailing duty reviews, the interested party must specify the individual producers or exporters covered by an antidumping finding or an antidumping or countervailing duty order or suspension agreement for which it is requesting a review. In addition, a domestic interested party or an interested party described in section 771(9)(B) of the Act must state why it desires the Secretary to review those particular producers or exporters. If the interested party intends for the Secretary to review sales of merchandise by an exporter (or a producer if that producer also exports merchandise from other suppliers) which was produced in more than one country of origin and each country of origin is subject to a separate order, then the interested party must state specifically, on an order-by-order basis, which exporter(s) the request is intended to cover.

Note that, for any party Commerce was unable to locate in prior segments, Commerce will not accept a request for an administrative review of that party absent new information as to the party's location. Moreover, if the interested party who files a request for review is unable to locate the producer or exporter for which it requested the review, the interested party must provide an explanation of the attempts it made to locate the producer or exporter at the same time it files its request for review, in order for the Secretary to determine if the interested party's attempts were reasonable, pursuant to 19 CFR 351.303(f)(3)(ii).

As explained in *Antidumping and Countervailing Duty Proceedings: Assessment of Antidumping Duties,* 68 FR 23954 (May 6, 2003), and *Non-Market Economy Antidumping Proceedings: Assessment of Antidumping Duties,* 76 FR 65694 (October 24, 2011), Commerce clarified its practice with respect to the collection of final antidumping duties on imports of merchandise where intermediate firms are involved. The public should be aware of this clarification in determining whether to request an administrative review of merchandise subject to antidumping findings and orders.[3]

Commerce no longer considers the non-market economy (NME) entity as an exporter conditionally subject to an antidumping duty administrative reviews.[4] Accordingly, the NME entity will not be under review unless Commerce specifically receives a request for, or self-initiates, a review of the NME entity.[5] In administrative reviews of antidumping duty orders on merchandise from NME countries where a review of the NME entity has not been initiated, but where an individual exporter for which a review was initiated does not qualify for a separate rate, Commerce will issue a final decision indicating that the company in question is part of the NME entity. However, in that situation, because no review of the NME entity was conducted, the NME entity's entries were not subject to the review and the rate for the NME entity is not subject to change as a result of that review (although the rate for the individual exporter may change as a function of the finding that the exporter is part of the NME entity). Following initiation of an antidumping administrative review when there is no review requested of the NME entity, Commerce will instruct CBP to liquidate entries for all exporters not named in the initiation notice, including those that were suspended at the NME entity rate.

All requests must be filed electronically in Enforcement and Compliance's Antidumping and Countervailing Duty Centralized Electronic Service System (ACCESS) on Enforcement and Compliance's ACCESS

[3] *See* the Enforcement and Compliance website at *https://legacy.trade.gov/enforcement/.*

[4] *See Antidumping Proceedings: Announcement of Change in Department Practice for Respondent Selection in Antidumping Duty Proceedings and Conditional Review of the Nonmarket Economy Entity in NME Antidumping Duty Proceedings,* 78 FR 65963 (November 4, 2013).

[5] In accordance with 19 CFR 351.213(b)(1), parties should specify that they are requesting a review of entries from exporters comprising the entity, and to the extent possible, include the names of such exporters in their request.

website at *https://access.trade.gov.*[6] Further, in accordance with 19 CFR 351.303(f)(l)(i), a copy of each request must be served on the petitioner and each exporter or producer specified in the request. Note that Commerce has temporarily modified certain of its requirements for serving documents containing business proprietary information, until July 17, 2020, unless extended.[7]

Commerce will publish in the **Federal Register** a notice of ''Initiation of Administrative Review of Antidumping or Countervailing Duty Order, Finding, or Suspended Investigation'' for requests received by the last day of June 2020. If Commerce does not receive, by the last day of June 2020, a request for review of entries covered by an order, finding, or suspended investigation listed in this notice and for the period identified above, Commerce will instruct CBP to assess antidumping or countervailing duties on those entries at a rate equal to the cash deposit of estimated antidumping or countervailing duties required on those entries at the time of entry, or withdrawal from warehouse, for consumption and to continue to collect the cash deposit previously ordered.

For the first administrative review of any order, there will be no assessment of antidumping or countervailing duties on entries of subject merchandise entered, or withdrawn from warehouse, for consumption during the relevant provisional-measures ''gap'' period of the order, if such a gap period is applicable to the period of review.

This notice is not required by statute but is published as a service to the international trading community.

Dated: May 27, 2020.

James Maeder,

Deputy Assistant Secretary for Antidumping and Countervailing Duty Operations.

[FR Doc. 2020–11887 Filed 6–1–20; 8:45 am]

BILLING CODE 3510–DS–P

[6] *See Antidumping and Countervailing Duty Proceedings: Electronic Filing Procedures; Administrative Protective Order Procedures,* 76 FR 39263 (July 6, 2011).

[7] *See Temporary Rule Modifying AD/CVD Service Requirements Due to COVID–19,* 85 FR 29615 (May 18, 2020).

DEPARTMENT OF COMMERCE

[C–570–127]

Certain Non-Refillable Steel Cylinders From the People's Republic of China: Postponement of Preliminary Determination in the Countervailing Duty Investigation

AGENCY: Enforcement and Compliance, International Trade Administration, Department of Commerce.

DATES: Applicable June 2, 2020.

FOR FURTHER INFORMATION CONTACT: Stephanie Moore, AD/CVD Operations, Enforcement and Compliance, International Trade Administration, U.S. Department of Commerce, 1401 Constitution Avenue NW, Washington, DC 20230; telephone: (202) 482–3692.

SUPPLEMENTARY INFORMATION:

Background

On April 16, 2020, the Department of Commerce (Commerce) initiated a countervailing duty (CVD) investigation of imports of certain non-refillable steel cylinders from the People's Republic of China.[1] Currently, the preliminary determination is due no later than June 22, 2020.

Postponement of Preliminary Determination

Section 703(b)(1) of the Tariff Act of 1930, as amended (the Act), requires Commerce to issue the preliminary determination in a CVD investigation within 65 days after the date on which Commerce initiated the investigation. However, section 703(c)(1) of the Act permits Commerce to postpone the preliminary determination until no later than 130 days after the date on which Commerce initiated the investigation if: (A) The petitioner makes a timely request for a postponement; or (B) Commerce concludes that the parties concerned are cooperating, that the investigation is extraordinarily complicated, and that additional time is necessary to make a preliminary determination. Under 19 CFR 351.205(e), the petitioner must submit a request for postponement 25 days or more before the scheduled date of the preliminary determination and must state the reasons for the request. Commerce will grant the request unless it finds compelling reasons to deny the request.[2]

On May 22, 2020, the petitioner in this investigation [3] submitted a timely request that Commerce postpone the preliminary CVD determination.[4] According to the petitioner, additional time is necessary to allow Commerce to analyze fully the questionnaire responses, request any necessary clarifications, and determine the extent to which countervailable subsidies have benefited the respondents in the preliminary phase of this proceeding.[5] Consistent with 19 CFR 351.205(e), the petitioner stated the reasons for its request, and Commerce finds no compelling reason to deny the request. Therefore, in accordance with section 703(c)(1)(A) of the Act, Commerce is postponing the deadline for the preliminary determination to no later than 130 days after the date on which this investigation was initiated, *i.e.,* August 24, 2020. Pursuant to section 705(a)(1) of the Act and 19 CFR 351.210(b)(1), the deadline for the final determination of this investigation will continue to be 75 days after the date of the preliminary determination, unless postponed at a later date.

Notification to Interested Parties

This notice is issued and published pursuant to section 703(c)(2) of the Act and 19 CFR 351.205(f)(1).

Dated: May 27, 2020.

Jeffrey I. Kessler,

Assistant Secretary for Enforcement and Compliance.

[FR Doc. 2020–11863 Filed 6–1–20; 8:45 am]

BILLING CODE 3510–DS–P

[1] *See Certain Non-Refillable Steel Cylinders from the People's Republic of China: Initiation of Countervailing Duty Investigation,* 85 FR 22407 (April 22, 2020).

[2] *See* 19 CFR 351.205(e).

[3] The petitioner is Worthington Industries.

[4] *See* Petitioner's Letter, ''Certain Non-Refillable Steel Cylinders from the People's Republic of China—Petitioner's Request to Postpone Preliminary Determination,'' dated May 22, 2020.

[5] *Id.*

DEPARTMENT OF COMMERCE

National Oceanic and Atmospheric Administration

[RTID 0648–XA205]

Schedules for Atlantic Shark Identification Workshops and Safe Handling, Release, and Identification Workshops; Correction

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

ACTION: Notice of public workshops; correction.

SUMMARY: NMFS announces that the dates for the Atlantic Shark Identification workshops originally scheduled for May 7, 2020, in Ronkonkoma, NY, and for June 11,

2020, in Manahawkin, NJ have been changed to August 20, 2020, and September 17, 2020, respectively. Also, NMFS is rescheduling the Safe Handling, Release, and Identification workshops originally scheduled for on, Key Largo, FL on May 1, 2020; and Kenner, LA on May 4, 2020. The dates for these workshops have been changed to July 13, 2020, and July 27, 2020, respectively. The workshop times and locations remains unchanged: 12 p.m.–4 p.m. for the Atlantic Shark Identification workshops; and, 9 a.m.–5 p.m. for the Safe Handling, Release, and Identification workshops. Atlantic Shark Identification workshops are mandatory for federally-permitted Atlantic shark dealers. Safe Handling, Release, and Identification workshops are mandatory for shark and swordfish limited-access permit holders who fish with longline or gillnet gear. Additional free workshops will be conducted during 2020.

DATES: The dates for the Atlantic Shark Identification workshops originally scheduled for May 7, 2020, in Ronkonkoma, NY, and for June 11, 2020, in Manahawkin, NJ have been changed to August 20, 2020, and September 17, 2020, respectively. Also, the dates for the Safe Handling, Release, and Identification workshops originally scheduled for Key Largo, FL on May 1, 2020, and Kenner, LA on May 4, 2020, have been changed to July 13, 2020, and July 27, 2020, respectively, unless further noticed. See **SUPPLEMENTARY INFORMATION** for further details.

ADDRESSES: The Atlantic Shark Identification workshops remain at La Quinta Inn, 10 Aero Road, Bohemia, NY 11716; and, Holiday Inn, 151 Route 72 West, Manahawkin, NJ 08050. The Safe Handling, Release, and Identification workshops remain at Holiday Inn, 99701 Overseas Highway, Key Largo, FL 33037; and, Hilton Hotel, 901 Airline Drive, Kenner, LA 70062. See **SUPPLEMENTARY INFORMATION** for further details.

FOR FURTHER INFORMATION CONTACT: Rick Pearson by phone: (727) 551–5742.

SUPPLEMENTARY INFORMATION: The workshop schedules, registration information, and a list of frequently asked questions regarding these workshops are posted on the internet at: *https://www.fisheries.noaa.gov/atlantic-highly-migratory-species/safe-handling-release-and-identification-workshops,* and *https://www.fisheries.noaa.gov/atlantic-highly-migratory-species/atlantic-shark-identification-workshops.*

Correction

In the **Federal Register** (Doc. 2020–04022) of February 27, 2020, on page 11346, in the third column, correct the dates of the second and third Atlantic Shark Identification workshops listed under the heading *Workshop Dates, Times, and Locations* to read:

''2. August 20, 2020, 12 p.m.–4 p.m., Hilton Garden Inn, 3485 Veterans Memorial Highway, Ronkonkoma, NY 11779.

3. September 17, 2020, 12 p.m.–4 p.m., Holiday Inn, 151 Route 72 West, Manahawkin, NJ 08050.''

In the **Federal Register** (Doc. 2020–04022) of February 27, 2020, on page 11347, in the first column, correct the dates of the third and fourth Safe Handling, Release, and Identification workshops listed under the heading *Workshop Dates, Times, and Locations* to read:

''3. July 13, 2020, 9 a.m.–5 p.m., Holiday Inn, 99701 Overseas Highway, Key Largo, FL 33037.

4. July 27, 2020, 9 a.m.–5 p.m., Hilton Hotel, 901 Airline Drive, Kenner, LA 70062.''

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

Dated: May 27, 2020.

Hélène M.N. Scalliet,

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

[FR Doc. 2020–11785 Filed 6–1–20; 8:45 am]

BILLING CODE 3510–22–P

DEPARTMENT OF COMMERCE

National Oceanic and Atmospheric Administration

RTID 0648–XV182

Availability of Draft NOAA Education Strategic Plan

AGENCY: Education Council, National Oceanic and Atmospheric Administration (NOAA), Department of Commerce.

ACTION: Notice of availability; request for comments.

SUMMARY: The National Oceanic and Atmospheric Administration (NOAA) publishes this notice to solicit comments on the draft 2020–2040 NOAA Education Strategic Plan (Plan). NOAA received broad legislative authority from Congress through the America COMPETES Act (2007, 2010) and the American Innovation and Competitiveness Act (2017) to conduct, develop, support, promote, and coordinate formal and informal education activities at all levels to enhance public awareness and understanding of ocean, coastal, Great Lakes, and atmospheric science and stewardship by the general public and other coastal stakeholders, including underrepresented groups in ocean and atmospheric science and policy careers. The legislative authority requires NOAA to develop a 20 year plan that is updated every 5 years. This Plan updates the goals for NOAA Education established in the 2015–2035 Education Strategic Plan. NOAA is seeking broad public review of the Plan and encourages all stakeholders and users to review the Plan and provide comments. All comments received will be reviewed and considered in the final drafting of the Plan.

DATES: Comments must be received on or before July 2, 2020.

ADDRESSES: The draft Plan will be available on the following website: *https://www.noaa.gov/office-education/noaa-education-council/strategic-planning-evaluation.*

You may submit comments on this document by the following method:

Electronic Submission: Submit comments via email to *Education.Plan@noaa.gov.* Please include the identifier, ''Education Plan Public Comment'' in the subject line.

FOR FURTHER INFORMATION CONTACT: Andrea Sassard, Education Specialist, NOAA Office of Education, (202) 482–2947, *andrea.sassard@noaa.gov.*

SUPPLEMENTARY INFORMATION: NOAA's Education Council is soliciting general comments on the NOAA Education Strategic Plan, which describes NOAA's education goals and strategies. The Plan focuses on conducting, developing, supporting, promoting, and coordinating education activities to enhance awareness and understanding of mission-related sciences.

Since its creation, an important role for NOAA has been imparting scientific knowledge of the Earth's natural systems to benefit society and support the agency's mission. During this time, education was guided by the vision of leadership, the findings of researchers, the mandates of legislation for programs within NOAA, and to respond to the needs of society.

In 2007, Congress officially recognized the role of education in NOAA with the passage of the America COMPETES Act (Pub. L. 110–69). This legislation states: ''The Administrator, appropriate National Oceanic and Atmospheric Administration programs, ocean atmospheric science and education experts, and interested members of the public shall develop a science education plan setting forth education goals and strategies for the

Administration, as well as programmatic actions to carry out such goals and priorities over the next 20 years, and evaluate and update such plan every 5 years.''

NOAA is revising its Education Strategic Plan as specified in the America COMPETES Act and subsequent legislation. Based on NOAA's mission, strengths, and the future needs of our society, the draft plan includes five education goals:

Goal 1—Science-Informed Society: An informed society has access to, interest in, and understanding of NOAA-related sciences and their implications for current and future events.

Goal 2—Conservation & Stewardship: Individuals and communities are actively involved in stewardship behaviors and decisions that conserve, restore, and protect natural and cultural resources related to NOAA's mission.

Goal 3—Ready, Responsive, Resilient: Individuals and communities are ready, responsive, and resilient to the increasing challenges and impacts of hazardous weather, changes in climate, and other environmental threats monitored by NOAA.

Goal 4—Future Workforce: A diverse and highly skilled future workforce pursues careers in disciplines that support NOAA's mission.

Goal 5—Organizational Excellence: NOAA functions in a unified manner to support, plan, and deliver effective educational programs and partnerships that advance NOAA's mission.

NOAA welcomes comments on all aspects of the draft Plan, including any inconsistencies perceived within the Plan and any omissions of important topics or issues. This draft Plan is being issued for comment only and is not intended for interim use. For any shortcomings noted within the draft Plan, please propose specific remedies. Suggested changes will be incorporated where appropriate, and a final Plan will be posted on the NOAA Education Council website.

Please follow this format guidance for preparing and submitting comments. Using the format guidance will facilitate the processing of comments and assure that all comments are appropriately considered. Overview comments should be provided first and should be numbered. Comments that are specific to particular pages, paragraphs, or lines of the section should identify the page and line numbers to which they apply. Please number each page of your comments.

Dated: May 27, 2020.

Louisa Koch,

Director of Education, National Oceanic and Atmospheric Administration.

[FR Doc. 2020–11776 Filed 6–1–20; 8:45 am]

BILLING CODE 3510–22–P

DEPARTMENT OF COMMERCE

National Oceanic and Atmospheric Administration

[RTID 0648–XA217]

Mid-Atlantic Fishery Management Council (MAFMC); Public Meeting

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

ACTION: Notice; public meeting.

SUMMARY: The Mid-Atlantic Fishery Management Council's (Council) Mackerel, Squid, and Butterfish (MSB) Monitoring Committee will meet via webinar to develop recommendations for MSB specifications, focusing on the *Illex* squid fishery.

DATES: The meeting will be held on Monday, June 15, 2020 from 10 a.m.–noon.

ADDRESSES: The meeting will be held via webinar. Details on the proposed agenda, connection information, and briefing materials will be posted at the MAFMC website: *www.mafmc.org.*

Council address: Mid-Atlantic Fishery Management Council, 800 N. State Street, Suite 201, Dover, DE 19901; telephone: (302) 674–2331; *www.mafmc.org.*

FOR FURTHER INFORMATION CONTACT: Christopher M. Moore, Ph.D., Executive Director, Mid-Atlantic Fishery Management Council, telephone: (302) 526–5255.

SUPPLEMENTARY INFORMATION: The MSB Monitoring Committee will develop recommendations for MSB specifications, focusing on the *Illex* squid fishery.

Special Accommodations

The meeting is physically accessible to people with disabilities. Requests for sign language interpretation or other auxiliary aid should be directed to M. Jan Saunders, (302) 526–5251, at least 5 days prior to any meeting date.

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

Dated: May 28, 2020.

Tracey L. Thompson,

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

[FR Doc. 2020–11874 Filed 6–1–20; 8:45 am]

BILLING CODE 3510–22–P

DEPARTMENT OF COMMERCE

National Oceanic and Atmospheric Administration

RTID 0648–XY102

Fisheries of the Exclusive Economic Zone Off Alaska; Prohibited Species Donation Program

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

ACTION: Notice; selection of an authorized distributor.

SUMMARY: NMFS announces the renewal of two prohibited species donation (PSD) permits to SeaShare, authorizing this organization to distribute Pacific salmon and Pacific halibut to economically disadvantaged individuals under the PSD program. Salmon and halibut are caught incidentally during directed fishing for groundfish with trawl gear off Alaska. This action is necessary to comply with provisions of the PSD program and is intended to promote the goals and objectives of the North Pacific Fishery Management Council.

DATES: The permits are effective from June 2, 2020 through May 28, 2023.

ADDRESSES: Electronic copies of the PSD permits for salmon and halibut prepared for this action may be obtained from the Alaska Region website at *https://www.fisheries.noaa.gov/region/alaska.*

FOR FURTHER INFORMATION CONTACT: Megan Mackey, 907–586–7228.

SUPPLEMENTARY INFORMATION:

Background

Fishing for groundfish by United States (U.S.) vessels in the exclusive economic zone of the Bering Sea and Aleutian Islands management area (BSAI) and Gulf of Alaska (GOA) is managed by NMFS in accordance with the Fishery Management Plan for Groundfish of the Bering Sea and Aleutian Islands Management Area (BSAI FMP) and the Fishery Management Plan for Groundfish of the Gulf of Alaska (GOA FMP). These fishery management plans (FMPs) were prepared by the North Pacific Fishery Management Council under the Magnuson-Stevens Fishery

Conservation and Management Act, 16 U.S.C. 1801 *et seq.* Regulations governing the Alaska groundfish fisheries and implementing the FMPs appear at 50 CFR parts 600 and 679. Fishing for halibut in waters in and off Alaska is governed by the Convention between the U.S. and Canada for the Preservation of the Halibut Fishery of the North Pacific Ocean and Bering Sea (Convention). The International Pacific Halibut Commission (IPHC) promulgates regulations pursuant to the Convention. The IPHC's regulations are subject to approval by the Secretary of State with concurrence from the Secretary of Commerce. After approval by the Secretary of State and the Secretary of Commerce, the IPHC regulations are published in the **Federal Register** as annual management measures pursuant to 50 CFR 300.62.

Retention of incidentally caught prohibited species is prohibited in the groundfish fisheries except for salmon and halibut for the purposes of the PSD program. Amendments 26 and 29 to the BSAI and GOA FMPs, respectively, authorize a salmon donation program and were approved by NMFS on July 10, 1996; a final rule implementing this program was published in the **Federal Register** on July 24, 1996 (61 FR 38358). The salmon donation program was expanded to include halibut as part of the PSD program under Amendments 50 and 50 to the FMPs that were approved by NMFS on May 6, 1998. A final rule implementing Amendments 50 and 50 was published in the **Federal Register** on June 12, 1998 (63 FR 32144). Although that final rule contained a sunset provision for the halibut PSD program of December 31, 2000, the halibut PSD program was permanently extended under a final rule published in the **Federal Register** on December 14, 2000 (65 FR 78119). A full description of the PSD program may be found in the preambles to the proposed rules for Amendments 26 and 29, and Amendments 50 and 50 (61 FR 24750, May 16, 1996, and 63 FR 10583, March 4, 1998).

Section 679.26 authorizes the voluntary distribution of salmon and halibut taken incidentally in the groundfish trawl fisheries off Alaska to economically disadvantaged individuals by tax-exempt organizations through an authorized distributor. The Administrator, Alaska Region, NMFS (Regional Administrator), may select one or more tax-exempt organizations to be authorized distributors, as defined by § 679.2, based on the information submitted by applicants under § 679.26. After review of qualified applicants, NMFS must announce the selection of each authorized distributor in the **Federal Register** and issue one or more PSD permits to each selected distributor.

Renewal of Permits to SeaShare

Currently, SeaShare, a tax-exempt organization founded to help the seafood industry donate to U.S. hunger relief efforts, is the sole authorized distributor of salmon and halibut taken incidentally in the groundfish trawl fisheries off Alaska. SeaShare's current salmon and halibut PSD permits became effective June 14, 2017, and authorize SeaShare to participate in the PSD program through June 15, 2020 (82 FR 27238, June 14, 2017).

On April 23, 2020, the Regional Administrator received an application from SeaShare to renew its salmon and halibut PSD permits. The Regional Administrator reviewed the application and determined that it is complete and that SeaShare continues to meet the requirements for an authorized distributor under the PSD program. As required by § 679.26(b)(2), the Regional Administrator based his selection on the following criteria:

1. *The number and qualifications of applicants for PSD permits.* SeaShare is the only applicant for PSD permits at this time. NMFS has previously approved applications submitted by SeaShare. As of the date of this notice, no other applications have been approved by NMFS. SeaShare has been coordinating the distribution of salmon taken incidentally in trawl fisheries since 1993, and of halibut taken incidentally in trawl fisheries since 1998, under exempted fishing permits from 1993 to 1998 and under the PSD program since 1998. SeaShare employs independent seafood quality control experts to ensure product quality is maintained by cold storage facilities and common carriers servicing the areas where salmon and halibut donations would take place.

2. *The number of harvesters and the quantity of fish that applicants can effectively administer.* Current participants in the PSD program administered by SeaShare include 12 shoreside processors and 136 catcher vessels delivering to shoreside processors, 34 catcher/processors, and 3 motherships. Two reprocessing plants that generate steaked salmon and halibut participate in the PSD program. SeaShare has the capacity to receive and distribute salmon and halibut from up to 60 processors and the associated catcher vessels. Therefore, it is anticipated that SeaShare has more than adequate capacity for any foreseeable expansion of donations.

Table 1 shows the total pounds of headed-and-gutted and steaked salmon and halibut donated to food bank organizations from 2017 through 2019. NMFS does not have information to convert accurately the net weights of salmon and halibut to numbers of salmon and numbers of halibut.

TABLE 1—HEADED-AND-GUTTED (H&G) AND STEAKED SALMON AND HALIBUT DONATED TO FOOD BANK ORGANIZATIONS

[Pounds]

	2017	2018	2019	Total
Salmon H&G	759	3,465	3,293	7,517
Salmon steaked	323,700	351,620	368,850	1,044,170
Halibut H&G	15,676	17,750	35,895	69,321
Halibut steaked	23,361	24,200	15,213	62,774
Total Inventory	363,496	397,035	423,251	1,183,782

3. *The anticipated level of salmon and halibut incidental catch based on salmon and halibut incidental catch from previous years.* The incidental catch of salmon and incidental catch mortality of halibut in the GOA and BSAI trawl fisheries are shown in Table 2.

TABLE 2—INCIDENTAL CATCH OF SALMON AND INCIDENTAL CATCH MORTALITY OF HALIBUT IN THE GOA AND BSAI TRAWL FISHERIES

[In number of fish or metric tons]

Area fishery	2017	2018	2019
BSAI Trawl Chinook Salmon Incidental Catch [1]	36,277 fish	17,394 fish	31,322 fish.
BSAI Trawl Other Salmon Incidental Catch [2]	471,447 fish	309,045 fish	358,804 fish.
GOA Trawl Chinook Salmon Incidental Catch [3]	24,801 fish	17,104 fish	23,893 fish.
GOA Trawl Other Salmon Incidental Catch [4]	5,634 fish	8,989 fish	6,407 fish.
BSAI Trawl Halibut Mortality [5]	1,635 mt	1,799 mt	2,079 mt.
GOA Trawl Halibut Mortality [6]	1,216 mt	1,163 mt	1,102 mt.

[1] *https://www.fisheries.noaa.gov/sites/default/files/akro/chinook_salmon_mortality2020.html* accessed on 04/26/20.
[2] *https://www.fisheries.noaa.gov/sites/default/files/akro/chum_salmon_mortality2020.html* accessed on 04/26/20.
[3] *https://www.fisheries.noaa.gov/sites/default/files/akro/chum_salmon_mortality2020.html* accessed on 4/27/20.
[4] *https://www.fisheries.noaa.gov/sites/default/files/akro/chum_salmon_mortality2020.html* accessed on 4/27/20.
[5] *https://www.fisheries.noaa.gov/alaska/commercial-fishing/fisheries-catch-and-landings-reports#bsai-prohibited-species* accessed on 4/27/20.
[6] *https://www.fisheries.noaa.gov/alaska/commercial-fishing/fisheries-catch-and-landings-reports#goa-prohibited-species* accessed on 4/27/20.

Halibut incidental catch amounts are constrained by an annual prohibited species catch (PSC) limits in the BSAI and GOA. Future halibut incidental catch levels likely will be similar to those experienced from 2017 through 2019.

Chinook salmon PSC limits are established for the Bering Sea and central and western GOA pollock fisheries that, when attained, result in the closure of pollock fishing. The Chinook salmon PSC limits for the Bering Sea pollock fisheries were originally established by Amendment 91 to the BSAI FMP (75 FR 53026, August 30, 2010) and established for the central and western GOA pollock fisheries by Amendment 93 to the GOA FMP (77 FR 42629, July 20, 2012). In 2016, Amendment 110 to the BSAI FMP was implemented to improve the management of Chinook and chum salmon bycatch in the Bering Sea pollock fishery by creating a comprehensive salmon bycatch avoidance program (81 FR 37534, June 10, 2016). In 2015, Amendment 97 to the GOA FMP established annual Chinook salmon PSC limits for the groundfish trawl fisheries, except for pollock trawl fisheries, in the Western and Central GOA (79 FR 71350, December 2, 2014). While salmon incidental catch amounts tend to vary between years, making it difficult to accurately predict future incidental take amounts, the total, or maximum, amount of annual Chinook salmon incidental catch in the Bering Sea and GOA pollock fisheries is constrained by the PSC limits.

4. *The number of vessels and processors participating in the PSD program.* For the 2020 permit renewal, there will be 12 shoreside processors, and vessels delivering to shoreside processors will decrease slightly from 137 to 136. Catcher/processors participating in the PSD program for salmon will decrease slightly from 35 to 34 under the 2020 permit renewal. Catcher vessels delivering to motherships will remain at 15 vessels.

NMFS issues PSD permits to SeaShare for a 3-year period unless the permits are suspended or revoked under § 679.26. The permits may not be transferred; however, they may be renewed following the application procedures in § 679.26.

If the authorized distributor modifies the list of participants in the PSD program or delivery locations, the authorized distributor must submit a modified list of participants or a modified list of delivery locations to the Regional Administrator.

These permits may be suspended, modified, or revoked under 15 CFR part 904 for violation of § 679.26 or other regulations in 50 CFR part 679.

Classification

This action is taken under § 679.26.

Authority: 16 U.S.C. 773 *et seq.;* 1801 *et seq.;* 3631 *et seq.;* Pub. L. 108–447; Pub. L. 111–281.

Dated: May 27, 2020.

Hélène M.N. Scalliet,

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

[FR Doc. 2020–11778 Filed 6–1–20; 8:45 am]

BILLING CODE 3510–22–P

COMMODITY FUTURES TRADING COMMISSION

Sunshine Act Meetings

TIME AND DATE: 10:00 a.m. EDT, Thursday, June 4, 2020.

PLACE: Conference call.

STATUS: Open.

MATTERS TO BE CONSIDERED: The Commodity Futures Trading Commission (''Commission'' or ''CFTC'') will hold this meeting to consider the following matter:

- Final Rule: Amendments to Registration and Compliance Requirements for Commodity Pool Operators and Commodity Trading Advisors: Prohibiting Exemptions under Regulation 4.13 on Behalf of Persons Subject to Certain Statutory Disqualifications.

The agenda for this meeting will be available to the public and posted on the Commission's website at *https://www.cftc.gov.* Instructions for public access to the live audio feed of the meeting will also be posted on the Commission's website. In the event that the time, date, or place of this meeting changes, an announcement of the change, along with the new time, date, or place of the meeting, will be posted on the Commission's website.

CONTACT PERSON FOR MORE INFORMATION: Christopher Kirkpatrick, Secretary of the Commission, 202–418–5964.

Authority: 5 U.S.C. 552b.

Dated: May 28, 2020.

Christopher Kirkpatrick,

Secretary of the Commission.

[FR Doc. 2020–11918 Filed 5–29–20; 11:15 am]

BILLING CODE 6351–01–P

DEPARTMENT OF DEFENSE

Office of the Secretary

[Docket ID DoD–2020–OS–0056]

Privacy Act of 1974; System of Records

AGENCY: Office of the Under Secretary of Defense (Comptroller) (OUSD(C)), Department of Defense (DoD).

ACTION: Notice of a new System of Records.

SUMMARY: The Office of the Secretary of Defense (OSD) is adding a new System

of Records entitled, ''Financial Management Online (FM Online), DUSDC 03.'' The DoD is required to strengthen the professional development of the DoD financial management workforce and to ensure DoD financial managers are properly trained to meet current and future Warfigher support requirements. The Defense Financial Management Certification Program (DFMCP) is the approved strategy to meet this requirement.

DATES: This new System of Records is effective upon publication; however, comments on the Routine Uses will be accepted on or before July 2, 2020. The Routine Uses are effective at the close of the comment period.

ADDRESSES: You may submit comments, identified by docket number and title, by any of the following methods:

- *Federal Rulemaking Portal: https://www.regulations.gov.*

Follow the instructions for submitting comments.

- *Mail:* DoD cannot receive written comments at this time due to the COVID–19 pandemic. Comments should be sent electronically to the docket listed above.

Instructions: All submissions received must include the agency name and docket number 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 *https://www.regulations.gov* as they are received without change, including any personal identifiers or contact information.

FOR FURTHER INFORMATION CONTACT: Mrs. Luz D. Ortiz, Chief, Records, Privacy and Declassification Division (RPDD), 1155 Defense Pentagon, Washington, DC 20311–1155, or by phone at (571) 372–0478.

SUPPLEMENTARY INFORMATION: The DFMCP implements DoD Instruction (DoDI) 1300.26, Operation of the DoD Financial Management Certification Program (DFMCP) and meets the business requirement to comply with 10 U.S.C. 1599d, Financial Management Positions: Authority to Prescribe Professional Certification and Credential Standards, as a condition of employment, authorizing the Secretary of Defense to establish a certification program for the 57,000 Financial Management (FM) workforce in order to improve audit readiness and analytic capability. The DFMCP is the approved strategy to meet this requirement and supports the DoDI 1400.25, Volume 250, DoD Civilian Personnel Management System: Civilian Strategic Human Capital Planning (SHCP).

FM Online, originally launched in 2011, is an online professional development portal for the DoD FM Workforce. The future state will enhance FM Online by adding a DoD FM Certification Tracking and Reporting module, thus creating a requirement to house Personally Identifiable Information (PII).

FM Online is sponsored by the OUSD(C). FM Online will support the DoD in administering a variety of professional development programs and tools to support the DoD Financial Management workforce. It will enable the OUSD(C) to identify skill and competency gaps and strengths and provide training and development tools to prepare the workforce to meet current and future requirements to support the mission. FM Online will support the mandatory three level professional certification program applicable to 57,000 members of the FM Workforce. Members must achieve the appropriate certification level for their positions within two years of notification of applicable certification requirements (or the period of any extension). Also, members must sustain their FM certification by the end of each two-year cycle by accomplishing Continuing Education and Training (CET) requirements.

The OSD notices for Systems of Records subject to the Privacy Act of 1974, as amended, have been published in the **Federal Register** and are available from the address in **FOR FURTHER INFORMATION CONTACT** or on the Defense Privacy, Civil Liberties, and Transparency Division website at *https://dpcld.defense.gov.*

The proposed system reports, as required by the Privacy Act, as amended, were submitted on April 13, 2020, to the House Committee on Oversight and Reform, the Senate Committee on Governmental Affairs, and the Office of Management and Budget (OMB) pursuant to Section 6 of OMB Circular No. A–108, ''Federal Agency Responsibilities for Review, Reporting, and Publication under the Privacy Act,'' revised December 23, 2016 (December 23, 2016, 81 FR 94424).

Dated: May 28, 2020.

Aaron T. Siegel,

Alternate OSD Federal Register Liaison Officer, Department of Defense.

SYSTEM NAME AND NUMBER:

Financial Management Online (FM Online), DUSDC 03.

SECURITY CLASSIFICATION:

Unclassified.

SYSTEM LOCATION:

Tinker Air Force Base, 8705 Industrial Blvd., Bldg. 3900, Oklahoma City, OK 73145–9037; and Maxwell Air Force Base, Gunter Annex, 401 E Moore Dr., Bldg. 857, Montgomery, AL 36114–6343.

SYSTEM MANAGER(S):

Program Manager, Financial Workforce Management, Human Capital and Resource Management Directorate, Office of the Under Secretary of Defense (Comptroller) (OUSD(C)), Room 3D755 Pentagon, Washington, DC 20301–1100. Email: *osd.pentagon.ousd-c.mbx.fwmd@mail.mil;* Telephone: (703) 697–0841.

AUTHORITY FOR MAINTENANCE OF THE SYSTEM:

5 U.S.C. Ch. 41: Training; 10 U.S.C. 1599d, Financial Management Positions: Authority to Prescribe Professional Certification and Credential Standards; Department of Defense Instruction (DoDI) 1300.26, Operation of the DoD Financial Management Certification Program (DFMCP); DoDI 1400.25, Volume 250, DoD Civilian Personnel Management System: Civilian Strategic Human Capital Planning (SHCP).

PURPOSE(S) OF THE SYSTEM:

To strengthen the professional development of the DoD Financial Management (FM) workforce and to ensure DoD financial managers are properly trained to meet current and future Warfighter support requirements. Records may also be used as a management tool for statistical analysis, tracking, reporting, evaluating program effectiveness, conducting research, and business management.

CATEGORIES OF INDIVIDUALS COVERED BY THE SYSTEM:

DoD FM military and civilian personnel obtaining and maintaining financial management certification.

CATEGORIES OF RECORDS IN THE SYSTEM:

Name, DoD Identification (DoD ID) Number; official duty address; work email address; official duty telephone; position, duty assignment, title, supervisor series; rank, grade; education level; Defense Civilian Personnel Data System (DCPDS) Identification Number, FM Online Unique Identification Number; DoD FM Certification Program (DFMCP) level, certificates of training completion; Non-Appropriated Funds Instrumentality (NAFI) number.

RECORD SOURCE CATEGORIES:

Individual; Component; DCPDS; and Military Personnel Data System (MilPDS).

ROUTINE USES OF RECORDS MAINTAINED IN THE SYSTEM, INCLUDING CATEGORIES OF USERS AND THE PURPOSES OF SUCH USES:

In addition to those disclosures generally permitted under 5 U.S.C. 552a(b) of the Privacy Act of 1974, as amended, the records contained herein may specifically be disclosed outside the DoD as a routine use pursuant to 5 U.S.C. 552(b)(3) as follows:

a. To contractors, grantees, experts, consultants, students, and others performing or working on a contract, service, grant, cooperative agreement, or other assignment for the federal government when necessary to accomplish an agency function related to this System of Records.

b. To the appropriate Federal, State, local, territorial, tribal, foreign, or international law enforcement authority or other appropriate entity where a record, either alone or in conjunction with other information, indicates a violation or potential violation of law, whether criminal, civil, or regulatory in nature.

c. To any component of the Department of Justice for the purpose of representing the DoD, or its components, officers, employees, or members in pending or potential litigation to which the record is pertinent.

d. In an appropriate proceeding before a court, grand jury, or administrative or adjudicative body or official, when the DoD or other Agency representing the DoD determines that the records are relevant and necessary to the proceeding; or in an appropriate proceeding before an administrative or adjudicative body when the adjudicator determines the records to be relevant to the proceeding.

e. To the National Archives and Records Administration for the purpose of records management inspections conducted under the authority of 44 U.S.C. 2904 and 2906.

f. To a Member of Congress or staff acting upon the Member's behalf when the Member or staff requests the information on behalf of, and at the request of, the individual who is the subject of the record.

g. To appropriate agencies, entities, and persons when (1) the DoD suspects or confirms a breach of the System of Records; (2) the DoD determines as a result of the suspected or confirmed breach there is a risk of harm to individuals, the DoD (including its information systems, programs, and operations), the Federal Government, or national security; and (3) the disclosure made to such agencies, entities, and persons is reasonably necessary to assist in connection with the DoD's efforts to respond to the suspected or confirmed breach or to prevent, minimize, or remedy such harm.

h. To another Federal agency or Federal entity, when the DoD determines information from this System of Records is reasonably necessary to assist the recipient agency or entity in (1) responding to a suspected or confirmed breach or (2) preventing, minimizing, or remedying the risk of harm to individuals, the recipient agency or entity (including its information systems, programs and operations), the Federal Government, or national security, resulting from a suspected or confirmed breach.

POLICIES AND PRACTICES FOR STORAGE OF RECORDS:

Electronic storage media.

POLICIES AND PRACTICES FOR RETRIEVAL OF RECORDS:

Information is retrieved by the individual's full name, DoD ID Number, office name where they were assigned or affiliated.

POLICIES AND PRACTICES FOR RETENTION AND DISPOSAL OF RECORDS:

Temporary. Cutoff annually, inactive accounts will be marked after 3 years. Destroy 6 years after inactivity.

ADMINISTRATIVE, TECHNICAL, AND PHYSICAL SAFEGUARDS:

Records are maintained in DoD controlled facilities. Physical entry is restricted by the use of locks, security guards, card swipe, closed circuit TV, and identification badges. Facilities are accessible only to authorized personnel. Access to records is limited to personnel responsible for servicing the record in performance of their official duties and who are properly screened and cleared for need-to-know. Access to system data is restricted through the use of a DoD issued Common Access Card (CAC), login pin and encryption. Access requires token authentication. Periodic security audits, regular monitoring of user's security practices and methods are applied to ensure only authorized personnel access system records.

RECORD ACCESS PROCEDURES:

Individuals seeking access to records about themselves should address written inquiries to the Office of the Secretary of Defense/Joint Staff Freedom of Information Act, Requester Service Center, Office of Freedom of Information, 1155 Defense Pentagon, Washington, DC 20301–1155. Signed, written requests should contain individual's full name, DoD ID Number, office name where they were assigned or affiliated, and office address and telephone number applicable to the period during which the records were maintained and the System of Records name and number. In addition, the requestor must provide either a notarized statement or a declaration made in accordance with 28 U.S.C. 1746, using the following format:

If executed within the United States, its territories, possessions, or commonwealths: ''I declare (or certify, verify, or state) under penalty of perjury that the foregoing is true and correct. Executed on (date). (Signature).''

If executed outside the United States: ''I declare (or certify, verify, or state) under penalty of perjury under the laws of the United States of America that the foregoing is true and correct. Executed on (date). (Signature).''

CONTESTING RECORD PROCEDURES:

The DoD rules for accessing records, for contesting contents and appealing initial agency determinations are published in 32 CFR part 310, or may be obtained from the system manager.

NOTIFICATION PROCEDURE:

Individuals seeking to determine whether information about themselves is contained in this System of Records should address written inquiries to Office of the Secretary of Defense/ Comptroller Human Capital and Resource Management Directorate, Financial Workforce Management Division, 1100 Defense Pentagon, Washington, DC 20301–1100. Signed written requests from individuals must include the following information for their records to be located: Full name, DoD ID Number, signature, available information regarding the type of information requested, the reason the individual believes this system contains information about him or her, the address to which the information should be sent, and System of Records name and number. In addition, the requestor must provide either a notarized statement or a declaration made in accordance with 28 U.S.C. 1746, using the following format:

If executed within the United States, its territories, possessions, or commonwealths: ''I declare (or certify, verify, or state) under penalty of perjury that the foregoing is true and correct. Executed on (date). (Signature).''

If executed outside the United States: ''I declare (or certify, verify, or state) under penalty of perjury under the laws of the United States of America that the foregoing is true and correct. Executed on (date). (Signature).''

EXEMPTIONS PROMULGATED FOR THE SYSTEM:

None.

HISTORY:

None.

[FR Doc. 2020–11860 Filed 6–1–20; 8:45 am]

BILLING CODE 5001–06–P

DEPARTMENT OF DEFENSE

Office of the Secretary

Charter Renewal of Department of Defense Federal Advisory Boards

AGENCY: Department of Defense (DoD).

ACTION: Renewal of Federal Advisory Board.

SUMMARY: The DoD is publishing this notice to announce that it is renewing the charter for the National Intelligence University Board of Visitors (''the Board'').

FOR FURTHER INFORMATION CONTACT: Jim Freeman, Advisory Board Management Officer for the Department of Defense, 703–692–5952.

SUPPLEMENTARY INFORMATION: The Board's charter is being renewed in accordance with the Federal Advisory Committee Act (FACA) (5 U.S.C., Appendix) and 41 CFR 102–3.50(d). The charter and contact information for the Board's Designated Federal Officer (DFO) are found at *https://www.facadatabase.gov/FACA/apex/FACAPublicAgencyNavigation.*

The Board shall provide independent advice and recommendations on matters related to mission, policy, accreditation, faculty, students, facilities, curricula, educational methods, research, and administration of the National Intelligence University.

The Board shall be comprised of no more than 12 individuals, who have extensive professional experience in the fields of national intelligence, national defense, and academia. The following ex officio positions shall also serve on the Board: The Under Secretary for Intelligence and Analysis, U.S. Department of Homeland Security, the Assistant Director of National Intelligence for Human Capital and Chief Human Capital Officer for the Intelligence Community, DoD Office of the Director of National Intelligence, and the Associate Director of the Central Intelligence Agency for Talent.

Board members who are not full-time or permanent part-time Federal civilian officers, employees, or active duty members of the Armed Forces will be appointed as experts or consultants, pursuant to 5 U.S.C. 3109, to serve as special government employee members. Board members who are full-time or permanent part-time Federal civilian officers, employees, or active duty members of the Armed Forces will be appointed pursuant to 41 CFR 102–3.130(a), to serve as regular government employee members.

All members of the Board are appointed to provide advice on the basis of their best judgment without representing any particular point of view and in a manner that is free from conflict of interest. Except for reimbursement of official Board-related travel and per diem, members serve without compensation.

The public or interested organizations may submit written statements to the Board membership about the Board's mission and functions. Written statements may be submitted at any time or in response to the stated agenda of planned meeting of the Board. All written statements shall be submitted to the DFO for the Board, and this individual will ensure that the written statements are provided to the membership for their consideration.

Dated: May 28, 2020.

Aaron T. Siegel,

Alternate OSD Federal Register Liaison Officer, Department of Defense.

[FR Doc. 2020–11873 Filed 6–1–20; 8:45 am]

BILLING CODE 5001–06–P

DEPARTMENT OF EDUCATION

[Docket No.: ED–2020–SCC–0082]

Agency Information Collection Activities; Comment Request; CARES Act, Recipient's Funding Certification and Agreement (SIP, MSI, FIPSE)

AGENCY: Office of Postsecondary Education (OPE), Department of Education (ED).

ACTION: Notice.

SUMMARY: In accordance with the Paperwork Reduction Act of 1995, ED is proposing an extension of an existing information collection.

DATES: Interested persons are invited to submit comments on or before August 3, 2020.

ADDRESSES: To access and review all the documents related to the information collection listed in this notice, please use *http://www.regulations.gov* by searching the Docket ID number ED–2020–SCC–0082. Comments submitted in response to this notice should be submitted electronically through the Federal eRulemaking Portal at *http://www.regulations.gov* by selecting the Docket ID number or via postal mail, commercial delivery, or hand delivery. If the *regulations.gov* site is not available to the public for any reason, ED will temporarily accept comments at *ICDocketMgr@ed.gov.* Please include the docket ID number and the title of the information collection request when requesting documents or submitting comments. *Please note that comments submitted by fax or email and those submitted after the comment period will not be accepted.* Written requests for information or comments submitted by postal mail or delivery should be addressed to the Director of the Strategic Collections and Clearance Governance and Strategy Division, U.S. Department of Education, 400 Maryland Ave. SW, LBJ, Room 6W–208D, Washington, DC 20202–4537.

FOR FURTHER INFORMATION CONTACT: For specific questions related to collection activities, please contact Gaby Watts, 202–453–7195.

SUPPLEMENTARY INFORMATION: The Department of Education (ED), in accordance with the Paperwork Reduction Act of 1995 (PRA) (44 U.S.C. 3506(c)(2)(A)), provides the general public and Federal agencies with an opportunity to comment on proposed, revised, and continuing collections of information. This helps the Department assess the impact of its information collection requirements and minimize the public's reporting burden. It also helps the public understand the Department's information collection requirements and provide the requested data in the desired format. ED is soliciting comments on the proposed information collection request (ICR) that is described below. The Department of Education is especially interested in public comment addressing the following issues: (1) Is this collection necessary to the proper functions of the Department; (2) will this information be processed and used in a timely manner; (3) is the estimate of burden accurate; (4) how might the Department enhance the quality, utility, and clarity of the information to be collected; and (5) how might the Department minimize the burden of this collection on the respondents, including through the use of information technology. Please note that written comments received in response to this notice will be considered public records.

Title of Collection: CARES Act, Recipient's Funding Certification and Agreement (SIP, MSI, FIPSE).

OMB Control Number: 1840–0843.

Type of Review: An extension of an existing information collection.

Respondents/Affected Public: State, Local, and Tribal Governments; Private Sector.

Total Estimated Number of Annual Responses: 2,620.

Total Estimated Number of Annual Burden Hours: 2,620.

Abstract: Section 18004(a)(2) of the CARES Act, Public Law 116–136 (March 27, 2020), authorizes the Secretary to make awards under parts A and B of title III, parts A and B of title V, and subpart 4 of part A of title VII of the Higher Education Act of 1965, as amended (''HEA''), to address needs directly related to the coronavirus. These awards are in addition to awards made in Section 18004(a)(1) of the CARES Act. Section 18004(a)(3) of the CARES Act, Pub. authorizes the Secretary to allocate funds for part B of Title VII of the HEA, for institutions of higher education (IHEs) that the Secretary determines have the greatest unmet needs related to coronavirus.

This information collection request (ICR) includes the certifications, and in some cases additional data, that IHEs must submit to request funds allocated under Sections 18004(a)(2) and 18004(a)(3) of the CARES Act. This ICR was previously approved as an emergency clearance in order to comply with the requirements of the CARES Act and expedite the release of funds to IHEs and students with pressing financial needs due to the pandemic.

Dated: May 28, 2020.

Kate Mullan,

PRA Coordinator, Strategic Collections and Clearance Governance and Strategy Division, Office of Chief Data Officer.

[FR Doc. 2020–11895 Filed 6–1–20; 8:45 am]

BILLING CODE 4000–01–P

DEPARTMENT OF EDUCATION

Annual Updates to the Income-Contingent Repayment (ICR) Plan Formula for 2020—William D. Ford Federal Direct Loan Program

AGENCY: Federal Student Aid, Department of Education.

ACTION: Notice.

SUMMARY: The Secretary announces the annual updates to the ICR plan formula for 2020 to give notice to borrowers and the public regarding how monthly ICR payment amounts will be calculated for the 2020–2021 year under the William D. Ford Federal Direct Loan (Direct Loan) Program, Catalog of Federal Domestic Assistance number 84.063.

DATES: The adjustments to the income percentage factors for the ICR plan formula contained in this notice are applicable from July 1, 2020, to June 30, 2021, for any borrower who enters the ICR plan or has his or her monthly payment amount recalculated under the ICR plan during that period.

FOR FURTHER INFORMATION CONTACT: Travis Sturlaugson, U.S. Department of Education, 830 First Street NE, Room 113H3, Washington, DC 20202. Telephone: (202) 377–4174. Email: *travis.sturlaugson@ed.gov.*

If you use a telecommunications device for the deaf (TDD) or a text telephone (TTY), call the Federal Relay Service, toll free, at 1–800–877–8339.

SUPPLEMENTARY INFORMATION: Under the Direct Loan Program, borrowers may choose to repay their non-defaulted loans (Direct Subsidized Loans, Direct Unsubsidized Loans, Direct PLUS Loans made to graduate or professional students, and Direct Consolidation Loans) under the ICR plan. The ICR plan bases the borrower's repayment amount on the borrower's Adjusted Gross Income (AGI), family size, loan amount, and the interest rate applicable to each of the borrower's loans.

ICR is one of several income-driven repayment plans. Other income-driven repayment plans include the Income-Based Repayment (IBR) plan, the Pay As You Earn Repayment (PAYE) plan, and the Revised Pay As You Earn Repayment (REPAYE) plan. The IBR, PAYE, and REPAYE plans provide lower payment amounts than the ICR plan for most borrowers.

A Direct Loan borrower who repays under the ICR plan pays the lesser of: (1) The monthly amount that would be required over a 12-year repayment period with fixed payments, multiplied by an income percentage factor; or (2) 20 percent of discretionary income.

Each year, to reflect changes in inflation, we adjust the income percentage factor used to calculate a borrower's ICR payment, as required by 34 CFR 685.209(b)(1)(ii)(A). We use the adjusted income percentage factors to calculate a borrower's monthly ICR payment amount when the borrower initially applies for the ICR plan or when the borrower submits his or her annual income documentation, as required under the ICR plan. This notice contains the adjusted income percentage factors for 2020, examples of how the monthly payment amount in ICR is calculated, and charts showing sample repayment amounts based on the adjusted ICR plan formula. This information is included in the following three attachments:

- *Attachment 1—Income Percentage Factors for 2020*
- *Attachment 2—Examples of the Calculations of Monthly Repayment Amounts*
- *Attachment 3—Charts Showing Sample Repayment Amounts for Single and Married Borrowers*

In Attachment 1, to reflect changes in inflation, we updated the income percentage factors that were published in the **Federal Register** on May 22, 2019 (84 FR 23539). Specifically, we have revised the table of income percentage factors by changing the dollar amounts of the incomes shown by a percentage equal to the estimated percentage change between the not-seasonally-adjusted Consumer Price Index for all urban consumers for December 2019 and December 2020.

The income percentage factors reflected in Attachment 1 may cause a borrower's payments to be lower than they were in prior years, even if the borrower's income is the same as in the prior year. The revised repayment amount more accurately reflects the impact of inflation on the borrower's current ability to repay.

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 at *www.govinfo.gov.* At this site, you can view this document, as well as all other documents of this Department published in the **Federal Register**, in text or Portable Document Format (PDF). To use PDF, you must have Adobe Acrobat Reader, which is available free at this 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. *Program Authority:* 20 U.S.C. 1087 *et seq.*

Mark A. Brown,

Chief Operating Officer, Federal Student Aid.

Attachment 1—Income Percentage Factors for 2020

INCOME PERCENTAGE FACTORS FOR 2020

Single		Married/head of household	
AGI	% Factor	AGI	% Factor
$12,392	55.00	$12,392	50.52
$17,051	57.79	$19,552	56.68
$21,940	60.57	$23,300	59.56
$26,940	66.23	$30,461	67.79
$31,715	71.89	$37,736	75.22
$37,736	80.33	$47,398	87.61
$47,398	88.77	$59,444	100.00
$59,445	100.00	$71,496	100.00
$71,496	100.00	$89,573	109.40
$85,929	111.80	$119,691	125.00
$110,029	123.50	$161,860	140.60
$155,839	141.20	$226,369	150.00
$178,683	150.00	$369,903	200.00
$318,265	200.00		

Attachment 2—Examples of the Calculations of Monthly Repayment Amounts

General notes about the examples in this attachment:

- We have a calculator that borrowers can use to estimate what their payment amounts would be under the ICR plan. The calculator is called the ''Loan Simulator'' and is available at *studentaid.gov/loan-simulator.* Based on information entered into the calculator by the borrower (for example, income, family size, and tax filing status), this calculator provides a detailed, individualized assessment of a borrower's loans and repayment plan options, including the ICR plan.
- The interest rates used in the examples are for illustration only. The actual interest rates on an individual borrower's Direct Loans depend on the loan type and when the postsecondary institution first disbursed the Direct Loan to the borrower.
- The Poverty Guideline amounts used in the examples are from the 2020 U.S. Department of Health and Human Services (HHS) Poverty Guidelines for the 48 contiguous States and the District of Columbia. Different Poverty Guidelines apply to residents of Alaska and Hawaii. The Poverty Guidelines for 2020 were published in the **Federal Register** on January 17, 2020 (85 FR 3060).
- All of the examples use an income percentage factor corresponding to an adjusted gross income (AGI) in the table in Attachment 1. If an AGI is not listed in the income percentage factors table in Attachment 1, the applicable income percentage can be calculated by following the instructions under the ''Interpolation'' heading later in this attachment.
- Married borrowers may repay their Direct Loans jointly under the ICR plan. If a married couple elects this option, we add the outstanding balance on the Direct Loans of each borrower and we add together both borrowers' AGIs to determine a joint ICR payment amount. We then prorate the joint payment amount for each borrower based on the proportion of that borrower's debt to the total outstanding balance. We bill each borrower separately.
- For example, if a married couple, John and Briana, has a total outstanding Direct Loan debt of $60,000, of which $40,000 belongs to John and $20,000 to Briana, we would apportion 67 percent of the monthly ICR payment to John and the remaining 33 percent to Briana. To take advantage of a joint ICR payment, married couples need not file taxes jointly; they may file separately and subsequently provide the other spouse's tax information to the borrower's Federal loan servicer.

Calculating the monthly payment amount using a standard amortization and a 12-year repayment period.

The formula to amortize a loan with a standard schedule (in which each payment is the same over the course of the repayment period) is as follows:

M = P × < (I ÷ 12) ÷ [1 − {1 + (I ÷ 12)}^ − N]>

In the formula—

- M is the monthly payment amount;
- P is the outstanding principal balance of the loan at the time the loan entered repayment;
- I is the annual interest rate on the loan, expressed as a decimal (for example, for a loan with an interest rate of 6 percent, 0.06); and
- N is the total number of months in the repayment period (for example, for a loan with a 12-year repayment period, 144 months).

For example, assume that Billy has a $10,000 Direct Unsubsidized Loan with an interest rate of 6 percent.

Step 1: To solve for M, first simplify the numerator of the fraction by which we multiply P, the outstanding principal balance. To do this divide I (the interest rate expressed as a decimal) by 12. In this example, Billy's interest rate is 6 percent. As a decimal, 6 percent is 0.06.

- 0.06 ÷ 12 = 0.005

Step 2: Next, simplify the denominator of the fraction by which we multiply P. To do this divide I (the interest rate expressed as a decimal) by 12. Then, add one. Next, raise the sum of the two figures to the negative power that corresponds to the length of the repayment period in months. In this example, because we are amortizing a loan to calculate the monthly payment amount under the ICR plan, the applicable figure is 12 years, which is 144 months. Finally, subtract the result from one.

- 0.06 ÷ 12 = 0.005
- 1 + 0.005 = 1.005
- 1.005 ∧ − 144 = 0.48762628
- 1 − 0.48762628 = 0.51237372

Step 3: Next, resolve the fraction by dividing the result from Step 1 by the result from Step 2.

- 0.005 ÷ 0.51237372 = 0.0097585

Step 4: Finally, solve for M, the monthly payment amount, by multiplying the outstanding principal balance of the loan by the result of Step 3.

- $10,000 × 0.0097585 = $97.59

The remainder of the examples in this attachment will only show the results of the formula. In each of the examples, the Direct Loan amounts represent the outstanding principal balance at the time the loans entered repayment.

Example 1. Kesha is single with no dependents and has $15,000 in Direct Subsidized and Unsubsidized Loans.

The interest rate on Kesha's loans is 6 percent, and she has an AGI of $31,715.

Step 1: Determine the total monthly payment amount based on what Kesha would pay over 12 years using standard amortization. To do this, use the formula that precedes Example 1. In this example, the monthly payment amount would be $146.38.

Step 2: Multiply the result of Step 1 by the income percentage factor shown in the income percentage factors table (see Attachment 1 to this notice) that corresponds to Kesha's AGI. In this example, an AGI of $31,715 corresponds to an income percentage factor of 71.89 percent.

- 0.7189 × $146.38 = $105.23

Step 3: Now, determine the monthly payment amount equal to 20 percent of Kesha's discretionary income (discretionary income is AGI minus the HHS Poverty Guideline amount for a borrower's family size and State of residence). To do this, subtract the HHS Poverty Guideline amount for a family of one from Kesha's AGI, multiply the result by 20 percent, and then divide by 12:

- $31,715 − $12,760 = $18,955
- $18,955 × 0.20 = $3,791
- $3,791 ÷ 12 = $315.91

Step 4: Compare the amount from Step 2 with the amount from Step 3. In this example, Kesha would pay the amount calculated under Step 2 ($105.23), since this is the lesser of the two payment amounts.

Note: Kesha would have a lower payment under other income-driven repayment plans. Specifically, Kesha's payment would be $104.79 under the PAYE and REPAYE plans. However, Kesha's payment would be $157.18 under the IBR plan, which is higher than the payment she would have under the ICR plan.

Example 2. Paul is married to Jesse and they have no dependents. They file their Federal income tax return jointly. Paul has a Direct Loan balance of $10,000, and Jesse has a Direct Loan balance of $15,000. Each of their Direct Loans has an interest rate of 6 percent.

Paul and Jesse have a combined AGI of $89,573 and are repaying their loans jointly under the ICR plan (for general information regarding joint ICR payments for married couples, see the fifth and sixth bullets under the heading ''General notes about the examples in this attachment'').

Step 1: Add Paul's and Jesse's Direct Loan balances to determine their combined aggregate loan balance:

- $10,000 + $15,000 = $25,000

Step 2: Determine the combined monthly payment amount for Paul and Jesse based on what both borrowers would pay over 12 years using standard amortization. To do this, use the formula that precedes Example 1. In this example, their combined monthly payment amount would be $243.96.

Step 3: Multiply the result of Step 2 by the income percentage factor shown in the income percentage factors table (see Attachment 1 to this notice) that corresponds to Paul and Jesse's combined AGI. In this example, the combined AGI of $89,573 corresponds to an income percentage factor of 109.40 percent.

- 1.094 × $243.96 = $266.90

Step 4: Now, determine the monthly payment amount equal to 20 percent of Paul and Jesse's combined discretionary income (discretionary income is AGI minus the HHS Poverty Guideline amount for a borrower's family size and State of residence). To do this, subtract the Poverty Guideline amount for a family of two from the combined AGI, multiply the result by 20 percent, and then divide by 12:

- $89,573 − $17,240 = $72,333
- $72,333 × 0.20 = $14,466.60
- $14,466.60 ÷ 12 = $1,205.55

Step 5: Compare the amount from Step 3 with the amount from Step 4. Paul and Jesse would jointly pay the amount calculated under Step 3 ($266.90), since this is the lesser of the two amounts.

Note: For Paul and Jesse, the ICR plan provides the lowest monthly payment of any income-driven repayment plan available. Paul and Jesse would not be eligible for the IBR or PAYE plans, and would have a combined monthly payment under the REPAYE plan of $530.94.

Step 6: Because Paul and Jesse are jointly repaying their Direct Loans under the ICR plan, the monthly payment amount calculated under Step 5 applies to Paul's and Jesse's combined loans. To determine the amount for which each borrower will be responsible, prorate the amount calculated under Step 4 by each spouse's share of the combined Direct Loan debt. Paul has a Direct Loan debt of $10,000 and Jesse has a Direct Loan debt of $15,000. For Paul, the monthly payment amount will be:

- $10,000 ÷ ($10,000 + $15,000) = 40 percent
- 0.40 × $266.90 = $106.76

For Jesse, the monthly payment amount will be:

- $15,000 ÷ ($10,000 + $15,000) = 60 percent
- 0.60 × $266.90 = $160.14

Example 3. Santiago is single with no dependents and has a combined balance of $60,000 in Direct Subsidized and Unsubsidized Loans. Each of Santiago's loans has an interest rate of 6 percent, and Santiago's AGI is $37,736.

Step 1: Determine the total monthly payment amount based on what Santiago would pay over 12 years using standard amortization. To do this, use the formula that precedes Example 1. In this example, the monthly payment amount would be $585.51.

Step 2: Multiply the result of Step 1 by the income percentage factor shown in the income percentage factors table (see Attachment 1 to this notice) that corresponds to Santiago's AGI. In this example, an AGI of $37,736 corresponds to an income percentage factor of 80.33 percent.

- 0.8033 × $585.51 = $470.34

Step 3: Now, determine the monthly payment amount equal to 20 percent of Santiago's discretionary income (discretionary income is AGI minus the HHS Poverty Guideline amount for a borrower's family size and State of residence). To do this, subtract the HHS Poverty Guideline amount for a family of one from Santiago's AGI, multiply the result by 20 percent, and then divide by 12:

- $37,736 − $12,760 = $24,976
- $24,976 × 0.20 = $4,995.20
- $4,995.20 ÷ 12 = $416.27

Step 4: Compare the amount from Step 2 with the amount from Step 3. In this example, Santiago would pay the amount calculated under Step 3 ($416.27), since this is the lesser of the two amounts.

Note: Santiago would have a lower payment under each of the other income-driven plans. Specifically, Santiago's payment would be $154.97 under the PAYE and REPAYE plans and $232.45 under the IBR plan.

Interpolation. If an AGI is not included on the income percentage factor table, calculate the income percentage factor through linear interpolation. For example, assume that Jocelyn is single with an AGI of $50,000.

Step 1: Find the closest AGI listed that is less than Jocelyn's AGI of $50,000 ($47,398) and the closest AGI listed that is greater than Jocelyn's AGI of $50,000 ($59,445).

Step 2: Subtract the lower amount from the higher amount (for this discussion we will call the result the ''income interval''):

- $59,445 − $47,398 = $12,047

Step 3: Determine the difference between the two income percentage factors that correspond to the AGIs used in Step 2 (for this discussion, we will call the result the ''income percentage factor interval''):

- 100.00 percent − 88.77 percent = 11.23 percent

Step 4: Subtract from Jocelyn's AGI the closest AGI shown on the chart that is less than Jocelyn's AGI of $50,000:

- $50,000 − $47,398 = $2,602

Step 5: Divide the result of Step 4 by the income interval determined in Step 2:

- $2,602 ÷ $12,047 = 21.60 percent

Step 6: Multiply the result of Step 5 by the income percentage factor interval that was calculated in Step 3:

- 11.23 percent × 21.60 percent = 2.43 percent

Step 7: Add the result of Step 6 to the lower of the two income percentage factors used in Step 3 to calculate the income percentage factor interval for an AGI of $50,000:

- 2.43 percent + 88.77 percent = 91.20 percent (rounded to the nearest hundredth)

The result is the income percentage factor that we will use to calculate Jocelyn's monthly repayment amount under the ICR plan.

Attachment 3—Charts Showing Sample Income-Driven Repayment Amounts for Single and Married Borrowers

Below are two charts that provide first-year payment amount estimates for a variety of loan debt sizes and AGIs under each of the income-driven repayment plans and the 10-Year Standard Repayment Plan. The first chart is for single borrowers who have a family size of one. The second chart is for a borrower who is married or a head of household and who has a family size of three. The calculations in Attachment 3 assume that the loan debt has an interest rate of 6 percent. For married borrowers, the calculations assume that the borrower files a joint Federal income tax return and that the borrower's spouse does not have Federal student loans. A field with a ''—'' character indicates that the borrower in the example would not be eligible to enter the applicable income-driven repayment plan based on the borrower's AGI, loan debt, and family size.

SAMPLE FIRST-YEAR MONTHLY REPAYMENT AMOUNTS FOR A SINGLE BORROWER

Family size = 1							
	AGI	Plan	$20,000	$40,000	$60,000	$80,000	$100,000
Initial Debt	$20,000	ICR	$116	$161	$195	$209	$232
		IBR	11	—	—	—	—
		PAYE	7	174	—	—	—
		REPAYE	7	174	340	507	674
		10-Year Standard	222	222	222	222	222
	40,000	ICR	121	321	390	417	463
		IBR	11	261	—	—	—
		PAYE	7	174	340	—	—
		REPAYE	7	174	340	507	674
		10-Year Standard	444	444	444	444	444
	60,000	ICR	121	454	586	626	695
		IBR	11	261	511	—	—
		PAYE	7	174	340	507	—
		REPAYE	7	174	340	507	674
		10-Year Standard	666	666	666	666	666
	80,000	ICR	121	454	781	835	926
		IBR	11	261	511	761	—
		PAYE	7	174	340	507	674
		REPAYE	7	174	340	507	674
		10-Year Standard	888	888	888	888	888
	100,000	ICR	121	454	787	1,044	1,158
		IBR	11	261	511	761	1,011
		PAYE	7	174	340	507	674
		REPAYE	7	174	340	507	674
		10-Year Standard	1,110	1,110	1,110	1,110	1,110

SAMPLE FIRST-YEAR MONTHLY REPAYMENT AMOUNTS FOR A MARRIED OR HEAD-OF-HOUSEHOLD BORROWER

Family size = 3							
	AGI	Plan	$20,000	$40,000	$60,000	$80,000	$100,000
Initial Debt	$20,000	ICR	$0	$152	$195	$204	$224
		IBR	0	93	—	—	—
		PAYE	0	62	—	—	—
		REPAYE	0	62	229	395	562
		10-Year Standard	222	222	222	222	222
	$40,000	ICR	0	305	390	408	448
		IBR	0	93	343	—	—
		PAYE	0	62	229	395	—
		REPAYE	0	62	229	395	562
		10-Year Standard	444	444	444	444	444
	$60,000	ICR	0	305	586	611	672
		IBR	0	93	343	593	—
		PAYE	0	62	229	395	562
		REPAYE	0	62	229	395	562
		10-Year Standard	666	666	666	666	666
	80,000	ICR	0	305	638	815	896
		IBR	0	93	343	593	843

SAMPLE FIRST-YEAR MONTHLY REPAYMENT AMOUNTS FOR A MARRIED OR HEAD-OF-HOUSEHOLD BORROWER—Continued

Family size = 3							
	AGI	Plan	$20,000	$40,000	$60,000	$80,000	$100,000
	100,000	PAYE	0	62	229	395	562
		REPAYE	0	62	229	395	562
		10-Year Standard	888	888	888	888	888
		ICR	0	305	638	971	1,120
		IBR	0	93	343	593	843
		PAYE	0	62	229	395	562
		REPAYE	0	62	229	395	562
		10-Year Standard	1,110	1,110	1,110	1,110	1,110

[FR Doc. 2020–11818 Filed 6–1–20; 8:45 am]
BILLING CODE 4000–01–P

DEPARTMENT OF EDUCATION

[Docket No.: ED–2020–SCC–0080]

Agency Information Collection Activities; Submission to the Office of Management and Budget for Review and Approval; Comment Request; Native American Language (NAL@ED) Application Package

AGENCY: Office of Elementary and Secondary Education (OESE), Department of Education (ED).

ACTION: Notice.

SUMMARY: In accordance with the Paperwork Reduction Act of 1995, ED is proposing a reinstatement of a previously approved information collection.

DATES: Interested persons are invited to submit comments on or before July 2, 2020.

ADDRESSES: Written comments and recommendations for proposed information collection requests should be sent within 30 days of publication of this notice to *www.reginfo.gov/public/do/PRAMain.* Find this particular information collection request by selecting ''Department of Education'' under ''Currently Under Review,'' then check ''Only Show ICR for Public Comment'' checkbox.

FOR FURTHER INFORMATION CONTACT: For specific questions related to collection activities, please contact Donna Sabis-Burns, 202–453–7077.

SUPPLEMENTARY INFORMATION: The Department of Education (ED), in accordance with the Paperwork Reduction Act of 1995 (PRA) (44 U.S.C. 3506(c)(2)(A)), provides the general public and Federal agencies with an opportunity to comment on proposed, revised, and continuing collections of information. This helps the Department assess the impact of its information collection requirements and minimize the public's reporting burden. It also helps the public understand the Department's information collection requirements and provide the requested data in the desired format. ED is soliciting comments on the proposed information collection request (ICR) that is described below. The Department of Education is especially interested in public comment addressing the following issues: (1) Is this collection necessary to the proper functions of the Department; (2) will this information be processed and used in a timely manner; (3) is the estimate of burden accurate; (4) how might the Department enhance the quality, utility, and clarity of the information to be collected; and (5) how might the Department minimize the burden of this collection on the respondents, including through the use of information technology. Please note that written comments received in response to this notice will be considered public records.

Title of Collection: Native American Language (NAL@ED) Application Package.

OMB Control Number: 1810–0731.

Type of Review: A reinstatement of a previously approved information collection.

Respondents/Affected Public: State, Local, and Tribal Governments.

Total Estimated Number of Annual Responses: 50.

Total Estimated Number of Annual Burden Hours: 1,500.

Abstract: On February 27, 2020 Department of Education (Department) published in the **Federal Register** a Notice of Proposed Priorities for the Native American Language Program (NAL@ED) (Vol. 85, No. 39, pages 11322–11329). The priorities, requirements, definitions, and selection criteria are proposed to foster the development, improvement, expansion, or maintenance of programs that support elementary or secondary schools in using Native American and Alaska Native languages as the primary language of instruction. At the time the notice of proposed priorities was published, no Information Collection Request was submitted. We are publishing a separate 30-day **Federal Register** notice to solicit public comment on the paperwork burden now. This is a request for a reinstatement with change of a previously approved information collection request. The previous application was used to implement the first NAL@ED competition under the statutory changes made to the Elementary and Secondary Education Act by the Every Student Succeeds Act, under a wavier of rulemaking (section 437(d)(1) of the General Education Provisions Act).

Dated: May 28, 2020.

Kate Mullan,

PRA Coordinator, Strategic Collections and Clearance Governance and Strategy Division, Office of Chief Data Officer.

[FR Doc. 2020–11884 Filed 6–1–20; 8:45 am]
BILLING CODE 4000–01–P

DEPARTMENT OF ENERGY

[Case Number 2018–004; EERE–2018–BT–WAV–0007]

Energy Conservation Program: Decision and Order Granting a Waiver to LG Electronics USA, Inc. From the Department of Energy Portable Air Conditioner Test Procedure

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

ACTION: Notice of decision and order.

SUMMARY: The U.S. Department of Energy (''DOE'') gives notice of a Decision and Order (Case Number 2018–004) that grants LG Electronics USA, Inc. (''LG'') a waiver from specified portions of the DOE test procedure for determining the energy efficiency of listed portable air conditioner basic models. Under the

Decision and Order, LG is required to test and rate the listed basic models of its portable air conditioners in accordance with the alternate test procedure specified in the Decision and Order.

DATES: The Decision and Order is effective on June 2, 2020. The Decision and Order will terminate upon the compliance date of any future amendment to the test procedure for portable air conditioners located in 10 CFR part 430, subpart B, appendix CC that addresses the issues presented in this waiver. At that time, LG must use the relevant test procedure for this product for any testing to demonstrate compliance with standards and any representations of energy use.

FOR FURTHER INFORMATION CONTACT:

Ms. Lucy deButts, U.S. Department of Energy, Office of Energy Efficiency and Renewable Energy, Building Technologies Office, EE–5B, 1000 Independence Avenue SW, Washington, DC, 20585–0121. Email: *AS_Waiver_Requests@ee.doe.gov.*

Ms. Sarah Butler, U.S. Department of Energy, Office of the General Counsel, GC–33, Forrestal Building, 1000 Independence Avenue SW, Washington, DC 20585–0103. Telephone: (202) 586–1777. Email: *Sarah.Butler@hq.doe.gov.*

SUPPLEMENTARY INFORMATION: In accordance with Title 10 of the Code of Federal Regulations (''CFR'') (10 CFR 430.27(f)(2)), DOE gives notice of the issuance of its Decision and Order as set forth below. The Decision and Order grants LG a waiver from the applicable test procedure in 10 CFR part 430, subpart B, appendix CC (''Appendix CC'') for listed basic models of portable air conditioners, if LG tests and rates those portable air conditioners using the alternate test procedure specified in the Decision and Order. LG's representations concerning the energy efficiency of the listed basic models must be based on testing according to the provisions and restrictions in the alternate test procedure set forth in the Decision and Order, and the representations must fairly disclose the test results. Distributors, retailers, and private labelers also must comply with the same requirements when making representations regarding the energy efficiency of these products. (42 U.S.C. 6293(c))

Consistent with 10 CFR 430.27(j), not later than August 3, 2020, any manufacturer currently distributing in commerce in the United States a product employing a technology or characteristic that results in the same need for a waiver from the applicable test procedure must submit a petition for waiver. Manufacturers not currently distributing such products in commerce in the United States must petition for and be granted a waiver prior to the distribution in commerce of those products in the United States. Manufacturers may also submit a request for interim waiver pursuant to the requirements of 10 CFR 430.27.

Signing Authority

This document of the Department of Energy was signed on May 8, 2020, by Alexander N. Fitzsimmons, Deputy Assistant Secretary for Energy Efficiency, pursuant to delegated authority from the Secretary of Energy. That document with the original signature and date is maintained by DOE. For administrative purposes only, and in compliance with requirements of the Office of the Federal Register, the undersigned DOE Federal Register Liaison Officer has been authorized to sign and submit the document in electronic format for publication, as an official document of the Department of Energy. This administrative process in no way alters the legal effect of this document upon publication in the **Federal Register**.

Signed in Washington, DC, on May 8, 2020.

Treena V. Garrett,

Federal Register Liaison Officer, U.S. Department of Energy.

Case #2018–004

Decision and Order

I. Background and Authority

The Energy Policy and Conservation Act (''EPCA''),[1] authorizes the U.S. Department of Energy (''DOE'') to regulate the energy efficiency of a number of consumer products and certain industrial equipment. (42 U.S.C. 6291–6317) Title III, Part B [2] of EPCA established the Energy Conservation Program for Consumer Products Other Than Automobiles, which sets forth a variety of provisions designed to improve energy efficiency for certain types of consumer products. In addition to specifying a list of covered products and industrial equipment, EPCA contains provisions that enable the Secretary of Energy to classify additional types of consumer products as covered products. (42 U.S.C. 6292(a)(20)) In a final determination of coverage published in the **Federal Register** on April 18, 2016, DOE classified portable air conditioners as covered products under EPCA. 81 FR 22514.

The energy conservation program under EPCA consists essentially of four parts: (1) Testing, (2) labeling, (3) Federal energy conservation standards, and (4) certification and enforcement procedures. Relevant provisions of EPCA include definitions (42 U.S.C. 6291), test procedures (42 U.S.C. 6293), labeling provisions (42 U.S.C. 6294), energy conservation standards (42 U.S.C. 6295), and the authority to require information and reports from manufacturers (42 U.S.C. 6296).

The Federal testing requirements consist of test procedures that manufacturers of covered products must use as the basis for: (1) Certifying to DOE that their products comply with the applicable energy conservation standards adopted pursuant to EPCA (42 U.S.C. 6295(s)), and (2) making other representations about the efficiency of that product (42 U.S.C. 6293(c)). Similarly, DOE must use these test procedures to determine whether the product complies with relevant standards promulgated under EPCA. (42 U.S.C. 6295(s))

Under 42 U.S.C. 6293, EPCA sets forth the criteria and procedures DOE is required to follow when prescribing or amending test procedures for covered products. EPCA requires that any test procedures prescribed or amended under this section must be reasonably designed to produce test results which reflect energy efficiency, energy use or estimated annual operating cost of a covered product during a representative average use cycle or period of use and requires that test procedures not be unduly burdensome to conduct. (42 U.S.C. 6293(b)(3)) The test procedure for portable air conditioners is contained in the Code of Federal Regulations (''CFR'') at 10 CFR part 430, subpart B, appendix CC, *Uniform Test Method for Measuring the Energy Consumption of Portable Air Conditioners* (''Appendix CC'').

Any interested person may submit a petition for waiver from DOE's test procedure requirements. 10 CFR 430.27(a)(1). DOE will grant a waiver from the test procedure requirements if DOE determines either that the basic model for which the waiver was requested contains a design characteristic that prevents testing of the basic model according to the prescribed test procedures, or that the prescribed test procedures evaluate the basic model in a manner so unrepresentative of its true energy consumption characteristics as to provide materially inaccurate comparative data. 10 CFR 430.27(f)(2). DOE may grant the waiver subject to

[1] All references to EPCA in this document refer to the statute as amended through America's Water Infrastructure Act of 2018, Public Law 115–270 (October 23, 2018).

[2] For editorial reasons, upon codification in the U.S. Code, Part B was redesignated as Part A.

conditions, including adherence to an alternate test procedure. *Id.*

II. LG's Petition for Waiver: Assertions and Determinations

By letter dated May 15, 2018, LG submitted a petition for waiver and application for an interim waiver from the portable air conditioner test procedure set forth in Appendix CC.[3]

The portable air conditioner test procedure in Appendix CC provides test instructions for two configurations of portable air conditioners: dual-duct and single-duct. Dual-duct units use two parallel airflow paths: With the first airflow path, air from the conditioned space (*i.e.,* indoors) is drawn into the unit, passes over a cold heat exchanger (*i.e.,* the evaporator), and is discharged back into the room. With the second airflow path, air from outdoors is drawn into the unit, passes over a hot heat exchanger (*i.e.,* the condenser), and is discharged back outdoors. In this type of system, the heat that is removed from the indoor airflow path is essentially transferred to the outdoor airflow path and discharged outdoors. The temperature of the air flowing across the condenser significantly affects a portable air conditioner's cooling capacity. Because the air passing across the condenser is drawn from outdoors, and outdoor air temperatures vary during portable air conditioner use, the cooling capacity of a dual-duct unit is significantly affected by changes in outdoor air temperatures. Therefore, to produce representative test results, Appendix CC requires dual-duct units to be tested at two different ''test conditions'' in the test chamber that supplies the condenser inlet air, representing two different outdoor temperatures: 95 degrees Fahrenheit (°F) and 83 °F. Under both test conditions, the test chamber in which the unit is installed is maintained at a temperature of 80 °F, which is a representative indoor temperature, and the unit is operated at full load.[4]

Single-duct units also use two parallel airflow paths; however, in contrast to dual-duct units, the condenser airflow path draws air from inside the conditioned space rather than from outside. This air is drawn into the unit through air grates in the unit's chassis, passes over the condenser, and is discharged to the outdoors through the single duct. During the test, the indoor air temperature remains steady, and thus the condenser always sees the same temperature at its inlet. Therefore, Appendix CC requires only one test condition for single-duct portable air conditioners, 80 °F in the test chamber in which the unit is installed (corresponding to the specified indoor air temperature). As with the dual-duct unit tests, the single-duct unit is operated at full load throughout the duration of the test.

The cooling capacity of both dual-duct and single-duct portable air conditioners is reduced by the infiltration of hotter outside air (*i.e.,* ''infiltration air'') into the conditioned space due to any indoor air being exhausted outside the conditioned space through the condenser duct.[5] Appendix CC accounts for infiltration air at the two different outdoor temperature operating conditions (95 °F and 83 °F) for both single-duct and dual-duct portable air conditioners. The infiltration air heat transfer is calculated (as opposed to being directly measured) using a set of equations provided in section 4.1.2 of Appendix CC. Finally, the cooling capacity of both dual-duct and single-duct portable air conditioners is also reduced by the heat transferred from the duct surface(s) to the conditioned space; *i.e.,* ''duct heat transfer.'' Duct heat transfer is accounted for in section 4.1.1 of Appendix CC based on measurements of the surface temperature of the duct(s) and the total surface area of the duct(s).

LG requested a waiver for the following portable air conditioner basic models: LP1419IVSM, LP1419HVSM, LP1219IVSM, LP1019IVSM, and LP0819IVSM, all of which are single-duct models.[6] LG noted that the current DOE test procedure for portable air conditioners has different requirements for dual-duct and single-duct products. For dual-duct products, testing must occur under two test conditions, (*i.e.,* at a high-temperature test condition and a lower-temperature test condition). For single-duct products, the test procedure requires testing at only a single full-load test condition. LG asserted that the current DOE test procedure for single-duct portable air conditioners does not take into account the specific performance and efficiency benefits associated with single-duct variable-speed portable air conditioners under part-load conditions.

LG stated that single-duct variable-speed portable air conditioners use frequency controls to constantly adjust the compressor rotation speed to maintain the desired temperature in the home without turning the motor on and off; that the compressor responds automatically to surrounding conditions to operate in the most efficient possible manner; and that this results in both significant energy savings and faster cooling compared to a portable air conditioner without a variable-speed compressor. LG asserted that, because the DOE test procedure does not account for the general part-load performance benefits of single-duct variable-speed portable air conditioners or properly account for the favorable difference in ''cycling losses'' [7] for single-duct variable-speed portable air conditioners resulting from use of variable-speed technology, the results of the test procedure are not representative of the actual energy consumption of single-duct variable-speed portable air conditioners.

In its petition, LG requested an alternate test procedure, which would provide for testing the listed basic models according to Appendix CC, except that units of the listed single-duct variable-speed basic models would be tested at the two test conditions defined for dual-duct units, at two different fixed compressor speeds; specifically, at the high-temperature (95 °F) outdoor air test condition with the compressor speed set to maximum; and at the lower-temperature (83 °F) outdoor air test condition with the compressor speed set to minimum. As

[3] LG's petition for a waiver and petition for an interim waiver is provided in the docket located at: *https://www.regulations.gov/document?D=EERE-2018-BT-WAV-00007-0001.*

[4] The requirement in section 3.1.2 of Appendix CC to set the controls on the unit to the lowest available temperature setpoint applies to both the 95 °F and 83 °F tests. The lowest available setpoint on any portable air conditioner is significantly less than the indoor air temperature of 80 °F, which is maintained by external reconditioning equipment throughout the duration of the test. Therefore, since the indoor temperature setpoint remains lower than the indoor air temperature throughout the duration of the test, the unit operates at full load throughout the duration of both tests.

[5] ''Infiltration air'' refers to air that infiltrates from outside the conditioned space (*e.g.,* from outdoors, attic, adjacent rooms) to inside the conditioned space as a result of negative air pressure induced as the outlet air is exhausted outside the conditioned space. This effect is particularly pronounced for single-duct units because single-duct units draw all of the air in the condenser airflow path from within the conditioned space and discharge that air outdoors. However, dual-duct units also typically draw a portion of their inlet air from the conditioned space (inadvertently), which creates a slight negative pressure in the conditioned space and results in some infiltration air for dual-duct units as well.

[6] LG provided these basic model numbers in an appendix to its May 15, 2018 petition.

[7] When the cooling load of the space is less than the full cooling power of the compressor, a single-speed compressor cycles on and off. This cycling behavior introduces inefficiencies, *i.e.,* ''cycling losses,'' due to the surge in power draw at the beginning of each ''on'' cycle, before the compressor reaches steady-state performance. As described above, the current DOE test procedure measures the performance of a portable air conditioner while operating under a full cooling load; *i.e.,* the compressor is operated continuously in its ''on'' state. As a result, Appendix CC does not capture any inefficiencies due to compressor cycling.

discussed, the current single-duct portable air conditioner test procedure in Appendix CC relies on a single test condition. LG's suggested alternate approach for single-duct variable-speed portable air conditioners would involve measuring performance at two different outdoor temperature conditions, with two compressor speeds, which would reflect how a single-duct variable-speed portable air conditioner would reduce its compressor speed under reduced load conditions accompanying lower outdoor temperature operating conditions.

Under the requested alternate test procedure, a single-duct variable-speed portable air conditioner unit's final combined energy efficiency ratio (''CEER'') metric would be calculated by multiplying a ''performance adjustment factor'' by the unit's measured weighted CEER value (as measured according to the existing procedure for a dual-duct portable air conditioner at two representative outdoor temperature test conditions). The performance adjustment factor would reflect the average performance improvement, relative to a theoretical comparable single-duct single-speed unit, resulting from the variable-speed unit avoiding cycling losses associated with the lower-temperature test condition currently used for testing dual-duct portable air conditioners. Determining a unit's performance adjustment factor would require calculating two CEER values for a theoretical comparable single-duct single-speed portable air conditioner (*i.e.,* a unit that has the same performance as the variable-speed test unit when operating at the full compressor speed). The two CEER values would reflect the unit's efficiency with and without efficiency losses due to compressor cycling. The performance adjustment factor would be calculated as the percent change of the weighted CEER value of the theoretical comparable single-duct single-speed portable air conditioner with accounting for cycling losses compared to the weighted CEER value of the theoretical comparable single-duct single-speed portable air conditioner without accounting for cycling losses. The performance adjustment factor represents the difference in real-world performance between the variable-speed unit and an actual comparable single-speed unit.

The requested alternate test procedure implements a performance adjustment factor because use of a performance adjustment factor allows for an appropriate comparison between a single-duct variable-speed portable air conditioner tested at two different compressor speeds and a single-duct single-speed portable air conditioner tested at a single speed. The performance adjustment factor represents the relative benefit under the conditions represented by the test of a variable-speed unit's avoidance of compressor cycling that would otherwise occur in a comparable single-speed unit. Applying it to the measured single-duct variable-speed portable air conditioner weighted CEER accounts for the avoidance of efficiency losses due to cycling and provides a more appropriate comparison to the existing CEER metric for single-duct single-speed portable air conditioners.

On August 9, 2019, DOE published a notice that announced its receipt of the petition for waiver and granted LG an interim waiver (''August 2019 Notice of Petition for Waiver''). 84 FR 39274. In the August 2019 Notice of Petition for Waiver, DOE presented LG's claim that the results of the test procedure in Appendix CC are not representative of the actual energy consumption of the variable-speed single-duct portable air conditioner basic models listed in LG's petition for waiver and LG's requested alternate test procedure described above.

In the August 2019 Notice of Petition for Waiver, DOE specified an alternate test procedure as suggested by LG with certain modifications and additional requirements. First, the alternate test procedure specified in the interim waiver provides compressor speed nomenclature and definitions that are derived from those in an industry standard for testing consumer central air conditioning products with variable-speed compressors. DOE clarified the low compressor speed definition to ensure the test unit provides adequate cooling capacity under reduced loads, based on the expected load at those conditions.[8] Second, LG must maintain the compressor speed required for each test condition in accordance with the instructions LG submitted to DOE on July 8, 2019.[9] DOE did not include measuring performance at two different outdoor temperature conditions, each at a different compressor speed, as suggested by LG. Given that the condenser airflow path on a single-duct unit draws air from inside the conditioned space rather than from outside, and the indoor air temperature is held constant during testing, changing the outdoor temperature conditions between each test would add unnecessary test burden with no impact on test results. Therefore, DOE specified a single temperature for only the condenser inlet air for the two test conditions, one at each compressor speed, and not the outdoor air test conditions in August 2019 Notice of Petition for Waiver.

For the reasons explained here and in the August 2019 Notice of Petition for Waiver, without a waiver, the five portable air conditioner basic models identified in the interim waiver, to which this Order applies, contain a design characteristic—variable-speed compressors—that yields test results unrepresentative of their true energy consumption, and thus efficiency. Thus, DOE is requiring LG to test and rate the five portable air conditioner basic models identified in this Order according to the alternate test procedure in this Order. The alternate test procedure in this Order is a modified version of the procedure in the interim waiver.

In the August 2019 Notice of Petition for Waiver, DOE also solicited comments from interested parties on all aspects of the petition. *Id.* DOE received comments from the Appliance Standards Awareness Project and the Natural Resources Defense Council,

[8] The compressor speed nomenclature and definition clarifications are derived from Air Conditioning, Heating, and Refrigeration Institute Standard (AHRI) 210/240–2017, ''Performance Rating of Unitary Air-conditioning & Air source Heat Pump Equipment,'' and adapted to apply to portable air conditioners. Equation 11.60 in AHRI 210/240–2017 relates the building load to an AC's full-load cooling capacity and outdoor temperature, and assumes full-load operation at 98 °F outdoor temperature. DOE adjusted (*i.e.* normalized) this equation to reflect full-load operation at 95 °F outdoor temperature, to provide consistency with the full-load test condition for portable air conditioners. Using the adjusted equation suggests that the representative cooling load at the 83 °F rating condition would be 60 percent of the full-load cooling capacity for portable air conditioners. DOE recognizes that variable-speed portable air conditioners may use compressors that vary their speed in discrete steps and may not be able to operate at a speed that provides exactly 60-percent cooling capacity; therefore, the defined cooling capacity associated with the low compressor speed is presented as a 10-percent range rather than a single value. A 60-percent cooling load is the upper bound of the 10-percent range defining the cooling capacity associated with the lower compressor speed (*i.e.,* the range is defined as 50 to 60 percent). This ensures that the variable-speed portable air conditioner is capable of matching the representative cooling load (60 percent of the maximum) at the 83 °F rating condition, while providing the performance benefits associated with variable-speed operation. In contrast, if the 10-percent range were to be defined as, for example, 55 to 65 percent (with 60 percent as the midpoint), a variable-speed portable air conditioner could be tested at 63 percent, for example, without demonstrating that the unit is capable of maintaining variable-speed performance down to 60 percent.

[9] The instructions provided by LG were marked as confidential and, as such, the instructions will be treated as confidential. The document is located in the docket at *https://www.regulations.gov/document?D=EERE-2018-BT-WAV-0007*.

jointly (hereinafter the ''Joint Advocates''); the Pacific Gas and Electric Company, San Diego Gas and Electric, and Southern California Edison, commenting jointly as the California Investor Owned Utilities (hereinafter the ''California IOUs''); GE Appliances, a Haier Company (''GEA''), and the Midea America Research Center (''Midea''). On September 27, 2019, LG subsequently submitted a rebuttal statement (pursuant to 10 CFR 430.27(d)(3)) in response to these comments.[10]

Commenters generally agreed that the current test procedure for portable air conditions does not produce results representative of the actual performance of single-duct variable speed portable air conditions. GEA generally supported the need for a test procedure waiver for portable air conditioners with variable-speed compressors, asserting that the current test procedure is not representative of the actual performance of single-duct variable-speed units. (GEA, No. 7 at p. 1) [11] Midea stated that it fully supports granting a final waiver to LG, subject to minor revisions that are discussed in the following paragraphs. (Midea, No. 8 at p. 3) The Joint Advocates stated that they share LG's concern that the current test procedure for portable air conditioners does not capture the potential benefits of variable-speed technology. (Joint Advocates, No. 5 at p. 1) The California IOUs stated that an alternate test procedure is warranted to demonstrate the benefits of variable-speed compressor technology, whose primary benefit in improving energy efficiency is the reduction of cyclic losses. (California IOUs, No. 6 at pp. 1–2)

The California IOUs urged DOE to make various changes. First, they asked DOE to ensure the test procedure was representative of real-world use, consistent with previously developed concepts, and justified with data. Second, they asked DOE to ensure the alternate test procedure results are comparable with existing single-speed units, assumptions are clearly justified, and methods are representative and reproducible. They also asked DOE to address a number of additional issues prior to granting the waiver. (California IOUs, No. 6 at pp. 1–2)

The Joint Advocates argued that, instead of granting a test procedure waiver to LG to address single-duct portable air conditioners with variable-speed compressors, DOE should instead investigate a load-based test procedure for all portable air conditioners to capture part-load operation for all unit configurations. Because the current test procedure is a fixed-conditions test, they argued it is not representative of how either single-speed or variable-speed units perform in the field. Specifically, variable-speed units are not allowed to adjust to reduced loads, and single-speed units do not cycle under the current fixed-conditions test. (Joint Advocates, No. 5 at p. 1)

In its rebuttal statement, LG stated that granting this test procedure waiver does not preclude DOE from investigating a load-based test procedure in a future portable air conditioner test procedure rulemaking that DOE must conduct after granting a test procedure waiver. LG stated that the current DOE test procedure misrepresents the actual energy consumption of LG's portable air conditioners that use variable-speed compressors, and that denying this test procedure waiver for these units would, contrary to statutory requirements, mislead consumers about the energy efficiency of variable-speed portable air conditioners until DOE completes a test procedure rulemaking. LG asserted that, because it has met all the criteria for a test procedure waiver, DOE must grant the waiver. (LG, No. 9, at pp. 3–4)

DOE has determined that the alternate test procedure in the August 2019 Notice of Petition for Waiver, as modified in this order, produces efficiency results for variable-speed portable air conditioners which are comparable with the results for single-speed units. The alternate test procedure accomplishes this by adjusting the efficiency rating of the variable-speed portable air conditioner by the amount the variable-speed unit would outperform a theoretical comparable single-speed unit in a representative period of use. The alternate test procedure is based on industry-accepted test procedures. Values used for the cycling loss factor at the 83 °F test condition are based on Air-Conditioning, Heating, and Refrigeration Institute (''AHRI'') Standard 210/240, ''Performance Rating of Unitary Air-conditioning & Air-source Heat Pump Equipment'' (''AHRI Standard 210/240''), as discussed below. The building load calculation is widely accepted by industry, used in AHRI Standard 210/240, and is constructed to be broadly applicable to a number of building cooling configurations. It also specifies that the compressor speed must be fixed at each test condition. LG has provided DOE instructions for fixing the compressor, to ensure that the alternate test procedure is repeatable and reproducible.

Portable air conditioners are tested in psychometric chambers [12] that are designed to maintain specific constant temperature conditions throughout the duration of the test (*i.e.,* a constant-temperature test). DOE agrees that the concept of a load-based test may be more representative of typical portable air conditioner operation, where the conditions within a room vary and the portable air conditioner operates to maintain the room conditions based on the set point and monitored conditions. However, implementing a load-based test for portable air conditioners would present a number of significant challenges.[13] First, implementing a part-load test condition would require first determining the full cooling capacity of a portable air conditioner unit, which is most easily and repeatably achieved with a constant-temperature test. In practice, this would result in the need for chambers to accommodate both constant-temperature and constant-load operation, which could require significant chamber redesigns associated with new or upgraded chamber reconditioning equipment and software adjustments. Second, the external reconditioning equipment in existing psychometric chambers is controlled using software with feedback control to maintain constant temperature conditions. Operating the chamber to provide a constant load—and thus allowing the temperature to vary—would require continuous manual override of the software controls, thus requiring more technician involvement, and resulting expense, throughout the test. Alternatively, the software controls could be redesigned to accommodate constant-load operation; however, this would require significant financial and time investments by test laboratories. Third, the current test procedure does not provide any requirements for the type of instrumentation, hardware, or other equipment that can occupy

[10] Comments submitted by the Joint Advocates, California IOUs, GEA, and Midea, and the rebuttal statement submitted by LG can be accessed at: *https://www.regulations.gov/docket?D=EERE-2018-BT-WAV-0007.*

[11] A notation in the form ''GEA, No. 7 at p. 1'' identifies a written comment: (1) Made by GE Appliances, a Haier Company; (2) recorded in document number 7 that is filed in the docket of this waiver (Docket No. EERE–2018–BT–WAV–0007) and available for review at *http://www.regulations.gov;* and (3) which appears on page 1 of document number 7.

[12] A psychometric chamber uses ducts installed on the evaporator and condenser exhausts to measure the air-enthalpy and calculate cooling capacity.

[13] DOE found that the same challenges applied to load-based testing for room air conditioners in calorimeter chambers in the notice of decision and order published on May 8, 2019, in which DOE granted a waiver to LG for variable-speed room air conditioners. 84 FR 20111, 20114.

existing chambers. The thermal mass of such equipment inside the chamber can affect the variation in chamber temperature as a function of the cooling load, and therefore could affect the test results under a constant-load test in which the temperature is allowed to change. Ensuring the reproducibility of the test would require closely specifying every aspect of the test chamber, including instrumentation, hardware, and other equipment inside the test chamber, which would increase test burden by adding complexities to the test method beyond what is already specified, although DOE is unable to exactly quantify this test burden increase at this time, particularly given the variability in existing test chamber designs. Further, DOE is unable to quantify the potential benefits of requiring a load-based test procedure at this time. For these reasons, DOE is not specifying a load-based test for variable-speed portable air conditioners in this Decision and Order. This does not preclude DOE from considering such testing in a future rulemaking, particularly if industry and third-party test laboratories were to implement load-based testing capabilities into psychrometric chambers, which are the type of test chamber typically used for portable air conditioner testing.

In addition to preferring a load-based test, the Joint Advocates expressed concern that the alternate test procedure in the interim waiver does not reflect real-world performance of variable-speed portable air conditioners, because the compressor speeds are fixed for each of the two test conditions (full speed at the 95 °F condition and low speed at the 83 °F condition). The Joint Advocates prefer capturing how the programmed control strategies change speeds in response to load changes and thus affect overall efficiency. (Joint Advocates, No. 5 at pp. 1–2)

DOE agrees that variable-speed portable air conditioners in the field are likely to adjust their compressor speed in real time in response to variations in the cooling load. However, as DOE discussed for variable-speed room air conditioners in the May 2019 RAC Decision and Order, because of the large variation in cooling loads, both for rooms within a house, and among different housing types and geographical areas, identifying a single or multiple representative cooling loads would not be feasible. (84 FR 20111, 20115) Furthermore, DOE determined in the May RAC 2019 Decision and Order that load-based testing would impose undue cost and burden on manufacturers and test laboratories due to the unique construction and capabilities of existing calorimeter chambers and unit response variability during load-based testing. *Id.* DOE concludes that the same burdens would be imposed by load-based testing of variable-speed portable air conditioners in psychrometric chambers, but the approach suggested by LG to measure performance for a representative range of variable-speed operation (*i.e.,* at low and full compressor speed under relevant outdoor temperature operating conditions), as modified in this order, provides a sufficient determination of variable-speed portable air conditioner performance.

The Joint Advocates stated that, according to LG, these variable-speed portable air conditioners can operate over a range of compressor speeds, and if a variable-speed unit provides sustained cooling at the high compressor speed (*i.e.,* at a higher compressor speed than a comparable single-speed unit at full-load operating conditions), the faster cooling would come at the expense of higher energy consumption, an effect that would not be captured by the waiver test procedure. (Joint Advocates, No. 5 at p. 2)

In its rebuttal statement, LG explained that its variable-speed portable air conditioners only cool the room at boost compressor speed (*i.e.,* a speed faster than full speed—the speed at full-load testing conditions) for less than 10 minutes when they begin cooling the room, making the energy consumption of this phase of cooling ''very small'' compared to the energy consumed during the remainder of cooling mode operation. LG noted that AHRI Standard 210/240 describes this operation as ''boost compressor speed,'' and that boost compressor speed is standard at start-up in all air conditioners with variable-speed compressors. (LG, No. 9 at pp. 5–6)

DOE has observed that a variable-speed room air conditioner operates at boost compressor speed to provide initial cooling to the conditioned space during testing. DOE expects its experience with boost compressor speed for variable-speed room air conditioners to be analogous to boost compressor speed operation in variable-speed portable air conditioners; this experience indicates that the amount of energy consumed in this operation is insignificant compared to the energy consumed during the remainder of cooling mode operation. As a result, the potential improvements in test procedure representativeness do not warrant the additional test burden associated with measuring variable-speed portable air conditioner performance at the boost compressor speed.

The Joint Advocates questioned what they stated is LG's apparent claim that the performance of dual-duct units, but not single-duct units, under reduced load conditions is accounted for in the DOE test procedure by testing at two test conditions. The Joint Advocates, however, assert that both dual-duct test conditions are full-load tests, and that Seasonally Adjusted Cooling Capacity (''SACC'') and Combined Energy Efficiency Ratio (''CEER'') are calculated to provide a direct comparison between dual-duct and single-duct units. (Joint Advocates, No. 5 at pp. 2–3)

DOE agrees that the portable air conditioner test procedure for dual-duct units at Appendix CC does not measure part-load performance. Instead, it requires full-load tests at each test condition, and as a result does not account for single-speed unit cycling under part-load conditions or variable-speed compressor speed adjustments to match part-load conditions. However, LG's claims regarding the test conditions and procedure for dual-duct portable air conditioners are not directly relevant to the August 2019 Notice of Petition for Waiver and this Decision and Order, which only address the single-duct variable-speed portable air conditioners listed in the LG petition for waiver submitted on May 15, 2018.

The Joint Advocates and the California IOUs stated that the portable air conditioner test procedure is only conducted at one outdoor temperature test condition for single-duct units because such portable air conditioners draw condenser inlet air from the conditioned space, so the indoor and outdoor temperature for each test condition should always be equal. (Joint Advocates, No. 5 at p. 3; California IOUs, No. 6 at p. 2) The Joint Advocates questioned why the alternate test procedure in the interim waiver provides for testing single-duct variable-speed portable air conditioners at two different condenser inlet test conditions. (Joint Advocates, No. 5 at p. 3) The California IOUs recommended that these units be tested at only the single test condition required by Appendix CC, but with varying compressor speeds. (California IOUs, No. 6 at p. 2)

In response to comments pertaining to the two test conditions listed in the August 2019 Notice of Petition for Waiver, LG stated that while outdoor air temperature minimally affects the cooling capacity test measurement, it does affect the calculation of CEER and SACC due to the influence of infiltration air. The outdoor air temperature affects the magnitude of the infiltration air

impact on portable air conditioners, and, therefore, it is necessary to calculate infiltration at two different test conditions.

DOE agrees with the Joint Commenters and the California IOUs that the specification for condenser inlet air found in Table 1 of the alternate test procedure in the interim waiver should be the same as the indoor temperature for single-duct portable air conditioners because the condenser inlet air for a single-duct unit is drawn from indoors. DOE notes that the alternate test procedure in the interim waiver included a note specifying that, for the purposes of this cooling mode test procedure, condenser inlet air is considered the ''outdoor air'' outside of the conditioned space. 84 FR 39274, 39277. As such, the outdoor air temperatures of 95 °F and 83 °F shown in Table 1 represent the outdoor temperature operating conditions, rather than the actual condenser inlet air test conditions, as the column heading would imply.[14] To alleviate any potential confusion about the distinction between outdoor air temperature and condenser inlet air temperature, in this Decision and Order DOE specifies in Table 1 of the alternate test procedure that variable-speed single-duct portable air conditioners must be tested at the same condenser inlet temperature as the indoor-side air temperature for both test conditions (*i.e.,* 80 °F).

The California IOUs and Midea suggested that the alternate calculation for infiltration air mass flowrate is incorrect because condenser inlet air for a single-duct portable air conditioner is drawn from the indoors, thus making the infiltration air associated with single-duct units independent of condenser inlet air. These commenters urged DOE to require that the mass flow rate of infiltration air for all single-duct portable air conditioners, including variable-speed units, be calculated using the existing formula in the DOE test procedure at Appendix CC, thus removing the terms in the mass flow rate of infiltration air accounting for condenser inlet air flow in the alternate test procedure. (California IOUs, No. 6 at p. 3; Midea, No. 8 at pp. 2–3)

LG responded that the alternate calculation in section 4.1.2 of the interim waiver test procedure provides the correct value for infiltration air mass flow. Because, for single-duct units, the average volumetric flow rate of the condenser inlet duct air is zero, the second term of the equation, referring to the condenser inlet duct air, is reduced to zero. (LG, No. 9, at pp. 2, 7)

DOE agrees that the equation for infiltration air mass flow from the interim waiver alternate test procedure produces the correct results when the average volumetric flow rate of the condenser inlet duct air is appropriately set to zero, given that single-duct portable air conditioners do not have a condenser inlet duct. However, DOE recognizes that including the condenser inlet air term for single-duct units may lead to confusion. To reduce the possibility of such confusion, the equation in the alternate test procedure specified in this Decision and Order to calculate the mass flow rate of infiltration air for variable-speed single-duct portable air conditioners is based on only the condenser exhaust air mass flow, like the current equation for single-speed single-duct portable air conditioners. Because the value of the condenser inlet air term is zero, as explained above, this revision does not change any values calculated using the interim waiver alternate test procedure.

The California IOUs suggested that DOE correct an error in the equation for adjusted cooling capacity at the higher outdoor temperature condition in section 5.1 of the alternate test procedure specified in the August 2019 Notice of Petition for Waiver. They noted that the two adjusted cooling capacity equations erroneously used two different equations to calculate the same Adjusted Cooling Capacity (''ACC'') value (*i.e.,* ACC_{83}), which the California IOUs stated should be two different values representing the two outdoor temperature conditions. The California IOUs further recommended subscripts for these two values based on compressor speed rather than outdoor temperature. (California IOUs, No. 6 at p. 4)

DOE acknowledges there was a typographical error in August 2019 Notice of Petition of Waiver. The two equations identified by the California IOUs calculate different adjusted cooling capacity values (*i.e.,* ACC_{95} and ACC_{83}), but were both labeled as calculating ACC_{83}. In this Decision and Order, DOE has corrected this typographical error and provides additional clarification of the alternate test procedure by implementing ''Full'' and ''Low'' subscripts to represent the compressor speed setting for each calculation. DOE also has standardized subscripts accordingly throughout the alternate test procedure to be consistent with this approach.

The California IOUs requested clarification on the use of the 83 °F outdoor temperature condition rather than the 95 °F condition in the equation when calculating the theoretical single-speed unit capacity at 83 °F. The California IOUs commented that both conditions hold true, because capacity is independent of the outdoor air temperature. The California IOU's had similar concerns about the mass flow of infiltration air equation, requesting clarification as to why the mass flow equation for the theoretical single-speed unit at 83 °F uses the volumetric air flow rate measured at 95 °F. (California IOUs, No. 6 at p. 5)

As noted above, DOE recognizes that, unlike for a dual-duct unit, for a single-duct unit, the outdoor air temperature has no direct bearing on the cooling capacity, because the condenser inlet air for a single-duct unit is drawn from within the conditioned space. DOE notes that section 5.5.1 of the alternate test procedure explicitly defines the theoretical comparable single-speed portable air conditioner capacity at the 83 °F outdoor temperature operating condition as equal to the full-load capacity of the variable-speed portable air conditioner at the 95 °F outdoor temperature operating condition because the theoretical comparable single-speed unit is based upon the full compressor speed of the variable-speed unit. DOE recognizes the confusion that may arise from these equations. This Decision and Order revises the nomenclature of the two variable-speed unit tests to refer to the compressor speed (*e.g.,* $Capacity_{Full}$) instead of the ''outdoor temperature test condition''. Further, in contrast to the alternate test procedure granted in the interim waiver, this Decision and Order specifies a condenser inlet air temperature of 80 °F—consistent with the 80 °F evaporator inlet air temperature—rather than specifying condenser inlet air temperatures of 83 °F and 95 °F for the two test conditions. DOE maintains the distinction between theoretical comparable single-speed unit capacity at 83 °F and 95 °F because the respective adjusted cooling capacities at each of these conditions reflect the impact of infiltration air at these two temperatures. While the infiltration air mass flow rate for the theoretical comparable single-speed unit remains constant, the heat entering the room due to infiltration air will differ based on the outdoor temperature. Therefore, DOE has provided equations for calculating the infiltration air mass flow rates at both temperatures for a theoretical

[14] DOE further notes that, for a single-duct portable air conditioner, because both the evaporator air and condenser air are drawn from the conditioned space through air grates that are integral to the unit itself, the evaporator and condenser inlet air temperature test conditions are necessarily the same.

comparable single-speed portable air conditioner.

The California IOUs requested that the manufacturer justify the cyclic loss factor proposed by citing references or providing data, although they stated that the value appears reasonable. (California IOUs, No. 6 at p. 5)

In response to this comment, LG noted that the cycling loss factor it suggested in the alternate test procedure was the value DOE provided based on DOE's research. (LG, No. 9, at pp. 7–8)

The cycling loss factor in the alternate test procedure is based on the default cycling loss factors in Section 11.2 of AHRI Standard 210/240, an industry-accepted test procedure. The cycling loss factor at the 83 °F condition for a theoretical comparable single-speed single-duct portable air conditioner is calculated using the default cooling degradation coefficient of 0.25, which corresponds to a part-load (cycling loss) factor of 0.875, as determined in Section 11.2 of AHRI Standard 210/240.

GEA commented that LG's proposed alternate test procedure calculates a weighted efficiency for a unit with a variable-speed compressor that reflects only decreased energy use but not reduced cooling capacity when the unit runs at a lower speed. GEA suggested the test procedure account for both the reduced energy usage and the reduced cooling capacity of a variable-speed compressor by incorporating the reduced cooling capacity in the SACC calculation equations. (GEA, No. 7 at p. 1)

GEA's suggestion that the alternate test procedure does not reflect decreased cooling capacity is incorrect. The reduced cooling capacity at the low compressor speed is used when calculating the adjusted cooling capacity at the lower outdoor temperature operating condition, ACC_{83}, in section 5.1 of the alternate test procedure. This lower adjusted cooling capacity is included in the weighted-average overall adjusted cooling capacity calculated in section 5.3 of the alternate test procedure. By calculating the adjusted cooling capacity based on performance at both outdoor temperature operating conditions and compressor speeds, the alternate test procedure accounts for not only the reduced energy usage of the variable-speed portable air conditioner but also the reduced cooling capacity from operation at the low compressor speed.

For the reasons explained here and in the August 2019 Notice of Petition for Waiver, the basic models identified by LG in its petition cannot be tested and rated for energy consumption on a basis representative of their true energy consumption characteristics using Appendix CC. DOE has reviewed the procedure suggested by LG and concludes that, subject to the modifications discussed in this Decision and Order, the test procedure in this Decision and Order will allow for the accurate measurement of the energy consumption of the listed models, while alleviating the problems associated with testing these models following DOE's portable air conditioner test procedure. LG must test and rate the five listed portable air conditioner basic models according to the alternate test procedure specified in the Decision and Order. This alternate test procedure is substantively consistent with the interim waiver's alternate test procedure but includes clarifying modifications.

Based on further review of the alternate test procedure required under the interim waiver order and the comments received, the alternate test procedure required under today's Decision and Order: (1) Corrects a typographical error in the Adjusted Cooling Capacity equations; (2) changes certain calculated value subscripts to refer to the compressor speed for which the value is being calculated, rather than the outdoor temperature test condition; (3) specifies in Table 1 of the alternate test procedure that single-duct portable air conditioners are only tested at one condenser inlet air temperature (*i.e.,* the indoor air temperature), although two different outdoor temperatures are represented by the two tests required by the alternate test procedure, and makes corresponding changes to references to Table 1 throughout the text; and (4) removes a term describing condenser inlet air from the air infiltration mass flow equation. DOE has determined that these changes ensure better repeatability and reproducibility of the alternate test procedure, improving the representativeness of the results. The changes will not affect the performance of single-duct variable-speed portable air conditioners as measured under the alternate test procedure specified in the interim waiver. Below is a more detailed discussion of each change.

DOE is changing a subscript to correct a typographical error in the two Adjusted Cooling Capacity equations in section 5.1, *Adjusted Cooling Capacity.* The interim waiver erroneously labeled both calculations for the adjusted cooling capacity at each test condition as ACC_{83}. This Order changes the label in the first calculation to ACC_{95}.

DOE is changing subscripts throughout the alternate test procedure to refer to specified compressor speed instead of the outdoor temperature test condition represented by the compressor speed setting (*i.e.,* instead of ''95'' and ''83,'' the subscripts now read ''Full'' and ''Low''). DOE made this change to clarify the compressor speed setting required.

DOE is revising Table 1 in the alternate test procedure to specify that the alternate test procedure only requires one condenser inlet air temperature for both tests. The condenser inlet air temperature is the same as the indoor air temperature because single-duct units draw air from the indoor room. While the outdoor temperature test condition represented by each test is different, it does not directly impact the performance of a test unit.

DOE is simplifying the equation to calculate the mass flow rate of infiltration air for variable-speed single-duct portable air conditioners using only the condenser exhaust air mass flow, reflecting the current approach for single-speed single-duct portable air conditioners in Appendix CC. This revision removes a second term that accounted for infiltration air due to condenser inlet air, which does not impact the mass flow rate of infiltration air for single-duct units, because single-duct units intake condenser inlet air from indoors, unlike dual-duct portable air conditioners, which intake condenser inlet air from the outdoors.

DOE further requires in this Decision and Order, testing of the listed basic models in accordance with the instructions submitted by LG on July 8, 2019, regarding the compressor frequencies and control settings used at each test condition for each basic model.[15]

This Decision and Order applies only to the five basic models listed in the Order and does not extend to any other basic models. DOE evaluates and grants waivers for only those basic models specifically set out in the petition, not future models that may be manufactured by the petitioner. LG may request that DOE extend the scope of this waiver to include additional basic models that employ the same technology as those listed in the Order. 10 CFR 430.27(g). LG may also submit another petition for waiver from the test procedure for additional basic models that employ a different technology and meet the criteria for test procedure waivers. 10 CFR 430.27(a)(1).

DOE notes that it may modify or rescind the waiver at any time upon a determination that the factual basis

[15] The instructions provided by LG were marked as confidential and, as such, the instructions will be treated as confidential. The document is located in the docket at *https://www.regulations.gov/document?D=EERE-2018-BT-WAV-0007-0002.*

underlying the petition for waiver is incorrect, or that the results from the alternate test procedure are unrepresentative of the basic models' true energy consumption characteristics. 10 CFR 430.27(k)(1). Likewise, LG may request that DOE rescind or modify the waiver if the company discovers an error in the information provided to DOE as part of its petition, determines that the waiver is no longer needed, or for other appropriate reasons. 10 CFR 430.27(k)(2).

As set forth above, the test procedure specified in this Decision and Order is not the same as the test procedure offered by LG. If LG believes that the alternate test method it suggested provides representative results and is less burdensome than the test method required by this Decision and Order, LG may submit a request for modification under 10 CFR 430.27(k)(2) that addresses the concerns that DOE has articulated about the procedure LG suggested. LG may also submit another less burdensome alternative test procedure not expressly considered in this notice under the same provision.

III. Consultations With Other Agencies

In accordance with 10 CFR 430.27(f)(2), DOE consulted with the Federal Trade Commission staff concerning the LG petition for waiver.

IV. Order

After careful consideration of all the material that LG and commenters submitted in this matter, it is *Ordered* that:

(1) LG must, as of the date of publication of this Order in the **Federal Register**, test and rate the following portable air conditioner basic models with the alternate test procedure as set forth in paragraph (2):

Brand	Basic model
LG Electronics USA, Inc	LP1419IVSM
LG Electronics USA, Inc	LP1419HVSM
LG Electronics USA, Inc	LP1219IVSM
LG Electronics USA, Inc	LP1019IVSM
LG Electronics USA, Inc	LP0819IVSM

(2) The alternate test procedure for the LG basic models listed in paragraph (1) of this Order is the test procedure for portable air conditioners prescribed by DOE at appendix CC to subpart B of 10 CFR part 430 (''Appendix CC'') and 10 CFR 430.23(dd), except: (i) Determine the combined energy efficiency ratio (''CEER'') as detailed below, and (ii) calculate the estimated annual operating cost in 10 CFR 430.23(dd)(2) as detailed below. In addition, for each basic model listed in paragraph (1), maintain compressor speeds at each test condition and set control settings for the variable components according to the instructions LG submitted to DOE (Docket No. EERE–2018–BT–WAV–0007–0002). Upon the compliance date of any new energy conservation standards for portable air conditioners, LG must report product-specific information pursuant to 10 CFR 429.12(b)(13) and 10 CFR 429.62(b). All other requirements of Appendix CC and DOE's other relevant regulations remain applicable.

In 10 CFR 430.23, in paragraph (dd) revise paragraph (2) to read as follows:

(2) Determine the estimated annual operating cost for a single-duct variable-speed portable air conditioner, expressed in dollars per year, by multiplying the following two factors:

(i) The sum of AEC_{95} multiplied by 0.2, AEC_{83} multiplied by 0.8, and AEC_T as measured in accordance with section 5.3 of appendix CC of this subpart; and

(ii) A representative average unit cost of electrical energy in dollars per kilowatt-hour as provided by the Secretary.

(iii) Round the resulting product to the nearest dollar per year.

In Appendix CC:

Add in Section 2, Definitions:

2.11 *Single-speed* means a type of portable air conditioner that cannot automatically adjust the compressor speed based on detected conditions.

2.12 *Variable-speed* means a type of portable air conditioner that can automatically adjust the compressor speed based on detected conditions.

2.13 *Full compressor speed (full)* means the compressor speed specified by LG (Docket No. EERE–2018–BT–WAV–0007–0002) at which the unit operates at full load testing conditions.

2.14 *Low compressor speed (low)* means the compressor speed specified by LG (Docket No. EERE–2018–BT–WAV–0007–0002), at which the unit operates at low load test conditions, such that $Capacity_{Low,}$ the measured cooling capacity at this speed at the test condition in Table 1 of this appendix, is no less than 50 percent and no greater than 60 percent of $Capacity_{Full}$, the measured cooling capacity with the full compressor speed at the test condition in Table 1 of this appendix.

2.15 *Theoretical comparable single-speed portable air conditioner* means a theoretical single-speed portable air conditioner with the same cooling capacity and electrical power input as the single-duct variable-speed portable air conditioner under test, with no cycling losses considered, when operating with the full compressor speed and at the test conditions in Table 1 of this appendix.

Add to the end of Section 3.1.2, *Control settings:*

Set the compressor speed during cooling mode testing as described in section 4.1 of this appendix, as amended by this Order.

Replace Section 4.1, *Cooling mode* with the following:

Cooling mode. Instead of the test conditions in Table 3 of ANSI/AHAM PAC–1–2015, establish the test conditions presented in Table 1 of this appendix. Test each sample unit twice, once at each test condition in Table 1. For each test condition, measure the sample unit's indoor room cooling capacity and overall power input in cooling mode in accordance with Section 7.1.b and 7.1.c of ANSI/AHAM PAC–1–2015 (incorporated by reference; see § 430.3), respectively, and determine the test duration in accordance with Section 8.7 of ASHRAE Standard 37–2009 (incorporated by reference; § 430.3). Conduct the first test in accordance with ambient conditions for Test Condition 1 in Table 1 of this appendix, with the compressor speed set to full, for the duration of cooling mode testing ($Capacity_{Full}$, P_{Full}), which represents an outdoor temperature operating condition of 95 °F dry-bulb and 67 °F wet-bulb temperatures. Conduct the second test in accordance with the ambient conditions for Test Condition 2, in Table 1 of this appendix, with the compressor speed set to low, for the duration of cooling mode testing ($Capacity_{Low}$, P_{Low}), which represents an outdoor temperature operating condition of 83 °F dry-bulb and 67.5 °F wet-bulb temperatures. Set the compressor speed required for each test condition in accordance with the instructions LG submitted to DOE (Docket No. EERE–2018–BT–WAV–0007–0002).

TABLE 1—EVAPORATOR AND CONDENSER (INDOOR) INLET TEST CONDITIONS

Test condition	Evaporator and condenser inlet air °F (°C)		Compressor speed
	Dry bulb	Wet bulb	
Test Condition 1	80 (26.7)	67 (19.4)	Full.
Test Condition 2	80 (26.7)	67 (19.4)	Low.

Replace the provisions in Section 4.1.1, *Duct Heat Transfer* that follow ''j represents the condenser exhaust duct and, for dual-duct units, the condenser exhaust duct and the condenser inlet duct.'' to read as follows:

Calculate the total heat transferred from the surface of the condenser exhaust duct to the indoor conditioned space while operating in cooling mode at each test condition in Table 1 of this appendix, as follows:

$Q_{duct\_Full} = 3 \times A_{duct} \times (T_{duct\_Full} - T_{ei})$

$Q_{duct\_Low} = 3 \times A_{duct} \times (T_{duct\_Low} - T_{ei})$

Where:

Q_{duct_Full} and Q_{duct_Low} = the total heat transferred from the condenser exhaust duct to the indoor conditioned space in cooling mode, in Btu/h, when tested at Test Condition 1 and Test Condition 2 in Table 1 of this appendix, respectively.

3 = convection coefficient in Btu/h per square foot per °F.

A_{duct} = surface area of the condenser exhaust duct, in square feet.

T_{duct_Full} and T_{duct_Low} = average surface temperature for the condenser exhaust duct, as measured at Test Condition 1 and Test Condition 2 in Table 1 of this appendix, respectively, as required in section 4.1 of this appendix.

T_{ei} = average evaporator inlet air dry-bulb temperature, as measured in this section, in °F.

Replace Section 4.1.2, *Infiltration Air Heat Transfer* with the following:

Infiltration Air Heat Transfer. Calculate the sample unit's heat contribution from infiltration air into the conditioned space for both cooling mode tests, which represent the 95 °F and the 83 °F dry-bulb outdoor temperature operating conditions, as described in this section. Calculate the dry air mass flow rate of infiltration air according to the following equations:

$$\dot{m}_{95} = \frac{V_{co\_Full} \times \rho_{co\_Full}}{(1 + \omega_{co\_Full})}$$

$$\dot{m}_{83} = \frac{V_{co\_Low} \times \rho_{co\_Low}}{(1 + \omega_{co\_Low})}$$

Where:

$\dot{m}_{95}$ and $\dot{m}_{83}$ = dry air mass flow rate of infiltration air, as calculated for Test Condition 1 and Test Condition 2 in Table 1 of this appendix, representative of the 95 °F and 83 °F dry-bulb outdoor temperature operating conditions, respectively, in pounds per minute (lb/m).

V_{co_Full} and V_{co_Low} = average volumetric flow rate of the condenser outlet air as determined in section 4.1 of this appendix, during cooling mode testing for Test Condition 1 and Test Condition 2 in Table 1 of this appendix, respectively, in cubic feet per minute (cfm).

ρ_{co_Full} and ρ_{co_Low} = average density of the condenser outlet air as determined in section 4.1 of this appendix, during cooling mode testing at Test Condition 1 and Test Condition 2 in Table 1 of this appendix, respectively, in pounds mass per cubic foot (lb_m/ft^3).

ω_{co_Full} and ω_{co_Low} = average humidity ratio of condenser outlet air as determined in section 4.1 of this appendix, during cooling mode testing at Test Condition 1 and Test Condition 2 in Table 1 of this appendix, respectively, in pounds mass of water vapor per pounds mass of dry air (lb_w/lb_{da}).

Replace Section 5.1, *Adjusted Cooling Capacity* with the following:

Adjusted Cooling Capacity. Calculate the adjusted cooling capacity at each outdoor temperature operating condition, ACC_{95} and ACC_{83}, expressed in Btu/h, according to the following equations:

$ACC_{95} = Capacity_{Full} - Q_{duct\_Full} - Q_{infiltration\_95}$

$ACC_{83} = Capacity_{Low} - Q_{duct\_Low} - Q_{infiltration\_83}$

Where:

$Capacity_{Full}$ and $Capacity_{Low}$ = cooling capacity, as measured in section 4.1 of this appendix, at Test Condition 1 and Test Condition 2 in Table 1 of this appendix, respectively, in Btu/h.

Q_{duct_Full} and Q_{duct_Low} = duct heat transfer while operating in cooling mode as calculated in section 4.1.1 of this appendix.

$Q_{infiltration\_95}$ and $Q_{infiltration\_83}$ = total infiltration air heat transfer in cooling mode as calculated in section 4.1.2 of this appendix, representative of the 95 °F and 83 °F dry-bulb outdoor temperature operating conditions, respectively, in Btu/h.

Replace Section 5.3, *Annual Energy Consumption* with the following:

Annual Energy Consumption. Calculate the sample unit's annual energy consumption in each operating mode according to the equation below. Use the following annual hours of operation and equation for each operating mode:

Operating mode	Subscript	Annual operating hours
Cooling Mode, Full [1]	full	750
Cooling Mode, Low [1]	low	750
Off-Cycle	oc	880
Inactive or Off	ia or om	1,355

[1] These operating mode hours are for the purposes of calculating annual energy consumption under different ambient conditions and are not a division of the total cooling mode operating hours. The total cooling mode operating hours are 750 hours.

$AEC_m = P_m \times t_m \times 0.001$

Where:

AEC_m = annual energy consumption in each operating mode, in kWh/year.

P_m = average power in each operating mode, in watts.

m represents the operating mode (''Full'' and ''Low'' cooling mode compressor speeds that represent operation at 95 °F and 83 °F dry-bulb outdoor temperature operating conditions, respectively, ''oc'' off-cycle, and ''ia'' inactive or ''om'' off mode).

t_m = number of annual operating time in each operating mode, in hours.

0.001 kWh/Wh = conversion factor from watt-hours to kilowatt-hours.

Calculate the sample unit's total annual energy consumption in off cycle

mode and inactive or off mode according to the equation below:

$AEC_T = \Sigma_m AEC_m$

Where:

AEC_T = total annual energy consumption attributed to off cycle mode and inactive or off mode, in kWh/year;

AEC_m = total annual energy consumption in each operating mode, in kWh/year.

m represents the operating modes, off cycle mode and inactive or off mode.

Replace Section 5.4, *Combined Energy Efficiency Ratio* with the following:

Unadjusted Combined Energy Efficiency Ratio. Using the annual operating hours, as outlined in section 5.3 of this appendix, calculate the sample unit's unadjusted combined energy efficiency ratio, $CEER_{UA}$, expressed in Btu/Wh, according to the following equation:

$$CEER_{UA} = \left[\frac{ACC_{95}}{\left(\frac{AEC_{Full} + AEC_T}{750 \times 0.001}\right)}\right] \times 0.2 + \left[\frac{ACC_{83}}{\left(\frac{AEC_{Low} + AEC_T}{750 \times 0.001}\right)}\right] \times 0.8$$

Where:

$CEER_{UA}$ = unadjusted combined energy efficiency ratio for the sample unit, in Btu/Wh.

ACC_{95} and ACC_{83} = adjusted cooling capacity, tested at Test Condition 1 and Test Condition 2 in Table 1 of this appendix, respectively, that are representative of operation at the 95 °F and 83 °F dry-bulb outdoor temperature operating conditions, respectively, as calculated in section 5.1 of this appendix, in Btu/h.

AEC_{Full} and AEC_{Low} = annual energy consumption for cooling mode operation at Test Condition 1 and Test Condition 2 in Table 1 in this appendix that represent operation at 95 °F and 83 °F dry-bulb outdoor temperature operating conditions, respectively, as calculated in section 5.3 of this appendix, in kWh/year.

AEC_T = total annual energy consumption attributed to off cycle mode and inactive or off mode, in kWh/year, calculated in section 5.3 of this appendix.

750 = number of cooling mode hours per year.

0.001 kWh/Wh = conversion factor for watt-hours to kilowatt-hours.

0.2 = weighting factor for the 95 °F dry-bulb outdoor temperature operating condition.

0.8 = weighting factor for the 83 °F dry-bulb outdoor temperature operating condition.

Add after Section 5.4, *Combined Energy Efficiency Ratio:*

5.5 *Adjustment of the Combined Energy Efficiency Ratio.* Adjust the sample unit's combined energy efficiency ratio as follows.

5.5.1 *Theoretical Comparable Single-Speed Portable Air Conditioner Cooling Capacity and Power at the Lower Outdoor Temperature Operating Condition.* Calculate the cooling capacity and cooling capacity with cycling losses, expressed in British thermal units per hour (Btu/h), and electrical power input, expressed in watts, for a theoretical comparable single-speed portable air conditioner at the 83 °F dry-bulb outdoor temperature operating condition.

$Capacity_{83\_SS} = Capacity_{Full}$

$Capacity_{83\_SS\_CLF} = Capacity_{Full} \times 0.875$

$P_{83\_SS} = P_{Full}$

Where:

$Capacity_{83\_SS}$ = theoretical comparable single-speed portable air conditioner cooling capacity, in Btu/h, calculated for the 83 °F dry-bulb outdoor temperature operating condition.

$Capacity_{83\_SS\_CLF}$ = theoretical comparable single-speed portable air conditioner cooling capacity with cycling losses, in Btu/h, calculated for the 83 °F dry-bulb outdoor temperature operating condition.

$Capacity_{Full}$ = cooling capacity, in Btu/h, measured in section 4.1 of this appendix at Test Condition 1 in Table 1 of this appendix.

P_{83_SS} = theoretical comparable single-speed portable air conditioner electrical power input, in watts, calculated for the 83 °F dry-bulb outdoor temperature operating condition.

P_{Full} = electrical power input, in watts, measured in section 4.1 of this appendix at Test Condition 1 in Table 1 of this appendix.

0.875 = cycling loss factor for the 83 °F dry-bulb outdoor temperature operating condition.

5.5.2 *Duct Heat Transfer for a Theoretical Comparable Single-Speed Portable Air Conditioner at the Lower Outdoor Temperature Operating Condition.* Calculate the condenser exhaust duct heat transfer to the conditioned space for a theoretical comparable single-speed portable air conditioner at the 83 °F dry-bulb outdoor temperature operating condition, as follows:

$Q_{duct\_83\_SS} = 3 \times A_{duct} \times (T_{duct\_Full} - T_{ei})$

Where:

$Q_{duct\_83\_SS}$ = total heat transferred from the condenser exhaust duct to the indoor conditioned space in cooling mode, for a theoretical comparable single-speed portable air conditioner at the 83 °F dry-bulb outdoor temperature operating condition, in Btu/h.

3 = convection coefficient, in Btu/h per square foot per °F.

A_{duct} = surface area of the condenser exhaust duct, as calculated in section 4.1.1 of this appendix, in square feet.

T_{duct_Full} = average surface temperature for the condenser exhaust duct, as measured in section 4.1.1 of this appendix at Test Condition 1 in Table 1 of this appendix, in °F.

T_{ei} = average evaporator inlet air dry-bulb temperature, measured in section 4.1.1 of this appendix, in °F.

5.5.3 *Infiltration Air Heat Transfer for a Theoretical Comparable Single-Speed Portable Air Conditioner at the Lower Outdoor Temperature Operating Condition.* Calculate the heat contribution from infiltration air for a theoretical comparable single-speed portable air conditioner at the 83 °F dry-bulb outdoor temperature operating condition, as described in this section. Calculate the dry air mass flow rate of infiltration air according to the following equation:

$$\dot{m}_{83\_SS} = \frac{V_{co\_Full} \times \rho_{co\_Full}}{(1 + \omega_{co\_Full})}$$

Where:

$\dot{m}_{83\_SS}$ = dry air mass flow rate of infiltration air for a theoretical comparable single-speed portable air conditioner at the 83 °F dry-bulb outdoor temperature operating condition, in lb/m.

V_{co_Full} = actual average volumetric flow rate of the condenser outlet air, as determined in section 4.1 of this appendix during cooling mode testing with the full compressor speed at Test Condition 1 in Table 1 of this appendix, in cfm.

ρ_{co_Full} = actual average density of the condenser outlet air, as determined in section 4.1 of this appendix during cooling mode at Test Condition 1 in Table 1 of this appendix, in lb_m/ft^3.

ω_{co_Full} = average humidity ratio of condenser outlet air, as determined in section 4.1 of this appendix during cooling mode testing at Test Condition 1 in Table 1 of this appendix, in pounds mass of water vapor per pounds mass of dry air (lb_w/lb_{da}).

Calculate the sensible component of infiltration air heat contribution for a theoretical comparable single-speed portable air conditioner at the 83 °F dry-

bulb outdoor temperature operating condition as follows:

$$Q_{s\_83\_SS} = \dot{m}_{83\_SS} \times 60 \times [(0.24 \times (T_{ia\_83} - 80)) + (0.444 \times (0.01086 \times T_{ia\_83} - 0.0112 \times 80))]$$

Where:

$Q_{s\_83\_SS}$ = sensible heat added to the room by infiltration air for a theoretical comparable single-speed portable air conditioner, at the 83 °F dry-bulb outdoor temperature operating condition, in Btu/h.

0.24 $Btu/lb_m - °F$ = specific heat of dry air.

0.444 $Btu/lb_m - °F$ = specific heat of water vapor.

80 = indoor chamber dry-bulb temperature, in °F.

T_{ia_95} and T_{ia_83} = infiltration air dry-bulb temperatures for the 95 °F and the 83 °F dry-bulb outdoor temperature operating conditions, 95 °F and 83 °F, respectively.

0.01086 = ω_{ia_83} = humidity ratio of the infiltration air for the 83 °F dry-bulb outdoor temperature operating condition, in lb_w/lb_{da}.

0.0112 = humidity ratio of the indoor chamber air at Test Condition 1 in Table 1 of this appendix, in lb_w/lb_{da}.

60 = conversion factor from minutes to hours.

$\dot{m}_{83\_SS}$ as previously calculated in this section.

Calculate the latent component of infiltration air heat contribution for a theoretical comparable single-speed portable air conditioner at the 83 °F dry-bulb outdoor temperature operating condition as follows:

$$Q_{l\_83\_SS} = \dot{m}_{83\_SS} \times 63660 \times (\omega_{ia\_83} - 0.0112)$$

Where:

$Q_{l\_83\_SS}$ = latent heat added to the room by infiltration air for a theoretical comparable single-speed portable air conditioner, at the 83 °F dry-bulb outdoor temperature operating condition, in Btu/h.

63660 $Btu - m/lb_m - h$ = latent heat of vaporization for water vapor, 1060 Btu/lb_m, multiplied by the conversion factor from minutes to hours, 60 m/h.

0.0112 lb_w/lb_{da} = humidity ratio of the indoor chamber air.

$\dot{m}_{83\_SS}$ and ω_{ia_83} as previously calculated and defined, respectively, in this section.

Calculate the total heat contribution of the infiltration air for a theoretical comparable single-speed portable air conditioner at the 83 °F dry-bulb outdoor temperature operating condition according to the following equation:

$$Q_{infiltration\_83\_SS} = Q_{s\_83\_SS} + Q_{l\_83\_SS}$$

Where:

$Q_{infiltration\_83\_SS}$ = total infiltration air heat in cooling mode for a theoretical comparable single-speed portable air conditioner at the 83 °F dry-bulb outdoor temperature operating condition, in Btu/h.

$Q_{s\_83\_SS}$, $Q_{l\_83\_SS}$ as previously calculated in this section

5.5.4 *Adjusted Cooling Capacity for a Theoretical Comparable Single-Speed Portable Air Conditioner at the Lower Outdoor Temperature Operating Condition.* Calculate the adjusted cooling capacity for a theoretical comparable single-speed portable air conditioner at the 83 °F dry-bulb outdoor temperature operating condition without cycling losses, ACC_{83_SS}, and with cycling losses, $ACC_{83\_SS\_CLF}$, in Btu/h, according to the following equations:

$$ACC_{83\_SS} = Capacity_{83\_SS} - Q_{duct\_83\_SS} - Q_{infiltration\_83\_SS}$$

$$ACC_{83\_SS\_CLF} = Capacity_{83\_SS\_CLF} - Q_{duct\_83\_SS} - Q_{infiltration\_83\_SS}$$

Where:

ACC_{83_SS} and $ACC_{83\_SS\_CLF}$ = adjusted cooling capacity for a theoretical comparable single-speed portable air conditioner at the 83 °F dry-bulb outdoor temperature operating condition without and with cycling losses, respectively, in Btu/h.

$Capacity_{83\_SS}$ and $Capacity_{83\_SS\_CLF}$ = theoretical comparable single-speed portable air conditioner cooling capacity without and with cycling losses, respectively, in Btu/h, at the 83 °F dry-bulb outdoor temperature operating condition, calculated in section 5.5.1 of this appendix.

$Q_{duct\_83\_SS}$ = total heat transferred from the ducts to the indoor conditioned space in cooling mode for a theoretical comparable single-speed portable air conditioner at the 83 °F dry-bulb outdoor temperature operating condition, in Btu/h, calculated in section 5.5.2 of this appendix.

$Q_{infiltration\_83\_SS}$ = total infiltration air heat in cooling mode for a theoretical comparable single-speed portable air conditioner at the 83 °F dry-bulb outdoor temperature operating condition, in Btu/h, calculated in section 5.5.3 of this appendix.

5.5.5 *Annual Energy Consumption in Cooling Mode for a Theoretical Comparable Single-Speed Portable Air Conditioner at the Lower Outdoor Temperature Operating Condition.* Calculate the annual energy consumption in cooling mode for a theoretical comparable single-speed portable air conditioner at the 83 °F dry-bulb outdoor temperature operating condition, in kWh/year, according to the following equation:

$$AEC_{83\_SS} = P_{83\_SS} \times 750 \times 0.001$$

Where:

AEC_{83_SS} = annual energy consumption for a theoretical comparable single-speed portable air conditioner in cooling mode at the 83 °F dry-bulb outdoor temperature operating condition, in kWh/year.

P_{83_SS} = electrical power input for a theoretical comparable single-speed portable air conditioner at the 83 °F dry-bulb outdoor temperature operating condition as calculated in section 5.5.1 of this appendix, in watts.

750 = number of cooling mode hours per year, as defined in section 5.3 of this appendix.

0.001 kWh/Wh = conversion factor from watt-hours to kilowatt-hours.

5.5.6 *Combined Energy Efficiency Ratio for a Theoretical Comparable Single-Speed Portable Air Conditioner.* Calculate the combined energy efficiency ratio for a theoretical comparable single-speed portable air conditioner without cycling losses, $CEER_{SS}$, and with cycling losses, $CEER_{SS\_CLF}$, in Btu/Wh, according to the following equations:

$$CEER_{SS} = \left[\frac{ACC_{95}}{\left(\frac{AEC_{Full} + AEC_T}{750 \times 0.001}\right)}\right] \times 0.2 + \left[\frac{ACC_{83\_SS}}{\left(\frac{AEC_{83\_SS} + AEC_T}{750 \times 0.001}\right)}\right] \times 0.8$$

$$CEER_{SS\_CLF} = \left[\frac{ACC_{95}}{\left(\frac{AEC_{Full} + AEC_T}{750 \times 0.001}\right)}\right] \times 0.2 + \left[\frac{ACC_{83\_SS\_CLF}}{\left(\frac{AEC_{83\_SS} + AEC_T}{750 \times 0.001}\right)}\right] \times 0.8$$

Where:

$CEER_{SS}$ and $CEER_{SS\_CLF}$ = combined energy efficiency ratio for a theoretical comparable single-speed portable air conditioner without and with cycling losses considered, respectively, in Btu/Wh.

ACC_{95} = adjusted cooling capacity for the sample unit, as calculated in section 5.1 of this appendix, when tested at Test Condition 1 in Table 1 of this appendix that is representative of operation at the 95 °F dry-bulb outdoor temperature operating condition, in Btu/h.

ACC_{83_SS} and $ACC_{83\_SS\_CLF}$ = adjusted cooling capacity for a theoretical comparable single-speed portable air conditioner at the 83 °F dry-bulb outdoor temperature operating condition without and with cycling losses, respectively, as calculated in section 5.5.4 of this appendix, in Btu/h.

AEC_{Full} = annual energy consumption for the sample unit, as calculated in section 5.3 of this appendix, for cooling mode operation at Test Condition 1 in Table 1 of this appendix that represents operation at a 95 °F dry-bulb outdoor temperature operating condition, in kWh/year.

AEC_{83_SS} = annual energy consumption for a theoretical comparable single-speed portable air conditioner in cooling mode at the 83 °F dry-bulb outdoor temperature operating condition, calculated in section 5.5.5 of this appendix, in kWh/year.

AEC_T = total annual energy consumption attributed to all operating modes except cooling for the sample unit, calculated in section 5.3 of this appendix, in kWh/year.

750 and 0.001 as defined previously in this section.

0.2 = weighting factor for the 95 °F dry-bulb outdoor temperature operating condition.

0.8 = weighting factor for the 83 °F dry-bulb outdoor temperature operating condition.

5.5.7 *Single-Duct Variable-Speed Portable Air Conditioner Performance Adjustment Factor.* Calculate the sample unit's performance adjustment factor, F_p, according to the following equation:

$$F_p = \frac{\left(CEER_{SS} - CEER_{SS\_CLF}\right)}{CEER_{SS\_CLF}}$$

Where:

$CEER_{SS}$ and $CEER_{SS\_CLF}$ = combined energy efficiency ratio for a theoretical comparable single-speed portable air conditioner without and with cycling losses considered, respectively, calculated in section 5.5.6 of this appendix, in Btu/Wh.

5.5.8 *Single-Duct Variable-Speed Portable Air Conditioner Combined Energy Efficiency Ratio.* Calculate the sample unit's final combined energy efficiency ratio, CEER, in Btu/Wh, according to the following equation:

$$CEER = CEER_{UA} \times (1 + F_p)$$

Where:

CEER = combined energy efficiency ratio for the sample unit, in Btu/Wh.

$CEER_{UA}$ = unadjusted combined energy efficiency ratio for the sample unit, calculated in section 5.4 of this appendix, in Btu/Wh.

F_p = sample unit's performance adjustment factor, determined in section 5.5.7 of this appendix.''

(3) *Representations.* LG may not make representations about the efficiency of any basic model listed in paragraph (1) of this Order for any purpose, including compliance and marketing, unless the basic model has been tested in accordance with the provisions set forth above and such representations fairly disclose the results of such testing.

(4) This waiver shall remain in effect according to the provisions of 10 CFR 430.27.

(5) DOE issues this waiver on the condition that the statements, representations, and information provided by LG are valid. If LG makes any modifications to the controls or configurations of a basic model subject to this waiver, such modifications will render the waiver invalid with respect to that basic model, and LG will either be required to use the current Federal test procedure or submit a new application for a test procedure waiver. DOE may rescind or modify this waiver at any time if it determines the factual basis underlying the petition for waiver is incorrect, or the results from the alternate test procedure are unrepresentative of a basic model's true energy consumption characteristics. 10 CFR 430.27(k)(1). Likewise, LG may request that DOE rescind or modify the waiver if LG discovers an error in the information provided to DOE as part of its petition, determines that the waiver is no longer needed, or for other appropriate reasons. 10 CFR 430.27(k)(2).

(6) LG remains obligated to fulfill the certification requirements set forth at 10 CFR part 429.

Signed in Washington, DC, on May 8, 2020.

Alexander N. Fitzsimmons,

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

[FR Doc. 2020–11765 Filed 6–1–20; 8:45 am]

BILLING CODE 6450–01–P

DEPARTMENT OF ENERGY

Fusion Energy Sciences Advisory Committee

AGENCY: Office of Science, Department of Energy.

ACTION: Notice of open meeting.

SUMMARY: This notice announces a meeting of the Fusion Energy Sciences Advisory Committee (FESAC). The Federal Advisory Committee Act requires that public notice of these meetings be announced in the **Federal Register**.

DATES: Tuesday, June 23, 2020 11:00 a.m. to 5:30 p.m. EDT
Wednesday, June 24, 2020 11:00 a.m. to 1:30 p.m. EDT

Location: This meeting will be held digitally via webcast using Zoom. Instructions for Zoom, as well as any updates to meeting times or meeting agenda, can be found on the FESAC meeting website at: *https://science.osti.gov/fes/fesac/Meetings.*

FOR FURTHER INFORMATION CONTACT: Dr. Samuel J. Barish, Acting Designated Federal Officer, Office of Fusion Energy Sciences (FES); U.S. Department of Energy; Office of Science; 1000 Independence Avenue SW; Washington, DC 20585; Telephone: (301) 903–2917; Email address: *sam.barish@science.doe.gov.*

SUPPLEMENTARY INFORMATION:

Purpose of the Board: The purpose of the Board is to provide advice on a continuing basis to the Director, Office of Science of the Department of Energy, on the many complex scientific and technical issues that arise in the development and implementation of the fusion energy sciences program.

Tentative Agenda Items:

- News from the Office of Science
- FES Perspective
- Update on the FESAC Subcommittee to Develop a Long-Range Plan for the FES Program
- 2020 NAS Report—*Plasma Science: Enabling Technology, Sustainability, Security, and Exploration*
- Diversity, Equity, and Inclusion Initiatives in the Office of Science
- Public Comment
- Adjourn

Public Participation: The meeting is open to the public. If you would like to file a written statement with the Committee, you may do so either before or after the meeting. If you would like to make an oral statement regarding any of the items on the agenda, you should contact Dr. Barish at *sam.barish@science.doe.gov* (Email). Reasonable provision will be made to include the scheduled oral statements during the Public Comment time on the agenda. The Chairperson of the Committee will conduct the meeting to facilitate the orderly conduct of business. Public comment will follow the 10-minute rule.

Minutes: The minutes of the meeting will be available for public review and copying within 30 days on the Fusion Energy Sciences Advisory Committee website—*http://science.energy.gov/fes/fesac/.*

Signed in Washington, DC, on May 27, 2020.

LaTanya Butler,

Deputy Committee Management Officer.

[FR Doc. 2020–11773 Filed 6–1–20; 8:45 am]

BILLING CODE 6450–01–P

DEPARTMENT OF ENERGY

Environmental Management Site-Specific Advisory Board, Savannah River Site

AGENCY: Office of Environmental Management, Department of Energy.

ACTION: Notice of open virtual meeting.

SUMMARY: This notice announces an online virtual meeting of the Environmental Management Site-Specific Advisory Board (EM SSAB), Savannah River Site. The Federal Advisory Committee Act requires that public notice of this online virtual meeting be announced in the **Federal Register**.

DATES: Monday, June 15, 2020 6:00 p.m.–8:00 p.m.

ADDRESSES: *Online Virtual Meeting*: To attend, please send an email to: *srscitizensadvisoryboard@gmail.com* by no later than 4:00 p.m. EDT on Friday, June 12, 2020.

To Submit Public Comments: Public comments will be accepted via email prior to and after the meeting. Comments related to the Integrated Priority List that are received by no later than 4:00 p.m. EDT on Friday, June 12, 2020 will be read aloud during the virtual meeting. Comments will also be accepted after the meeting, by no later than 4:00 p.m. EDT on Friday, June 22, 2020. Please submit comments to *srscitizensadvisoryboard@gmail.com.*

FOR FURTHER INFORMATION CONTACT: Please send an email to: *srscitizensadvisoryboard@gmail.com,* or Amy Boyette, Office of External Affairs, U.S. Department of Energy, Savannah River Operations Office, P.O. Box A, Aiken, SC 29802; Phone: (803) 952–6120.

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:

—Meeting Rules and Agenda Review
—Opening and Chair Update
—Presentation: Budget and Integrated Priority List
—Discussion on Integrated Priority List Letter
—Reading of Public Comments
—Voting: Integrated Priority List Letter
—Adjourn

Public Participation: Written statements may be filed with the Board either before or after the meeting as there will not be opportunities for live public comment during this online virtual meeting. 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 submit public comments should email them as directed above.

Minutes: Minutes will be available by writing or calling Amy Boyette, Office of External Affairs, U.S. Department of Energy, Savannah River Operations Office, P.O. Box A, Aiken, SC 29802; Phone: (803) 952–6120. Minutes will also be available at the following website: *https://cab.srs.gov/srs-cab.html.*

Signed in Washington, DC, on May 27, 2020.

LaTanya Butler,

Deputy Committee Management Officer.

[FR Doc. 2020–11772 Filed 6–1–20; 8:45 am]

BILLING CODE 6450–01–P

DEPARTMENT OF ENERGY

Federal Energy Regulatory Commission

[Project No. 14634–002]

New England Hydro Power Company, LLC; Notice of Conference Call

a. *Date and Time of Meeting:* June 3, 2020 at 10:00 a.m. Eastern Standard Time

b. *FERC Contact:* John Baummer at *john.baummer@ferc.gov* or (202) 502–6837

c. *Purpose of Meeting:* On May 14, 2020, New England Hydropower Company, LLC (NEHC) filed a letter requesting a meeting with Commission staff to discuss amendments to its pending license application for the Ashton Dam Hydroelectric Project (P–14634–002). The project would be located on the Blackstone River, near the Towns of Cumberland and Lincoln, Providence County, Rhode Island. NEHC states that it is now proposing to install submersible Kaplan turbine-generator units instead of the Archimedes Screw turbine-generator units proposed in the license application. NEHC also states that it is proposing to convert its pending license application to an application for a small hydroelectric (10 megawatt or less) exemption from licensing. NEHC is requesting a conference call with Commission staff to ''lay out a process and schedule'' for these changes.

d. *Proposed Agenda:* (1) Introduction of participants; (2) NEHC presentation on purpose of meeting; (3) Discussion on NEHC's proposed changes and schedule; and (4) Meeting conclusion.

e. A summary of the meeting will be prepared and filed in the Commission's public file for the project.

f. All local, state, and federal agencies, Indian tribes, and other interested parties are invited to participate by phone. If interested, please contact John Baummer at *john.baummer@ferc.gov* or (202) 502–6837, by June 01, 2020, to receive the conference call number and access code.

Dated: May 27, 2020.

Kimberly D. Bose,

Secretary.

[FR Doc. 2020–11871 Filed 6–1–20; 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: EC20–68–000.

Applicants: DTE Electric Company, Gichi Noodin Wind Farm, LLC.

Description: Application for Authorization Under Section 203 of the Federal Power Act, et al. of DTE Electric Company, et al.

Filed Date: 5/27/20.

Accession Number: 20200527–5140.

Comments Due: 5 p.m. ET 6/17/20.

Take notice that the Commission received the following electric rate filings:

Docket Numbers: ER10–3115–006.

Applicants: Waterside Power, LLC.

Description: Supplement to April 20, 2020 Triennial Market Power Update for the Northeast Region of Waterside Power, LLC.

Filed Date: 5/26/20.

Accession Number: 20200526–5242.

Comments Due: 5 p.m. ET 6/16/20.

Docket Numbers: ER10–3117–008.

Applicants: Lea Power Partners, LLC.

Description: Supplement to April 20, 2020 Triennial Market Power Update for

the Southwest Power Pool Region of Lea Power Partners, LLC.

Filed Date: 5/26/20.

Accession Number: 20200526–5241.

Comments Due: 5 p.m. ET 6/16/20.

Docket Numbers: ER14–1421–005.

Applicants: Diamond State Generation Partners, LLC.

Description: Compliance filing: Compliance Filing to be effective 7/1/2019.

Filed Date: 5/27/20.

Accession Number: 20200527–5000.

Comments Due: 5 p.m. ET 6/17/20.

Docket Numbers: ER20–1901–000.

Applicants: Midcontinent Independent System Operator, Inc.

Description: Request for Waiver of Midcontinent Independent System Operator, Inc.

Filed Date: 5/26/20.

Accession Number: 20200526–5239.

Comments Due: 5 p.m. ET 6/16/20.

Docket Numbers: ER20–1902–000.

Applicants: Midcontinent Independent System Operator, Inc., PJM Interconnection, L.L.C.

Description: § 205(d) Rate Filing: 2020–05–27_MISO–PJM JOA EMS Models and Data Exchange Filing to be effective 7/27/2020.

Filed Date: 5/27/20.

Accession Number: 20200527–5112.

Comments Due: 5 p.m. ET 6/17/20.

Docket Numbers: ER20–1903–000.

Applicants: Midcontinent Independent System Operator, Inc., PJM Interconnection, L.L.C.

Description: § 205(d) Rate Filing: Revisions to the MISO–PJM Joint Operating Agreement re EMS Data Confidentiality to be effective 7/27/2020.

Filed Date: 5/27/20.

Accession Number: 20200527–5134.

Comments Due: 5 p.m. ET 6/17/20.

Docket Numbers: ER20–1904–000.

Applicants: California Independent System Operator Corporation.

Description: § 205(d) Rate Filing: 2020–05–27 Proxy Demand Resources to Provide Flexible RA Capacity to be effective 8/1/2020.

Filed Date: 5/27/20.

Accession Number: 20200527–5152.

Comments Due: 5 p.m. ET 6/17/20.

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: May 27, 2020.

Nathaniel J. Davis, Sr.,

Deputy Secretary.

[FR Doc. 2020–11841 Filed 6–1–20; 8:45 am]

BILLING CODE 6717–01–P

DEPARTMENT OF ENERGY

Federal Energy Regulatory Commission

[Docket No. CP20–456–000]

Enable Mississippi River Transmission, LLC; Notice of Application

Take notice that on May 15, 2020, Enable Mississippi River Transmission, LLC (MRT), 910 Louisiana Street, Suite 4840, Houston, Texas 77002, filed in the above referenced docket an application pursuant to section 7(c) of the Natural Gas Act (NGA), 15 U.S.C. 717f(c) of the regulations of the Federal Energy Regulatory Commission requesting authorization for an amendment to its certificate of public convenience necessity pursuant to Part 157, Subpart A of the Commission's regulations for the East Unionville Storage Field located in Lincoln Parish, Louisiana. MRT seeks authorization to reduce East Unionville's certificated cushion gas capacity to 19.1 Bcf and to increase East Unionville's working gas capacity to 36.1 Bcf. MRT states that with the approval of these proposed changes, the East Unionville's certificated total capacity of 55.2 Bcf will not change. MRT also requests approval of the accounting entries associated with the amendments to the East Unionville Certificate, all as more fully set forth in the application which is on file with the Commission and open to public inspection. The filing is available for review on the Commission's website web at *http://www.ferc.gov* using the ''eLibrary'' link. Enter the docket number excluding the last three digits in the docket number field to access the document. For assistance, contact FERC at *FERCOnlineSupport@ferc.gov* or call toll-free, (866) 208–3676 or TYY, (202) 502–8659. At this time, the Commission has suspended access to the Commission's Public Reference Room, due to the proclamation declaring a National Emergency concerning the Novel Coronavirus Disease (COVID–19), issued by the President on March 13, 2020.

Any questions concerning this application may be directed to Jonathan Christian, Associate General Counsel, Enable Mississippi River Transmission, LLC, 910 Louisiana Street, 48th Floor, Houston, TX 77002, by phone at (346) 701–2146, or by email at *jonathan.christian@enablemidstream.com.*

Pursuant to section 157.9 of the Commission's rules (18 CFR 157.9), within 90 days of this Notice, the Commission staff will either: Complete its environmental assessment (EA) and place it into the Commission's public record (eLibrary) for this proceeding; or issue a Notice of Schedule for Environmental Review. If a Notice of Schedule for Environmental Review is issued, it will indicate, among other milestones, the anticipated date for the Commission staff's issuance of the final environmental impact statement (FEIS) or EA for this proposal. The filing of the EA in the Commission's public record for this proceeding or the issuance of a Notice of Schedule for Environmental Review will serve to notify federal and state agencies of the timing for the completion of all necessary reviews, and the subsequent need to complete all federal authorizations within 90 days of the date of issuance of the Commission staff's FEIS or EA.

There are two ways to become involved in the Commission's review of this project. First, any person wishing to obtain legal status by becoming a party to the proceedings for this project should, on or before the comment date stated below file with the Federal Energy Regulatory Commission, 888 First Street NE, Washington, DC 20426, a motion to intervene in accordance with the requirements of the Commission's Rules of Practice and Procedure (18 CFR 385.214 or 385.211) and the Regulations under the NGA (18 CFR 157.10). A person obtaining party status will be placed on the service list maintained by the Secretary of the Commission and will receive copies of all documents filed by the applicant and by all other parties. Only parties to the proceeding can ask for court review of Commission orders in the proceeding.

However, a person does not have to intervene in order to have comments considered. The second way to participate is by filing with the Secretary of the Commission, as soon as possible, an original and two copies of comments in support of or in opposition

to this project. The Commission will consider these comments in determining the appropriate action to be taken, but the filing of a comment alone will not serve to make the filer a party to the proceeding. The Commission's rules require that persons filing comments in opposition to the project provide copies of their protests only to the party or parties directly involved in the protest.

Persons who wish to comment only on the environmental review of this project should submit an original and two copies of their comments to the Secretary of the Commission. Environmental commentors will be placed on the Commission's environmental mailing list and will be notified of any meetings associated with the Commission's environmental review process. Environmental commentors will not be required to serve copies of filed documents on all other parties. However, the non-party commentors will not receive copies of all documents filed by other parties or issued by the Commission and will not have the right to seek court review of the Commission's final order.

In addition to publishing the full text of this document in the **Federal Register**, the Commission provides all interested persons an opportunity to view and/or print the contents of this document via the internet through the Commission's Home Page (*http://ferc.gov*) using the ''eLibrary'' link. Enter the docket number excluding the last three digits in the docket number field to access the document. At this time, the Commission has suspended access to the Commission's Public Reference Room, due to the proclamation declaring a National Emergency concerning the Novel Coronavirus Disease (COVID–19), issued by the President on March 13, 2020. For assistance, contact the Federal Energy Regulatory Commission at *FERCOnlineSupport@ferc.gov* or call toll-free, (886) 208–3676 or TYY, (202) 502–8659.

The Commission strongly encourages electronic filings of comments, protests and interventions in lieu of paper using the ''eFiling'' link at *http://www.ferc.gov.* Persons unable to file electronically may mail similar pleadings to the Federal Energy Regulatory Commission, 888 First Street NE, Washington, DC 20426. Hand delivered submissions in docketed proceedings should be delivered to Health and Human Services, 12225 Wilkins Avenue, Rockville, Maryland 20852.

Comment Date: 5:00 p.m. Eastern Standard Time on June 17, 2020.

Dated: May 27, 2020.

Kimberly D. Bose,

Secretary.

[FR Doc. 2020–11867 Filed 6–1–20; 8:45 am]

BILLING CODE 6717–01–P

DEPARTMENT OF ENERGY

Federal Energy Regulatory Commission

[Project No. 2309–032]

Jersey Central Power & Light Company, PSEG Fossil, LLC, Yards Creek Energy, LLC; Notice of Application for Partial Transfer of License and Soliciting Comments, Motions to Intervene, and Protests

On May 6, 2020, Jersey Central Power & Light Company (JCP&L or transferor) and PSEG Fossil, LLC (PSEG) current co-licensees, and Yards Creek Energy, LLC (YCE or transferee) filed a joint application for a partial transfer of the license for the Yards Creek Pumped Storage Hydroelectric Project No. 2309. The project is located on Yards Creek in Warren County, New Jersey.

The applicants seek Commission approval for a partial transfer of the license for the project to remove JCP&L as a co-licensee and to add YCE as co-licensee.

Applicants Contact: For transferor: Anne M. Rericha, Attorney, FirstEnergy Service Company, 76 S. Maine Street, Akron, Ohio 44308, Phone: (330) 374–6550, Email: *arericha@firstenergycorp.com* and Morgan E. Parke, Associate General Counsel, FirstEnergy Service Company, 76 S. Maine Street, Akron, Ohio 44308, Phone: (330) 384–4595, Email: *mparke@firstenergycorp.com*

For co-licensee: Cara J. Lewis, Managing Counsel—Federal Regulatory, PSEG Services Corporation, 80 Park Plaza—T5G, Newark, New Jersey 07102, Phone: (973) 430–8836, Email: *cara.lewis@pseg.com*

For transferee: Kimberly Ognisty, Winston & Strawn LLC, 1901 L Street NW, Washington, DC 20036, Phone: (202) 282–5217, Email: *kognisty@winston.com*

FERC Contact: Anumzziatta Purchiaroni, (202) 502–6191, *Anumzziatta.purchiaroni@ferc.gov.*

Deadline for filing comments, motions to intervene, and protests: 30 days from the date that the Commission issues this notice. The Commission strongly encourages electronic filing. Please file comments, motions to intervene, and protests using the Commission's eFiling system at *http://www.ferc.gov/docs-filing/efiling.asp.* Commenters can submit brief comments up to 6,000 characters, without prior

registration, using the eComment system at *http://www.ferc.gov/docs-filing/ecomment.asp.* You must include your name and contact information at the end of

your comments. For assistance, please contact FERC Online Support at *FERCOnlineSupport@ferc.gov,* (866) 208–3676 (toll free), or (202) 502–8659 (TTY). In lieu of electronic filing, please send a paper copy to: Secretary, Federal Energy Regulatory Commission, 888 First Street NE, Washington, DC 20426. The first page of any filing should include docket number P–2309–032.

Dated: May 27, 2020.

Kimberly D. Bose,

Secretary.

[FR Doc. 2020–11868 Filed 6–1–20; 8:45 am]

BILLING CODE 6717–01–P

DEPARTMENT OF ENERGY

Federal Energy Regulatory Commission

[Project No. 15022–000]

Warrior Hydro, LLC; Notice of Preliminary Permit Application Accepted for Filing and Soliciting Comments, Motions To Intervene, and Competing Applications

On January 28, 2020, Warrior Hydro, LLC filed an application for a preliminary permit, pursuant to section 4(f) of the Federal Power Act (FPA), proposing to study the feasibility of a hydropower project to be located at the U.S. Army Corps of Engineers' (Corps) William Bacon Oliver Lock and Dam on the Black Warrior River near the towns of Tuscaloosa and Northport in Tuscaloosa County, Alabama. The sole purpose of a preliminary permit, if issued, is to grant the permit holder priority to file a license application during the permit term. A preliminary permit does not authorize the permit holder to perform any land-disturbing activities or otherwise enter upon lands or waters owned by others without the owners' express permission.

The proposed project would consist of the following: (1) An 80-foot-long, 140-foot-wide intake channel; (2) four 10-foot-diameter, 60-foot-long steel siphon penstocks, near the south abutment of the Corps' dam; (3) a 80-foot-long, 40-foot-wide powerhouse containing four generating units with a total capacity of 9.2 megawatts; (4) a 100-foot-long, 140-foot-wide tailrace; and (5) a 0.9-mile-long, 34.5kV transmission line. The proposed project would have an

estimated average annual generation of 59,000 megawatt-hours, and operate as directed by the Corps.

Applicant Contact: Mr. Jeremy Wells, Wells Engineering, LLC, 5962 Zebulon Rd #144, Macon, GA 35565; (478) 238–3054

FERC Contact: Michael Spencer; *michael.spencer@ferc.gov;* (202) 502–6093.

Deadline for filing comments, motions to intervene, competing applications (without notices of intent), or notices of intent to file competing applications: Sixty (60) days from the issuance of this notice. Competing applications and notices of intent must meet the requirements of 18 CFR 4.36.

The Commission strongly encourages electronic filing. Please file comments, motions to intervene, notices of intent, and competing applications using the Commission's eFiling system at *http://www.ferc.gov/docs-filing/efiling.asp.* Commenters can submit brief comments up to 6,000 characters, without prior registration, using the eComment system at *http://www.ferc.gov/docs-filing/ecomment.asp.* You must include your name and contact information at the end of your comments. For assistance, please contact FERC Online Support at *FERCOnlineSupport@ferc.gov,* (866) 208–3676 (toll free), or (202) 502–8659 (TTY). In lieu of electronic filing, please send a paper copy to: Secretary, Federal Energy Regulatory Commission, 888 First Street NE, Washington, DC 20426. The first page of any filing should include docket number P–15022–000.

More information about this project, including a copy of the application, can be viewed or printed on the ''eLibrary'' link of Commission's website at *http://www.ferc.gov/docs-filing/elibrary.asp.* Enter the docket number (P–15022) in the docket number field to access the document. For assistance, contact FERC Online Support.

Dated: May 27, 2020.

Kimberly D. Bose,

Secretary.

[FR Doc. 2020–11866 Filed 6–1–20; 8:45 am]

BILLING CODE 6717–01–P

DEPARTMENT OF ENERGY

Federal Energy Regulatory Commission

[Docket No. ER20–1879–000]

Oliver Wind I, 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 Oliver Wind I, 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 June 16, 2020.

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 may mail similar pleadings to the Federal Energy Regulatory Commission, 888 First Street NE, Washington, DC 20426. Hand delivered submissions in docketed proceedings should be delivered to Health and Human Services, 12225 Wilkins Avenue, Rockville, Maryland 20852.

In addition to publishing the full text of this document in the **Federal Register**, the Commission provides all interested persons an opportunity to view and/or print the contents of this document via the internet through the Commission's Home Page (*http://ferc.gov*) using the ''eLibrary'' link. Enter the docket number excluding the last three digits in the docket number field to access the document. At this time, the Commission has suspended access to the Commission's Public Reference Room, due to the proclamation declaring a National Emergency concerning the Novel Coronavirus Disease (COVID–19), issued by the President on March 13, 2020. For assistance, contact the Federal Energy Regulatory Commission at *FERCOnlineSupport@ferc.gov* or call toll-free, (886) 208–3676 or TYY, (202) 502–8659.

Dated: May 27, 2020.

Nathaniel J. Davis, Sr.,

Deputy Secretary.

[FR Doc. 2020–11836 Filed 6–1–20; 8:45 am]

BILLING CODE 6717–01–P

DEPARTMENT OF ENERGY

Federal Energy Regulatory Commission

[Docket No. ER20–1769–000]

Chicot Solar, 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 Chicot Solar, 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 June 16, 2020.

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 may mail similar pleadings to the Federal Energy Regulatory Commission, 888 First Street NE, Washington, DC 20426. Hand delivered submissions in docketed proceedings should be delivered to Health and Human Services, 12225 Wilkins Avenue, Rockville, Maryland 20852.

In addition to publishing the full text of this document in the **Federal Register**, the Commission provides all

interested persons an opportunity to view and/or print the contents of this document via the internet through the Commission's Home Page (*http://ferc.gov*) using the ''eLibrary'' link. Enter the docket number excluding the last three digits in the docket number field to access the document. At this time, the Commission has suspended access to the Commission's Public Reference Room, due to the proclamation declaring a National Emergency concerning the Novel Coronavirus Disease (COVID–19), issued by the President on March 13, 2020. For assistance, contact the Federal Energy Regulatory Commission at *FERCOnlineSupport@ferc.gov* or call toll-free, (886) 208–3676 or TYY, (202) 502–8659.

Dated: May 27, 2020.

Nathaniel J. Davis, Sr.,

Deputy Secretary.

[FR Doc. 2020–11835 Filed 6–1–20; 8:45 am]

BILLING CODE 6717–01–P

DEPARTMENT OF ENERGY

Federal Energy Regulatory Commission

[Docket No. AD19–16–000]

Common Performance Metrics; Request for Information on Performance Metrics for ISOs, RTOs, and Regions Outside ISOs and RTOs

On April 21, 2020, the Office of Management and Budget (OMB) approved the Federal Energy Regulatory Commission (Commission or FERC) staff's request for reinstatement and revision of the FERC–922 (Performance Metrics for ISOs, RTOs, and Regions Outside ISOs and RTOs, OMB Control No. 1902–0262) information collection, as discussed in Docket No. AD19–16–000. Consistent with the OMB-approved information collection, ISOs, RTOs, and utilities in regions outside ISOs and RTOs are encouraged to submit responsive information by October 30, 2020.[1]

Respondents should submit their responses in Docket No. AD19–16–000 via the Commission's electronic filing (eFiling) system.[2] Submissions should be made using the OMB-approved Information Collection Input Spreadsheet (Excel workbook) and the associated Common Metrics Information Collection User Guide.[3]

For further information, please contact: Darren Sheets, Office of Energy Policy and Innovation, Federal Energy Regulatory Commission, 888 First Street NE, Washington, DC 20426,

(202) 502–8742, *Darren.Sheets@FERC.gov.*

Dated: May 27, 2020.

Kimberly D. Bose,

Secretary.

[FR Doc. 2020–11872 Filed 6–1–20; 8:45 am]

BILLING CODE 6717–01–P

DEPARTMENT OF ENERGY

Federal Energy Regulatory Commission

[Docket No. CP20–461–000]

Lower Valley Energy, Inc.; Notice of Application

Take notice that on May 22, 2020, Lower Valley Energy, Inc. (LVE), 236 North Washington, P.O. Box 188, Afton, Wyoming 83110 filed in Docket No. CP20–461–000, an application pursuant to section 7(f) of the Natural Gas Act and Part 157 of the Commission's regulations requesting that the Commission grant it a determination of service area within which LVE may, without further Commission authorization, own and operate an approximately 49-mile pipeline from Montpelier, Idaho to Afton Wyoming to displace semi-trailer deliveries of LNG to its Afton LNG storage and distribution facilities and for possible natural gas delivery to seven properties within its existing electric service territory in Caribou County Idaho. LVE also requests a finding that it qualifies for treatment as an LDC for purposes of Section 311 of the Natural Gas Policy Act and a waiver of various Commission requirements as appropriate and consistent with the requested determination.

In addition to publishing the full text of this document in the **Federal Register**, the Commission provides all interested persons an opportunity to view and/or print the contents of this document via the internet through the Commission's Home Page (*http://ferc.gov*) using the ''eLibrary'' link. Enter the docket number excluding the last three digits in the docket number field to access the document. At this time, the Commission has suspended access to the Commission's Public Reference Room, due to the proclamation declaring a National Emergency concerning the Novel Coronavirus Disease (COVID–19), issued by the President on March 13, 2020. For assistance, contact FERC at *FERCOnlineSupport@ferc.gov* or call toll-free, (886) 208–3676 or TYY, (202) 502–8659.

Any questions regarding this application should be directed to Craig Coles, Director of Gas Operations, Lower Valley Energy, Inc, P.O. Box 188, Afton, Wyoming 83110 or via email at *ccoles@lvenergy.com.*

Pursuant to section 157.9 of the Commission's rules, 18 CFR 157.9, within 90 days of this Notice the Commission staff will either: complete its environmental assessment (EA) and place it into the Commission's public record (eLibrary) for this proceeding; or issue a Notice of Schedule for Environmental Review. If a Notice of Schedule for Environmental Review is issued, it will indicate, among other milestones, the anticipated date for the Commission staff's issuance of the EA for this proposal. The filing of the EA in the Commission's public record for this proceeding or the issuance of a Notice of Schedule for Environmental Review will serve to notify federal and state agencies of the timing for the completion of all necessary reviews, and the subsequent need to complete all federal authorizations within 90 days of the date of issuance of the Commission staff's FEIS or EA.

There are two ways to become involved in the Commission's review of this project. First, any person wishing to obtain legal status by becoming a party to the proceedings for this project should, on or before the comment date stated below, file with the Federal Energy Regulatory Commission, 888 First Street NE, Washington, DC 20426, a motion to intervene in accordance with the requirements of the Commission's Rules of Practice and Procedure (18 CFR 385.214 or 385.211) and the Regulations under the NGA (18 CFR 157.10). A person obtaining party status will be placed on the service list maintained by the Secretary of the Commission and will receive copies of all documents filed by the applicant and by all other parties. A party must submit 3 copies of filings made with the

[1] In the OMB request for reinstatement and revision of the FERC–922 information collection, Commission staff indicated that respondents would be given 90 days to submit responses to the information collection. However, given the emergency conditions caused by the Novel Coronavirus Disease (COVID–19), there is good cause to extend the deadline for submitting responses to this information collection an additional 60 days.

[2] More information on the Commission's eFiling system is posted at: *https://www.ferc.gov/docs-filing/efiling.asp.* All submissions to the Commission must be formatted and filed in accordance with submission guidelines described at: *http://www.ferc.gov/help/submission-guide.asp.*

[3] Links to the approved Information Collection Input Spreadsheet (Excel workbook) and the Common Metrics Information Collection User Guide can be found at: *http://www.ferc.gov/industries/electric/indus-act/rto/rto-iso-performance.asp.*

Commission and must provide a copy to the applicant and to every other party in the proceeding. Only parties to the proceeding can ask for court review of Commission orders in the proceeding.

However, a person does not have to intervene in order to have comments considered. The second way to participate is by filing with the Secretary of the Commission, as soon as possible, an original and two copies of comments in support of or in opposition to this project. The Commission will consider these comments in determining the appropriate action to be taken, but the filing of a comment alone will not serve to make the filer a party to the proceeding. The Commission's rules require that persons filing comments in opposition to the project provide copies of their protests only to the party or parties directly involved in the protest.

Persons who wish to comment only on the environmental review of this project should submit an original and two copies of their comments to the Secretary of the Commission. Environmental commenters will be placed on the Commission's environmental mailing list and will be notified of any meetings associated with the Commission's environmental review process. Environmental commenters will not be required to serve copies of filed documents on all other parties. However, the non-party commenters will not receive copies of all documents filed by other parties or issued by the Commission and will not have the right to seek court review of the Commission's final order.

As of the February 27, 2018 date of the Commission's order in Docket No. CP16–4–001, the Commission will apply its revised practice concerning out-of-time motions to intervene in any new Natural Gas Act section 3 or section 7 proceeding.[1] Persons desiring to become a party to a certificate proceeding are to intervene in a timely manner. If seeking to intervene out-of-time, the movant is required to ''show good cause why the time limitation should be waived,'' and should provide justification by reference to factors set forth in Rule 214(d)(1) (18 CFR 385.214(d)(1)) of the Commission's Rules and Regulations.

The Commission strongly encourages electronic filings of comments, protests and interventions in lieu of paper using the ''eFiling'' link at *http://www.ferc.gov.* Persons unable to file electronically may mail similar pleadings to the Federal Energy Regulatory Commission, 888 First Street NE, Washington, DC 20426. Hand delivered submissions in docketed proceedings should be delivered to Health and Human Services, 12225 Wilkins Avenue, Rockville, Maryland 20852.

Comment Date: 5:00 p.m. Eastern Standard Time on June 17, 2020.

Dated: May 27, 2020.

Kimberly D. Bose,

Secretary.

[FR Doc. 2020–11865 Filed 6–1–20; 8:45 am]

BILLING CODE 6717–01–P

DEPARTMENT OF ENERGY

Federal Energy Regulatory Commission

[Docket No. RM98–1–000]

Records Governing Off-the-Record Communications; Public Notice

This constitutes notice, in accordance with 18 CFR 385.2201(b), of the receipt of prohibited and exempt off-the-record communications.

Order No. 607 (64 FR 51222, September 22, 1999) requires Commission decisional employees, who make or receive a prohibited or exempt off-the-record communication relevant to the merits of a contested proceeding, to deliver to the Secretary of the Commission, a copy of the communication, if written, or a summary of the substance of any oral communication.

Prohibited communications are included in a public, non-decisional file associated with, but not a part of, the decisional record of the proceeding. Unless the Commission determines that the prohibited communication and any responses thereto should become a part of the decisional record, the prohibited off-the-record communication will not be considered by the Commission in reaching its decision. Parties to a proceeding may seek the opportunity to respond to any facts or contentions made in a prohibited off-the-record communication and may request that the Commission place the prohibited communication and responses thereto in the decisional record. The Commission will grant such a request only when it determines that fairness so requires. Any person identified below as having made a prohibited off-the-record communication shall serve the document on all parties listed on the official service list for the applicable proceeding in accordance with Rule 2010, 18 CFR 385.2010.

Exempt off-the-record communications are included in the decisional record of the proceeding, unless the communication was with a cooperating agency as described by 40 CFR 1501.6, made under 18 CFR 385.2201(e)(1)(v).

The following is a list of off-the-record communications recently received by the Secretary of the Commission. The communications listed are grouped by docket numbers in ascending order. In addition to publishing the full text of this document in the **Federal Register**, the Commission provides all interested persons an opportunity to view and/or print the contents of this document via the internet through the Commission's Home Page (*http://ferc.gov*) using the ''eLibrary'' link. Enter the docket number excluding the last three digits in the docket number field to access the document. At this time, the Commission has suspended access to the Commission's Public Reference Room, due to the proclamation declaring a National Emergency concerning the Novel Coronavirus Disease (COVID–19), issued by the President on March 13, 2020. For assistance, contact the Federal Energy Regulatory Commission at *FERCOnlineSupport@ferc.gov* or toll free at (866) 208–3676, or for TTY, contact (202) 502–8659.

Docket Nos.	File date	Presenter or requester
Prohibited		
1. CP20–47–000, RP20–41–000, RP20–41–001	5–21–2020	FERC Staff.[1]
2. CP17–495–000, CP17–495–001	5–21–2020	FERC Staff.[2]
3. CP16–9–000, CP16–9–010	5–21–2020	FERC Staff.[3]

[1] *Tennessee Gas Pipeline Company, L.L.C.,* 162 FERC ¶ 61,167 at ¶ 50 (2018).

Docket Nos.	File date	Presenter or requester
Exempt		
P–10624–026	5–20–2020	FERC Staff.[4]

Dated: May 27, 2020.

Nathaniel J. Davis, Sr.,

Deputy Secretary.

[FR Doc. 2020–11837 Filed 6–1–20; 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:

Docket Numbers: CP20–458–000.

Applicants: Tennessee Gas Pipeline Company, L.L.C.

Description: Abbreviated Application for Authorization to Abandon Exchange and Transportation Service of Tennessee Gas Pipeline Company, L.L.C.

Filed Date: 5/20/20.

Accession Number: 20200520–5039.

Comments Due: 5 p.m. ET 6/10/20.

Docket Numbers: RP20–649–000.

Applicants: Trailblazer Pipeline Company LLC.

Description: Report Filing: TPC 2020 Annual L&U Cash-out Refund Report.

Filed Date: 5/18/20.

Accession Number: 20200518–5126.

Comments Due: 5 p.m. ET 6/1/20.

Docket Numbers: RP20–869–001.

Applicants: Transcontinental Gas Pipe Line Company, LLC.

Description: Tariff Amendment: Supplement to Rate Schedule S–2 Tracker Filing in Docket No. RP20–869–000 to be effective 6/1/2020.

Filed Date: 5/20/20.

Accession Number: 20200520–5027.

Comments Due: 5 p.m. ET 6/1/20.

The filings are accessible in the Commission's eLibrary system by clicking on the links or querying the docket number.

Any person desiring to intervene or protest in any of the above proceedings must file in accordance with Rules 211 and 214 of the Commission's Regulations (18 CFR 385.211 and 385.214) on or before 5:00 p.m. Eastern time on the specified date(s). Protests may be considered, but intervention is necessary to become a party to the proceeding.

eFiling is encouraged. More detailed information relating to filing requirements, interventions, protests, service, and qualifying facilities filings can be found at: *http://www.ferc.gov/docs-filing/efiling/filing-req.pdf.* For other information, call (866) 208–3676 (toll free). For TTY, call (202) 502–8659.

Dated: May 27, 2020.

Nathaniel J. Davis, Sr.,

Deputy Secretary.

[FR Doc. 2020–11838 Filed 6–1–20; 8:45 am]

BILLING CODE 6717–01–P

DEPARTMENT OF ENERGY

Federal Energy Regulatory Commission

[Docket No. RM19–4–000]

Implementation of Amended Section of the Federal Power Act

AGENCY: Federal Energy Regulatory Commission, DOE.

ACTION: Notice of Availability of Report; Request for Public Comment.

SUMMARY: Pursuant to ''An Act to amend section 203 of the Federal Power Act'' (Act), the Commission issues an initial report on the effects of the amendment on mergers or consolidations by a public utility as well as the information collected since this amendment and the Commission's final rule implementing this amendment became effective.

DATES: Comments are due on or before June 29, 2020.

ADDRESSES: Comments, identified by docket number, may be filed electronically at *http://www.ferc.gov* in acceptable native applications and print-to-PDF, but not in scanned or picture format. For those unable to file electronically, comments may be filed by mail or hand-delivery to: Federal Energy Regulatory Commission, Secretary of the Commission, 888 First Street NE, Washington, DC 20426. The Comment Procedures Section of this document contains more detailed filing procedures.

FOR FURTHER INFORMATION CONTACT:

Tina Briscoe (Technical Information), Office of Energy Market Regulation, 888 First Street NE, Washington, DC 20426, (202) 502–8751, *Tina.Briscoe@ferc.gov.*

Regine Baus (Legal Information), Office of the General Counsel, 888 First Street NE, Washington, DC 20426, (202) 502–8757, *Regine.Baus@ferc.gov.*

United States of America Federal Energy Regulatory Commission

Implementation of Amended Section 203(a)(1)(B) of the Federal Power Act; Notice Of Availability Of Report; Request For Public Comment

May 22, 2020

I. Introduction

1. On September 28, 2018, Congress passed ''An Act to amend section 203 of the Federal Power Act'' (Act) in Public Law 115–247. As discussed in further detail below, the Act resulted in two changes to section 203 of the Federal Power Act (FPA).[1] The Act also directed the Commission to issue a report, subject to notice and comment, on the changes to FPA section 203 and to submit that report to Congress. As discussed below, interested persons may submit comments on this report by June 29, 2020.

II. Background

A. Public Law 115–247

2. Section 1 of the Act amended section 203(a)(1)(B)[2] to provide that no public utility shall, without first having secured an order of the Commission authorizing it to do so, merge or consolidate, directly or indirectly, its facilities subject to the jurisdiction of the Commission, or any part thereof, with the facilities of any other person, or any part thereof, that are subject to the jurisdiction of the Commission and have a value in excess of $10 million, by any means whatsoever. Section 3 of the Act provided that the amendment to section 203(a)(1)(B) shall take effect 180 days after the date of the enactment of the Act, *i.e.,* March 28, 2019. The primary effect of this amendment was to establish a $10 million threshold for

[1] Memorandum regarding ex parte communication with Ms. Aurelle Sprout on 4/21/2020.

[2] Memorandum regarding ex parte communication with Ms. Faith Strigler on 4/21/2020.

[3] Memorandum regarding ex parte communication with Mr. Chris Cramer and 6 other individuals on 4/16/2020.

[4] Email regarding the 5/20/2020 communication between Commission staff and the Michigan State Historic Preservation Office.

[1] 16 U.S.C. 824b (2018).

[2] *Id.* 824b(a)(1)(B).

transactions that are subject to the Commission's review and authorization under section 203(a)(1)(B).

3. In section 2 of the Act, Congress amended section 203(a) to add section 203(a)(7) to require notification for certain transactions. Section 203(a)(7) provides that, not later than 180 days after the date of the enactment of section 203(a)(7), the Commission shall promulgate a rule requiring any public utility that is seeking to merge or consolidate, directly or indirectly, its facilities subject to the jurisdiction of the Commission, or any part thereof, with those of any other person, to notify the Commission of such transactions not later than 30 days after the date on which the transaction is consummated if: (1) The facilities, or any part thereof, to be acquired are of a value in excess of $1 million; and (2) such public utility is not required to secure a Commission order under amended section 203(a)(1)(B).

4. The Act also specified that, not later than two years after the date of the enactment of the Act, the Commission shall submit to Congress a report that assesses the effects of the amendment made by section 1 and that such report shall take into account any information collected under section 203(a)(7). The Act required that the Commission provide for notice and comment with respect to the report.

B. Order No. 855

5. The Commission issued Order No. 855 on February 21, 2019,[3] to revise its regulations to implement the amendments in the Act. Specifically, the Commission revised section 33.1(a)(1)(ii) to provide that part 33 applies to any public utility seeking authorization under section 203 to merge or consolidate, directly or indirectly, its facilities subject to the jurisdiction of the Commission, or any part thereof, with the facilities of any other person, or any part thereof, that are subject to the jurisdiction of the Commission and have a value in excess of $10 million, by any means whatsoever.[4]

6. In addition, the Commission added section 33.12 to its regulations to require that public utilities submit a notification filing for transactions subject to section 203(a)(7). The Commission required that such public utilities include the following information in the notification filing: (1) The exact name of the public utility and its principal business address; and (2) a narrative description of the transaction, including the identity of all parties involved in the transaction and all jurisdictional facilities associated with or affected by the transaction, the location of such jurisdictional facilities, the date on which the transaction was consummated, the consideration for the transaction, and the effect of the transaction on the ownership and control of such jurisdictional facilities. The Commission also required that the notification filing contain a statement regarding whether the parties to the transaction are affiliates to provide transparency as to whether these transactions are negotiated at arm's length and whether these transactions could have an effect on a public utility's rates.[5]

7. The Commission directed public utilities to file the notification filings within a dedicated docket number associated with section 203 filings. Filings for each fiscal year (FY) are submitted into the designated docket number and made accessible through the Commission's eLibrary system.[6]

III. Review of Section 203 Filings Following Amendment to Section 203(a)(1)(B)

8. As to the effects of the amendment adding the $10 million threshold to section 203(a)(1)(B), the Act has resulted in two notable changes with respect to transactions that were previously and remain subject to section 203(a)(1)(B). The first such change is that, in general, since the Act took effect on September 28, 2018, the Commission has seen a reduction in the overall number of section 203 filings from previous years. For example, in FY 2018 and FY 2019, respectively, the Commission received 164 and 142 filings under section 203. However, to date in FY 2020, the Commission has received 66 filings.

9. In addition, since the Act took effect, the Commission has seen fewer filings requesting authorization for transactions under section 203(a)(1)(B). Generally, these transactions involve acquisitions by a public utility of Commission-jurisdictional facilities, usually transmission facilities. Before the Act took effect, the Commission would receive a significant number of filings requesting authorization for transactions where the facilities at issue were valued at less than $10 million, many less than $1 million. Since the Act took effect, only a few filings requesting authorization under section 203(a)(1)(B) have been submitted. For example, in FY 2018, the Commission received 30 filings requesting authorization under section 203(a)(1)(B). In contrast, in FY 2020, to date, the Commission has received only 17 filings requesting authorization for transactions under section 203(a)(1)(B). The Commission expects to continue to see fewer section 203 filings as a result of the Act's addition of the $10 million threshold to this section of the FPA.

IV. Information Collected in Notification Filings

10. Since the Act took effect, the Commission has received 14 notification filings pursuant to section 203(a)(7) of the FPA and section 33.12 of the Commission's regulations. Below is a brief description of those filings. Interested persons may view the notification filings in Docket Nos. EC19–1–000 (for FY2019 transaction) and EC20–1–000 (for FY2020 transactions) for more detailed information.

11. Specifically, in Docket No. EC19–1–000, the Commission received notification filings for eight transactions submitted by the following entities: Virginia Electric and Power Company, Monongahela Power Company, and The Potomac Edison Company; NSTAR Electric Company; Entergy Louisiana, LLC (Entergy Louisiana); FPL Energy Wyman IV LLC (FPL Energy); ITC Midwest LLC, Westar Energy, Inc., and American Transmission Systems, Inc. For example, Entergy Louisiana submitted a filing indicating that it had acquired from a non-affiliated customer certain limited transmission facilities that were subject to the Commission's jurisdiction with a total value in excess of $1 million, but less than $10 million. Entergy Louisiana stated that the total cost of the transmission facilities and equipment was $6,043,750.

12. Thus far for FY 2020, in Docket No. EC20–1–000 the Commission has received six notification filings, including notices filed by Michigan Electric Transmission Company, LLC; Paulding Wind Farm IV, LLC (Paulding IV); International Transmission Company; Little Bear Solar 1, LLC; and American Electric Power Service Corporation. For example, Paulding IV submitted a filing in connection with its acquisition of an undivided interest in certain Commission-jurisdictional shared interconnection facilities from Paulding Wind Farm III LLC (Paulding III). According to Paulding IV, both parties were indirectly owned by EDP Renewables North America LLC and are

[3] *Implementation of Amended Section 203(a)(1)(B) of the Federal Power Act,* Order No. 855, 166 FERC ¶ 61,120 (2019); *see also Mergers or Consolidations by a Public Utility,* 84 FR 6069 (Feb. 26, 2019).

[4] 18 CFR 33.1(a)(1)(ii) (2019).

[5] *Id.* 33.12 (2019).

[6] Filings for the FY are included in a separate docket denoted as EC19–1 for FY 2019, EC20–1 for FY 2020, etc.

affiliated. Paulding IV acquired the undivided ownership interests from Paulding III for $4,694,270, which the parties stated was net book value.

13. Given the Commission's more limited oversight over transactions subject to section 203(a)(7), we believe that the information collected in these notification filings was adequate to ensure compliance with the statute and the Commission's regulations. That is, the information collected is far less than the information required for full section 203 applications pursuant to part 33 of the Commission's regulations, but more than a brief notice establishing that the underlying transaction was consummated. Thus, the Commission continues to be able to track who controls the Commission-jurisdictional facilities at issue in these transactions as well as whether these transactions are executed at arm's length or could affect a public utility's rates.

V. Request for Comment

14. As discussed above, the Act specified that, not later than two years after the date of enactment of the Act, the Commission shall submit to Congress a report that assesses the effects of the amendment made by section 1 and takes into account any information collected under section 203(a)(7). The Act also required that the Commission provide for notice and comment with respect to this report.

15. Consistent with this directive from Congress, we request comment on this report. Comments are due June 29, 2020. The Commission will review the comments prior to submitting the report to Congress by September 28, 2020.

VI. Comment Procedures

16. The Commission invites interested persons to submit comments on the matters and issues proposed in the report, including any related matters that commenters may wish to discuss. Comments are due on or before June 29, 2020. Comments must refer to Docket No. RM19–4–000 and must include the commenter's name, the organization they represent, if applicable, and their address.

17. The Commission encourages comments to be filed electronically via the eFiling link on the Commission's website at *http://www.ferc.gov.* The Commission accepts most standard word processing formats. Documents created electronically using word processing software should be filed in native applications or print-to-PDF format and not in a scanned format. Commenters filing electronically do not need to make a paper filing.

18. Commenters that are not able to file comments electronically must send an original of their comments to: Federal Energy Regulatory Commission, Secretary of the Commission, 888 First Street NE, Washington, DC 20426.

19. All comments will be placed in the Commission's public files and may be viewed, printed, or downloaded remotely. Commenters on this report are not required to serve copies of their comments on other commenters.

Dated: May 27, 2020.

Kimberly D. Bose,

Secretary.

[FR Doc. 2020–11869 Filed 6–1–20; 8:45 am]

BILLING CODE 6717–01–P

DEPARTMENT OF ENERGY

Federal Energy Regulatory Commission

[Docket No. CP20–457–000]

National Fuel Gas Supply Corporation; Notice of Application

Take notice that on May 19, 2020, National Fuel Gas Supply Corporation (National Fuel), 6363 Main Street, Williamsville, New York 14221, filed in Docket No. CP20–457–000, a prior notice request pursuant to Sections 157.205, and 157.216 of the Federal Energy Regulatory Commission's regulations under the Natural Gas Act, and National Fuel's blanket certificate issued in Docket No. CP83–4–000, for authorization to abandon certain facilities in its Sheridan Storage Field, located in Chautauqua County, New York. National Fuel proposes to plug and abandon two injection/withdrawal storage wells, Wells I–2062 and I–2054, and abandon in place the associated well lines RW2062 and RW2054, all as more fully set forth in the request that is on file with the Commission and open to public inspection.

In addition to publishing the full text of this document in the **Federal Register**, the Commission provides all interested persons an opportunity to view and/or print the contents of this document via the internet through the Commission's Home Page (*http://ferc.gov*) using the ''eLibrary'' link. Enter the docket number excluding the last three digits in the docket number field to access the document. At this time, the Commission has suspended access to the Commission's Public Reference Room, due to the proclamation declaring a National Emergency concerning the Novel Coronavirus Disease (COVID–19), issued by the President on March 13, 2020. For assistance, contact the Federal Energy Regulatory Commission at *FERCOnlineSupport@ferc.gov* or call toll-free, (886) 208–3676 or TYY, (202) 502–8659.

Any questions regarding this application should be directed to Meghan M. Emes, Attorney for National Fuel, 6363 Main Street, Williamsville, New York 14221, or call at (716) 857–7004.

Any person or the Commission's staff may, within 60 days after issuance of the instant notice by the Commission, file pursuant to Rule 214 of the Commission's Procedural Rules (18 CFR 385.214) a motion to intervene or notice of intervention and pursuant to section 157.205 of the regulations under the NGA (18 CFR 157.205), a protest to the request. If no protest is filed within the time allowed therefore, the proposed activity shall be deemed to be authorized effective the day after the time allowed for filing a protest. If a protest is filed and not withdrawn within 30 days after the allowed time for filing a protest, the instant request shall be treated as an application for authorization pursuant to section 7 of the NGA.

Pursuant to section 157.9 of the Commission's rules, 18 CFR 157.9, within 90 days of this Notice the Commission staff will either: complete its environmental assessment (EA) and place it into the Commission's public record (eLibrary) for this proceeding; or issue a Notice of Schedule for Environmental Review. If a Notice of Schedule for Environmental Review is issued, it will indicate, among other milestones, the anticipated date for the Commission staff's issuance of the EA for this proposal. The filing of the EA in the Commission's public record for this proceeding or the issuance of a Notice of Schedule for Environmental Review will serve to notify federal and state agencies of the timing for the completion of all necessary reviews, and the subsequent need to complete all federal authorizations within 90 days of the date of issuance of the Commission staff's EA.

Persons who wish to comment only on the environmental review of this project should submit an original and two copies of their comments to the Secretary of the Commission. Environmental commenter's will be placed on the Commission's environmental mailing list, and will be notified of any meetings associated with the Commission's environmental review process. Environmental commenter's will not be required to serve copies of filed documents on all other parties. However, the non-party commenters,

will not receive copies of all documents filed by other parties or issued by the Commission and will not have the right to seek court review of the Commission's final order.

The Commission strongly encourages electronic filings of comments, protests and interventions in lieu of paper using the ''eFiling'' link at *http://www.ferc.gov.* Persons unable to file electronically may mail similar pleadings to the Federal Energy Regulatory Commission, 888 First Street NE, Washington, DC 20426. Hand delivered submissions in docketed proceedings should be delivered to Health and Human Services, 12225 Wilkins Avenue, Rockville, Maryland 20852.

Comment Date: 5:00 p.m. Eastern Standard Time on June 17, 2020.

Dated: May 27, 2020.

Kimberly D. Bose,

Secretary.

[FR Doc. 2020–11870 Filed 6–1–20; 8:45 am]

BILLING CODE 6717–01–P

ENVIRONMENTAL PROTECTION AGENCY

[EPA–HQ–ORD–2015–0635; FRL–10010–20–ORD]

Board of Scientific Counselors (BOSC) Chemical Safety for Sustainability and Health and Environmental Risk Assessment Subcommittee Meeting—June 2020

AGENCY: Environmental Protection Agency (EPA).

ACTION: Notice of public meeting.

SUMMARY: The Environmental Protection Agency (EPA), Office of Research and Development (ORD), gives notice of a meeting of the Board of Scientific Counselors (BOSC) Chemical Safety for Sustainability and Health and Environmental Risk Assessment (CSS–HERA) Subcommittee to finalize their preliminary report on the draft FY19–22 HERA Strategic Research Action Plan (StRAP). Due to unforeseen administrative circumstances, EPA is announcing this meeting with less than 15 calendar days' notice.

DATES: The videoconference meeting will be held on Wednesday, June 10, 2020, from 3:00 p.m. to 6:00 p.m. (EDT). Meeting times are subject to change. This meeting is open to the public. Those who wish to attend must register by June 9, 2020. Comments must be received by June 9, 2020, to be considered by the subcommittee. Requests for the draft agenda or making a presentation at the meeting will be accepted until June 9, 2020.

ADDRESSES: Instructions on how to connect to the videoconference will be provided upon registration at *https://www.eventbrite.com/e/us-epa-bosc-chemical-safety-for-sustainability-css-and-health-and-environmental-risk-assessment-tickets-105445763116.* Attendees should register no later than June 9, 2020.

Submit your comments to Docket ID No. EPA–HQ–ORD–2015–0635 by one of the following methods:

- *www.regulations.gov:* Follow the online instructions for submitting comments.
- *Note:* Comments submitted to the *www.regulations.gov* website are anonymous unless identifying information is included in the body of the comment.
- *Email:* Send comments by electronic mail (email) to: *ORD.Docket@epa.gov,* Attention Docket ID No. EPA–HQ–ORD–2015–0635.
- *Note:* Comments submitted via email are not anonymous. The sender's email will be included in the body of the comment and placed in the public docket which is made available on the internet.

Instructions: All comments received, including any personal information provided, will be included in the public docket without change and may be made available online at *www.regulations.gov.* Information claimed to be Confidential Business Information (CBI) or other information whose disclosure is restricted by statute will not be included in the public docket, and should not be submitted through *www.regulations.gov* or email. For additional information about the EPA's public docket visit the EPA Docket Center homepage at *http://www.epa.gov/dockets/.*

Public Docket: Publicly available docket materials may be accessed *Online* at *www.regulations.gov.* Copyrighted materials in the docket are only available via hard copy. The telephone number for the ORD Docket Center is (202) 566–1752.

FOR FURTHER INFORMATION CONTACT: The Designated Federal Officer (DFO), Tom Tracy, via phone/voice mail at: (202) 564–6518; or via email at: *tracy.tom@epa.gov.* Any member of the public interested in receiving a draft agenda, attending the meeting, or making a presentation at the meeting should contact Tom Tracy.

SUPPLEMENTARY INFORMATION: The Board of Scientific Counselors (BOSC) is a federal advisory committee that provides advice and recommendations to EPA's Office of Research and Development on technical and management issues of its research programs. Meeting agenda and materials will be posted to *https://www.epa.gov/bosc.* Proposed agenda items for the meeting include but are not limited to the following: Review of draft subcommittee report and subcommittee discussion.

Information on Services Available: For information on translation services, access, or services for individuals with disabilities, please contact Tom Tracy at (202) 564–6518 or *tracy.tom@epa.gov.* To request accommodation of a disability, please contact Tom Tracy at least ten days prior to the meeting to give the EPA adequate time to process your request.

Authority: Pub. L. 92–463, 1, Oct. 6, 1972, 86 Stat. 770.

Dated: May 27, 2020.

Mary Ross,

Director, Office of Science Advisor, Policy, and Engagement.

[FR Doc. 2020–11816 Filed 6–1–20; 8:45 am]

BILLING CODE 6560–50–P

FEDERAL COMMUNICATIONS COMMISSION

[OMB 3060–XXXX, OMB 3060–1204; FRS 16794]

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 PRA comments should be submitted on or before August 3, 2020. 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 Nicole Ongele, FCC, via email *PRA@fcc.gov* and to *Nicole.ongele@fcc.gov.*

FOR FURTHER INFORMATION CONTACT: For additional information about the information collection, contact Nicole Ongele, (202) 418–2991.

SUPPLEMENTARY INFORMATION:

OMB Control Number: 3060–XXXX.

Title: Alaska Plan End of Term Commitments.

Form Number: N/A.

Type of Review: New information collection.

Respondents: Business or other for-profit entities.

Number of Respondents and Responses: 21 respondents; 21 responses.

Estimated Time per Response: 10 hours.

Frequency of Response: One-time reporting requirement.

Obligation to Respond: Required to retain benefits. Statutory authority for this information collection is contained in 47 U.S.C. 151, 152, 154(i), 155, 201–206, 214, 218–220, 251, 252, 254, 256, 303(r), 332, 403, and 1302.

Total Annual Burden: 210 hours.

Total Annual Cost: No Cost.

Privacy Act Impact Assessment: No impact(s).

Nature and Extent of Confidentiality: For this information request, parties may submit confidential information. Requests for confidentiality may be submitted to the Commission to be withheld from public inspection under 47 C FR 0.459 of the FCC's rules.

Needs and Uses: The Commission is requesting the Office of Management and Budget (OMB) approval for this new information collection. On August 23, 2016, the Commission adopted the *Alaska Plan Order. See Connect America Fund et al.,* WC Docket Nos. 10–90, 16–271, WT Docket No. 10–208, Report and Order and Further Notice of Proposed Rulemaking, 31 FCC Rcd 10139 (2016) (*Alaska Plan Order*). In that order, the Commission adopted a plan for providing Alaskan rate-of-return carriers and competitive Eligible Telecommunications Carriers (ETCs) the option to obtain a fixed level of funding for a defined term in exchange for committing to deployment obligations that are tailored to each Alaskan carrier's circumstances. A requirement adopted in the *Alaska Plan Order* requires that participating carriers update their end-of-term commitments no later than the end of the fourth year of support, *i.e.,* by December 31, 2020. The purpose of this information collection is to collect from the participating carriers their updated end-of-term commitments and addresses the burdens associated with that requirement.

OMB Control Number: 3060–1204.

Title: Deployment of Text-to-911.

Form Number: N/A.

Type of Review: Revision of a currently approved collection.

Respondents: Business or other-for profit, State, Local, or Tribal government.

Number of Respondents and Responses: 3,882 respondents; 52,963 responses.

Estimated Time per Response: 1–8 hours.

Frequency of Response: One-time; annual reporting requirements and third-party disclosure requirement.

Obligation to Respond: Required to obtain or retain benefits. Statutory authority for these collections is contained in 47 U.S.C. 151, 152, 154(i), 154(j), 154(o), 251(e), 303(b), 303(g), 303(r), 316, and 403.

Total Annual Burden: 76,766 hours.

Total Annual Cost: No Cost.

Privacy Act Impact Assessment: No impact(s).

Nature and Extent of Confidentiality: There is no need for confidentiality with this collection of information.

Needs and Uses: Deployment of Text-to-911. In a Second Report and Order released on August 13, 2014, FCC 14–118, published at 79 FR 55367, September 16, 2014, the Commission adopted final rules—containing information collection requirements—to enable the Commission to implement text-to-911 service. The text-to-911 rules provide enhanced access to emergency services for people with disabilities and fulfilling a crucial role as an alternative means of emergency communication for the general public in situations where sending a text message to 911 as opposed to placing a voice call could be vital to the caller's safety. The Second Report and Order adopted rules to commence the implementation of text-to-911 service with an initial deadline of December 31, 2014 for all covered text providers to be capable of supporting text-to-911 service. The Second Report and Order also provided that covered text providers would then have a six-month implementation period. They must begin routing all 911 text messages to a Public Safety Answering Point (PSAP) by June 30, 2015 or within six months of a valid PSAP request for text-to-911 service, whichever is later. To implement these requirements, the Commission seeks to collect information primarily for a database in which PSAPs voluntarily register that they are technically ready to receive text messages to 911. As PSAPs become text-ready, they may either register in the PSAP database (or submit a notification to PS Docket Nos. 10–255 and 11–153), or provide other written notification reasonably acceptable to a covered text messaging provider. Either measure taken by the PSAP constitutes sufficient notification pursuant to the rules in the Second Report and Order. PSAPs and covered text providers may also agree to an alternative implementation timeframe (other than six months). Covered text providers must notify the FCC of the dates and terms of any such alternate timeframe within 30 days of the parties' agreement. Additionally, the rules adopted by the Second Report and Order include other information collections for third party notifications necessary for the implementation of text-to-911, including notifications to consumers, covered text providers, and the Commission. These notifications are essential to ensure that all affected parties are aware of the limitations, capabilities, and status of text-to-911 services. These information collections enable the Commission to meet the objectives for implementation of text-to-911 service and for compliance by covered text providers with the six-month implementation period in furtherance of the Commission's core mission to ensure the public's safety.

Real Time Text. In a Report and Order and Further Notice of Proposed Rulemaking, released on December 16, 2016, in CG Docket No. 16–145 and GN Docket No. 15–178, the Commission amended its rules to facilitate a transition from text telephone (TTY) technology to RTT as a reliable and interoperable universal text solution over wireless internet protocol (IP) enabled networks for people who are deaf, hard of hearing, deaf-blind, or have a speech disability. Section 9.10(c) of the rules requires Commercial Mobile

Radio Service (CMRS) providers to be ''capable of transmitting 911 calls from individuals with speech or hearing disabilities through means other than mobile radio handsets, *e.g.,* through the use of [TTY devices].'' Additionally, ''CMRS providers that provide voice communications over IP facilities are not required to support 911 access via TTYs if they provide 911 access via [RTT] communications, in accordance with 47 CFR part 67, except that RTT support is not required to the extent that it is not achievable for a particular manufacturer to support RTT on the provider's network.'' Section 9.10(c). The Commission's Report and Order provides that once a PSAP is so capable, the requested service provider must begin delivering RTT communications in an RTT format within six months after a valid request is made—to the extent the provider has selected RTT as its accessible text communication method.

Dispatchable Location. Section 506 of RAY BAUM'S Act requires the Commission to ''consider adopting rules to ensure that the dispatchable location is conveyed with a 9–1–1 call, regardless of the technological platform used [. . .].'' In a Report and Order released on August 2019, in PS Docket Nos. 18–261 and 17–239 and GN Docket No. 11–117, the Commission amended its rules to implement Kari's Law and Section 506 of RAY BAUM'S Act. Specifically, for mobile text, the Commission adopted Section 9.10(q)(10)(v) to provide that no later than January 6, 2022, covered text providers must provide the following location information with all 911 text messages routed to a PSAP:

Automated dispatchable location, if technically feasible; otherwise, either end-user manual provision of location information, or enhanced location information, which may be coordinate-based, consisting of the best available location that can be obtained from any available technology or combination of technologies at reasonable cost.

47 CFR 20.18 renumbered as 47 CFR 9.10. Additionally, the Commission renumbered Section 20.18 as new Section 9.10. Accordingly, we update the references to Section 20.18 with Section 9.10 in this supporting statement.

Federal Communications Commission.

Marlene Dortch,

Secretary, Office of the Secretary.

[FR Doc. 2020–11854 Filed 6–1–20; 8:45 am]

BILLING CODE 6712–01–P

FEDERAL DEPOSIT INSURANCE CORPORATION

[OMB No. 3064–0087; –0143]

Agency Information Collection Activities: Proposed Collection Renewal; Comment Request

AGENCY: Federal Deposit Insurance Corporation (FDIC).

ACTION: Notice and request for comment.

SUMMARY: The FDIC, as part of its obligations under the Paperwork Reduction Act of 1995 (PRA), invites the general public and other Federal agencies to take this opportunity to comment on the renewal of the existing information collections described below (OMB Control No. 3064–0087; –0143).

DATES: Comments must be submitted on or before August 3, 2020.

ADDRESSES: Interested parties are invited to submit written comments to the FDIC by any of the following methods:

- *https://www.FDIC.gov/regulations/laws/federal.*
- *Email: comments@fdic.gov.* Include the name and number of the collection in the subject line of the message.
- *Mail:* Manny Cabeza (202–898–3767), Regulatory Counsel, MB–3128, Federal Deposit Insurance Corporation, 550 17th Street NW, Washington, DC 20429.
- *Hand Delivery:* Comments may be hand-delivered to the guard station at the rear of the 17th Street building (located on F Street), on business days between 7:00 a.m. and 5:00 p.m.

All comments should refer to the relevant OMB control number. A copy of the comments may also be submitted to the OMB desk officer for the FDIC: Office of Information and Regulatory Affairs, Office of Management and Budget, New Executive Office Building, Washington, DC 20503.

FOR FURTHER INFORMATION CONTACT: Manny Cabeza, Regulatory Counsel, 202–898–3767, *mcabeza@fdic.gov,* MB–3128, Federal Deposit Insurance Corporation, 550 17th Street NW, Washington, DC 20429.

SUPPLEMENTARY INFORMATION:

Proposal to renew the following currently approved collections of information:

1. *Title:* Procedures for Monitoring Bank Secrecy Act Compliance.

OMB Number: 3064–0087.

Affected Public: Insured State Nonmember Banks and Savings Associations.

Burden Estimate:

SUMMARY OF ANNUAL BURDEN

Information collection description	Type of burden	Obligation to respond	Estimated number of respondents	Estimated frequency of responses	Estimated time per response (hours)	Estimated annual burden (hours)
Procedures for Monitoring BSA Compliance—*Small Institutions (Less than $500 million).*	Recordkeeping ..	Mandatory	2,523	On Occasion	35	88,305
Procedures for Monitoring BSA Compliance—*Medium Institutions ($500 million–$10 billion).*	Recordkeeping ..	Mandatory	774	On Occasion	250	193,500
Procedures for Monitoring BSA Compliance—*Large Institutions (0ver $10 billion).*	Recordkeeping ..	Mandatory	47	On Occasion	450	21,150
Total Estimated Annual Burden	.....	.....	.....	.....	.....	302,955 hours

General Description of Collection: Respondents must establish and maintain procedures designed to monitor and ensure their compliance with the requirements of the Bank Secrecy Act and the implementing regulations promulgated by the Department of Treasury at 31 CFR Chapter X. Respondents must also provide training for appropriate personnel. There is no change in the method or substance of the collection. The overall reduction in burden hours is a result of economic fluctuation. In particular, the number of respondents has decreased while the hours per response remain the same.

2. *Title:* Forms Relating to Processing Deposit Insurance Claims.

OMB Number: 3064–0143.

Affected Public: Private sector individuals and entities maintaining deposits at insured depository institutions.

Burden Estimate:

SUMMARY OF ESTIMATED ANNUAL BURDEN

	Type of burden	Estimated number of respondents	Estimated time per response	Frequency of response	Total estimated annual burden
Combined Deposit Brokers and Individuals:					
7200/04—Declaration for Government Deposit	Reporting	14	0.5	On Occasion	7
7200/05—Declaration for Revocable Trust	Reporting	165	0.5	On Occasion	83
7200/06—Declaration of Independent Activity	Reporting	1	0.5	On Occasion	0.5
7200/07—Declaration of Independent Activity for Unincorporated Association.	Reporting	1	0.5	On Occasion	0.5
7200/08—Declaration for Joint Ownership Deposit	Reporting	1	0.5	On Occasion	0.5
7200/09—Declaration for Testamentary Deposit	Reporting	21	0.5	On Occasion	11
7200/10—Declaration for Defined Contribution Plan	Reporting	1	1.0	On Occasion	1
7200/11—Declaration for IRA/KEOGH Deposit	Reporting	1	0.5	On Occasion	0.5
7200/12—Declaration for Defined Benefit Plan	Reporting	1	1.0	On Occasion	1
7200/13—Declaration of Custodian Deposit	Reporting	1	0.5	On Occasion	0.5
7200/14—Declaration or Health and Welfare Plan	Reporting	12	1.0	On Occasion	12
7200/15—Declaration for Plan and Trust	Reporting	1	0.5	On Occasion	0.5
7200/18—Declaration for Irrevocable Trust	Reporting	1	0.5	On Occasion	0.5
7200/24—Claimant Verification	Reporting	218	0.5	On Occasion	109
7200/26—Depositor Interview Form	Reporting	198	0.5	On Occasion	99
Subtotal: Combined Brokers and Individuals		637			326.5
Deposit Brokers Only:					
Deposit Broker Submission Checklist	Reporting	136	0.0833	On Occasion	11.33
Diskette, following ''Broker Input File Requirements''—burden will vary depending on the broker's number of brokered accounts.	Reporting	102	0.750	On Occasion	76.5
	Reporting	34	5.0	On Occasion	170
Exhibit B, the standard agency agreement, or the non-standard agency agreement.	Reporting	136	0.0167	On Occasion	2.27
Subtotal: Deposit Brokers Only		136			260.13
Total Estimated Annual Burden					581.10

General Description of Collection: When an insured depository institution (''IDI'') is closed by its primary regulatory authority, the FDIC has the responsibility to pay the insured deposits pursuant to Section 11(a) and (f) of the Federal Deposit Insurance Act (FDI Act), 12 U.S.C. 1821(a) and (f), and the FDIC's regulations, ''Deposit Insurance Coverage'', 12 CFR part 330, and ''Recordkeeping for Timely Deposit Insurance Determination'', 12 CFR part 370. In the event that the requisite information is not available in a failed IDI's records, the FDIC will utilize these forms, declarations and affidavits to request the necessary information from a depositor.

Generally, deposits are insured to a maximum of $250,000. This maximum coverage is based on ''ownership rights and capacities.'' All deposits that are maintained in the same right and capacity are added together and insured up to $250,000 in accordance with the regulations relating to deposit insurance of that particular deposit insurance ownership category. Deposits held in different ownership categories are eligible for $250,000 coverage per category. For example, as a general rule, single ownership accounts are separately insured from trust accounts held for qualified beneficiaries.

At the time of an IDI's closing, the FDIC obtains information about customer accounts from the IDI's deposit account records. Based on the IDI's records, the FDIC makes determinations about insurance coverage for each depositor. Depositors deemed to be uninsured because their deposits are over $250,000 may qualify for additional insurance coverage if they can provide documentation substantiating eligibility.

a. *General Deposit Accounts.* The forms, declarations, and affidavits in this collection facilitate customers providing the FDIC with the information that may permit a more comprehensive deposit insurance determination.

b. *Deposit Brokers.* A failed IDI's deposit account records may not reveal the actual owner(s) of a particular deposit account. Rather, the deposit account records may indicate that the deposit was placed at the insured institution by a deposit broker on behalf of one or more third parties. In some cases, the broker's customer may not be an actual owner of the deposit but merely a ''second-tier'' deposit broker with its own customers. In turn, these customers could be ''third-tier'' deposit brokers with their own customers. Deposits held in the name of a deposit broker on behalf of clients are covered by federal deposit insurance (up to the $250,000 limit) the same as if the broker's clients had deposited the funds directly into the insured institution (assuming that the clients are the actual owners of the deposits). This is called ''pass-through'' deposit insurance coverage.

In order to analyze ownership interest and provide pass-through insurance coverage, the FDIC must obtain certain information from both first- and lower-tier deposit brokers: (1) Evidence that each deposit broker is not an owner but an agent or custodian with respect to some or all of the funds at issue; (2) a list of all parties for whom each deposit broker acted as agent or custodian; and (3) the dollar amount of funds held by each deposit broker for each such party as of the date of the IDI's failure.

There is no change in the substance or methodology of this information collection. The change in burden is due to the FDIC estimating one respondent for certain forms where FDIC previously estimated zero respondents. In the table above, one respondent is being used as a placeholder to preserve the burden estimate for forms in case they come into use in the future.

Request for Comment

Comments are invited on: (a) Whether the collection of information is necessary for the proper performance of the FDIC's functions, including whether the information has practical utility; (b) the accuracy of the estimates of the burden of the information collection, including the validity of the methodology and assumptions used; (c) ways to enhance the quality, utility, and clarity of the information to be collected; and (d) ways to minimize the burden of the collection of information

on respondents, including through the use of automated collection techniques or other forms of information technology. All comments will become a matter of public record.

Federal Deposit Insurance Corporation.

Dated at Washington, DC, on May 28, 2020.

Robert E. Feldman,

Executive Secretary.

[FR Doc. 2020–11855 Filed 6–1–20; 8:45 am]

BILLING CODE 6714–01–P

FEDERAL RESERVE SYSTEM

[Docket No. OP–1719]

Announcement of Financial Sector Liabilities

Section 622 of the Dodd-Frank Wall Street Reform and Consumer Protection Act, implemented by the Board's Regulation XX, prohibits a merger or acquisition that would result in a financial company that controls more than 10 percent of the aggregate consolidated liabilities of all financial companies (aggregate financial sector liabilities). Specifically, an insured depository institution, a bank holding company, a savings and loan holding company, a foreign banking organization, any other company that controls an insured depository institution, and a nonbank financial company designated by the Financial Stability Oversight Council (each, a ''financial company'') is prohibited from merging or consolidating with, acquiring all or substantially all of the assets of, or acquiring control of, another company if the resulting company's consolidated liabilities would exceed 10 percent of the aggregate financial sector liabilities.[1]

Pursuant to Regulation XX, the Federal Reserve will publish the aggregate financial sector liabilities by July 1 of each year. Aggregate financial sector liabilities equals the average of the year-end financial sector liabilities figure (as of December 31) of each of the preceding two calendar years.

FOR FURTHER INFORMATION CONTACT: Lesley Chao, Lead Financial Institution Policy Analyst, (202) 974–7063; Sean Healey, Lead Financial Institution Policy Analyst, (202) 912–4611; Laura Bain, Counsel, (202) 736–5546; for the hearing impaired, TTY (202) 263–4869.

Aggregate Financial Sector Liabilities

Aggregate financial sector liabilities is equal to $21,229,884,414,000.[2] This measure is in effect from July 1, 2020 through June 30, 2021.

Calculation Methodology

Aggregate financial sector liabilities equals the average of the year-end financial sector liabilities figure (as of December 31) of each of the preceding two calendar years. The year-end financial sector liabilities figure equals the sum of the total consolidated liabilities of all top-tier U.S. financial companies and the U.S. liabilities of all top-tier foreign financial companies, calculated using the applicable methodology for each financial company, as set forth in Regulation XX and summarized below.

Consolidated liabilities of a U.S. financial company that was subject to consolidated risk-based capital rules as of December 31 of the year being measured, equal the difference between its risk-weighted assets (as adjusted upward to reflect amounts that are deducted from regulatory capital elements pursuant to the Federal banking agencies' risk-based capital rules) and total regulatory capital, as calculated under the applicable risk-based capital rules. Companies in this category include (with certain exceptions listed below) bank holding companies, savings and loan holding companies, and insured depository institutions. The Federal Reserve used information collected on the Consolidated Financial Statements for Holding Companies (FR Y–9C) and the Bank Consolidated Reports of Condition and Income (Call Report) to calculate liabilities of these institutions.

Consolidated liabilities of a U.S. financial company not subject to consolidated risk-based capital rules as of December 31 of the year being measured, equal liabilities calculated in accordance with applicable accounting standards. Companies in this category include nonbank financial companies supervised by the Board, bank holding companies and savings and loan holding companies subject to the Federal Reserve's Small Bank Holding Company Policy Statement, savings and loan holding companies substantially engaged in insurance underwriting or commercial activities, and U.S. companies that control insured depository institutions but are not bank holding companies or savings and loan holding companies. ''Applicable accounting standards'' is defined as Generally Accepted Accounting Principles (GAAP), or such other accounting standard or method of estimation that the Board determines is appropriate.[3] The Federal Reserve used information collected on the FR Y–9C, the Parent Company Only Financial Statements for Small Holding Companies (FR Y–9SP), and the Financial Company Report of Consolidated Liabilities (FR XX–1) to calculate liabilities of these institutions.

Section 622 provides that the U.S. liabilities of a ''foreign financial company'' equal the risk-weighted assets and regulatory capital attributable to the company's ''U.S. operations.'' Under Regulation XX, liabilities of a foreign banking organization's U.S. operations are calculated using the risk-weighted asset methodology for subsidiaries subject to the risk-based capital rule, plus the assets of all branches, agencies, and nonbank subsidiaries, calculated in accordance with applicable accounting standards. Liabilities attributable to the U.S. operations of a foreign financial company that is not a foreign banking organization are calculated in a similar manner to the method described for foreign banking organizations, but liabilities of a U.S. subsidiary not subject to the risk-based capital rule are calculated based on the U.S. subsidiary's liabilities under applicable accounting standards. The Federal Reserve used information collected on the Capital and Asset Report for Foreign Banking Organizations (FR Y–7Q), the FR Y–9C, and the FR XX–1 to calculate liabilities of these institutions.

By order of the Board of Governors of the Federal Reserve System, acting through the Director of Supervision and

[1] 12 U.S.C. 1852(a)(2), (b).

[2] This number reflects the average of the financial sector liabilities figure for the year ending December 31, 2018 ($20,841,478,070,000) and the year ending December 31, 2019 ($21,618,290,757,000).

[3] A financial company may request to use an accounting standard or method of estimation other than GAAP if it does not calculate its total consolidated assets or liabilities under GAAP for any regulatory purpose (including compliance with applicable securities laws). 12 CFR 251.3(e). In previous years, the Board received and approved requests from eleven financial companies to use an accounting standard or method of estimation other than GAAP to calculate liabilities. Ten of the companies are insurance companies that report financial information under Statutory Accounting Principles (SAP), and one is a foreign company that controls a U.S. industrial loan company that reports financial information under International Financial Reporting Standards (IFRS). For the insurance companies, the Board approved a method of estimation that was based on line items from SAP-based reports, with adjustments to reflect certain differences in accounting treatment between GAAP and SAP. For the foreign company, the Board approved the use of IFRS. Such companies that continue to be subject to Regulation XX continue to use the previously approved methods. The Board did not receive any new requests this year.

Regulation under delegated authority, May 27, 2020.

Ann Misback,

Secretary of the Board.

[FR Doc. 2020–11771 Filed 6–1–20; 8:45 am]

BILLING CODE P

FEDERAL TRADE COMMISSION

Agency Information Collection Activities; Submission for OMB Review; Comment Request; Extension

AGENCY: Federal Trade Commission.

ACTION: Notice.

SUMMARY: The Federal Trade Commission (''FTC'' or ''Commission'') requests that the Office of Management and Budget (''OMB'') extend for an additional three years the current Paperwork Reduction Act (''PRA'') clearance for information collection requirements associated with its Funeral Industry Practice Rule (''Funeral Rule'' or ''Rule''). That clearance expires on June 30, 2020.

DATES: Comments must be filed by July 2, 2020.

ADDRESSES: Written comments and recommendations for the proposed information collection should be sent within 30 days of publication of this notice to *www.reginfo.gov/public/do/PRAMain.* Find this particular information collection by selecting ''Currently under Review—Open for Public Comments'' or by using the search function.

FOR FURTHER INFORMATION CONTACT: Patricia H. Poss, Division of Marketing Practices, Bureau of Consumer Protection, Federal Trade Commission, 600 Pennsylvania Ave. NW, Washington, DC 20580, *pposs@ftc.gov,* (202) 326–2413.

SUPPLEMENTARY INFORMATION: Pursuant to the Paperwork Reduction Act of 1995 (44 U.S.C. 3501 *et seq.*), the FTC has submitted to the Office of Management and Budget (''OMB'') this request for extension of the previously approved collection of information discussed below.

Title of Collection: Funeral Industry Practice Rule, 16 CFR 453.

OMB Control Number: 3084–0025.

Type of Review: Extension without change of currently approved collection.

Affected Public: Private Sector: Businesses and other for-profit entities.

Estimated Number of Annual Respondents: 19,136.

Estimated Annual Burden Hours: 164,006.

Estimated Annual Labor Costs: $5,429,859.

Abstract

The Funeral Rule ensures that consumers who are purchasing funeral goods and services have access to accurate itemized price information so they can purchase only the funeral goods and services they want or need. Among other things, the Rule requires a funeral provider to: (1) Provide consumers a copy of the funeral provider's General Price List that itemizes the goods and services it offers; (2) show consumers a Casket Price List and an Outer Burial Container Price List at the outset of any discussion of those items or their prices, and in any event before showing consumers caskets or vaults; (3) provide price information from its price lists over the telephone; and (4) give consumers a Statement of Funeral Goods and Services Selected after determining the funeral arrangements with consumers. The Rule requires that funeral providers disclose this information to consumers and maintain records documenting their compliance with the Rule.

Request for Comment

On February 4, 2020, the FTC sought public comment on the information collection requirements in the Funeral Rule. 85 FR 6185 (Feb. 4, 2020). No relevant comments were received. Pursuant to the OMB regulations, 5 CFR part 1320, the FTC is providing this second opportunity for public comment while seeking OMB approval to renew clearance for the Rule's information collection requirements.

Your comment—including your name and your state—will be placed on the public record of this proceeding. Because your comment will be made public, you are solely responsible for making sure that your comment does not include any sensitive personal information, like anyone's Social Security number, date of birth, driver's license number or other state identification number or foreign country equivalent, passport number, financial account number, or credit or debit card number. You are also solely responsible for making sure that your comment does not include any sensitive health information, like medical records or other individually identifiable health information. In addition, do not include any ''[t]rade secret or any commercial or financial information which is . . . privileged or confidential'' as provided in Section 6(f) of the FTC Act 15 U.S.C. 46(f), and FTC Rule 4.10(a)(2), 16CFR 4.10(a)(2). In particular, do not include competitively sensitive information such as costs, sales statistics, inventories, formulas, patterns devices, manufacturing processes, or customer names.

Josephine Liu,

Assistant General Counsel for Legal Counsel.

[FR Doc. 2020–11877 Filed 6–1–20; 8:45 am]

BILLING CODE 6750–01–P

DEPARTMENT OF HEALTH AND HUMAN SERVICES

Centers for Disease Control and Prevention

[60Day–20–1204; Docket No. CDC–2020–0053]

Proposed Data Collection Submitted for Public Comment and Recommendations

AGENCY: Centers for Disease Control and Prevention (CDC), Department of Health and Human Services (HHS).

ACTION: Notice with comment period.

SUMMARY: The Centers for Disease Control and Prevention (CDC), as part of its continuing efforts to reduce public burden and maximize the utility of government information, 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. This notice invites comment on the ''Behavioral Risk Factor Surveillance System (BRFSS) Asthma Call-back Survey (ACBS)'' (OMB Control No. 0920–1204, expiration date 11/30/2020). The ACBS is an in-depth asthma survey conducted on a subset of BRFSS respondents with an asthma diagnosis. The goal of this survey is to strengthen the existing body of asthma data and to address critical questions surrounding the health and experiences of persons with asthma.

DATES: Written comments must be received on or before August 3, 2020.

ADDRESSES: You may submit comments, identified by Docket No. CDC–2020–0053 by any of the following methods:

- *Federal eRulemaking Portal: Regulation.gov.* Follow the instructions for submitting comments.
- *Mail:* Jeffrey M. Zirger, Information Collection Review Office, Centers for Disease Control and Prevention, 1600 Clifton Road NE, MS–D74, Atlanta, Georgia 30329.

Instructions: All submissions received must include the agency name and Docket Number. CDC will post, without change, all relevant comments to *Regulations.gov*.

Please note: Submit all comments through the Federal eRulemaking portal

(*regulations.gov*) or by U.S. mail to the address listed above.

FOR FURTHER INFORMATION CONTACT: To request more information on the proposed project or to obtain a copy of the information collection plan and instruments, contact Jeffrey M. Zirger, Information Collection Review Office, Centers for Disease Control and Prevention, 1600 Clifton Road NE, MS–D74, Atlanta, Georgia 30329; phone: 404–639–7570; Email: *omb@cdc.gov.*

SUPPLEMENTARY INFORMATION: Under the Paperwork Reduction Act of 1995 (PRA) (44 U.S.C. 3501–3520), Federal agencies must obtain approval from the Office of Management and Budget (OMB) for each collection of information they conduct or sponsor. In addition, the PRA also requires Federal agencies to provide a 60-day notice in the **Federal Register** concerning each proposed collection of information, including each new proposed collection, each proposed extension of existing collection of information, and each reinstatement of previously approved information collection before submitting the collection to the OMB for approval. To comply with this requirement, we are publishing this notice of a proposed data collection as described below.

The OMB is particularly interested in comments that will help:

1. Evaluate whether the proposed collection of information is necessary for the proper performance of the functions of the agency, including whether the information will have practical utility;

2. Evaluate the accuracy of the agency's estimate of the burden of the proposed collection of information, including the validity of the methodology and assumptions used;

3. Enhance the quality, utility, and clarity of the information to be collected; and

4. Minimize the burden of the collection of information on those who are to respond, including through the use of appropriate automated, electronic, mechanical, or other technological collection techniques or other forms of information technology, *e.g.,* permitting electronic submissions of responses.

5. Assess information collection costs.

Proposed Project

Behavioral Risk Factor Surveillance System (BRFSS) Asthma Call-back Survey (ACBS)—Revision—National Center for Environmental Health (NCEH), Centers for Disease Control and Prevention (CDC).

Background and Brief Description

The CDC's National Center for Environmental Health (NCEH) is requesting a three-year Paperwork Reduction Act (PRA) clearance to revise and continue to collect information under the ''Behavioral Risk Factor Surveillance System (BRFSS) Asthma Call-back Survey (ACBS)'' (OMB Control No. 0920–1204, expiration date 11/30/2020). The ACBS is funded by the NCEH National Asthma Control Program (NACP) in the Asthma and Community Health Branch (ACHB). The NACP provides its 40 participating states with technical and methodological assistance.

The ACBS is a follow-up survey on asthma and is administered on behalf of NCEH by the CDC's National Center for Chronic Disease Prevention and Health Promotion (NCCDPHP) BRFSS Program. The BRFSS (OMB Control No. 0920–1061, expiration date 3/31/2021) is a nationwide system of customized, cross-sectional telephone health surveys. The BRFSS information collection is conducted in a continuous, three-part telephone interview process: screening, participation in a common BRFSS core survey, and participation in optional question modules that states use to customize survey content. BRFSS coordinators in the health departments in U.S. states, territories, and the District of Columbia (collectively referred to as ''states'' and ''jurisdictions'') are responsible for both the BRFSS and the ACBS administration. The ACBS is conducted within two days after the BRFSS survey.

The purpose of ACBS is to gather state-level asthma data and to make them available to track the burden of the disease, to monitor adherence to asthma guidelines, and to direct and evaluate interventions undertaken by asthma control programs located in state health departments. Beyond asthma prevalence estimates, for most states, the ACBS provides the only sources of adult and child asthma data on the state and local level.

Data collection for ACBS involves screening, obtaining permission, consenting, and telephone interviewing on a subset of the BRFSS respondents from participating states. The ACBS eligible respondents are BRFSS adults, 18 years and older, who report ever being diagnosed with asthma. In addition, some states include children, below 18 years of age, who are randomly selected subjects in the BRFSS household. Parents or guardians serve as ACBS proxy respondents for their children ever diagnosed with asthma. If both the BRFSS adult respondent and the selected child in the household have asthma, then only one or the other is eligible for the ACBS.

State BRFSS Coordinators submit de-identified data files to CDC on a monthly or quarterly basis for cleaning and weighting. The CDC BRFSS ACBS operation team returns clean, weighted data files to the state of origin for its use. The ACBS adds considerable state-level depth to the existing body of asthma data. It addresses critical questions surrounding the health and experiences of persons with asthma. Health data include symptoms, environmental factors, and medication use among persons with asthma. Data on their experiences include activity limitation, health system use, and self-management education. These asthma data are needed to direct and evaluate interventions undertaken by asthma control programs located in state health departments. Federal agencies and other entities also rely on this critical information for planning and evaluating efforts and to reduce the burden from this disease. The CDC makes annual ACBS datasets available for public use and provides guidance on statistically appropriate uses of the data.

The time burden estimates are based on the 2016 ACBS data collection, which is the most recent data released. The burden table reflects the landline and cell phone data collection methods used in 2016 and later years. Additionally, the time burden accounts for reporting burden incurred by the states for the monthly or quarterly adult and child ACBS data submissions to CDC. The total estimated annualized time burden for all respondents is 6,615 hours. Participation in the ACBS is voluntary and there are no costs to respondents other than their time.

ESTIMATED ANNUALIZED BURDEN TO RESPONDENTS

Type of respondents	Form name	Number of respondents	Number of responses per respondent	Average burden per response (in hrs.)	Total burden hours
BRFSS Adults	ACBS Landline Screener—Adult	17,800	1	1/60	297
	ACBS Cell Phone Screener—Adult	16,733	1	1/60	279
BRFSS Parents or Guardians of Children.	ACBS Landline Screener—Child	2,576	1	1/60	43
	ACBS Cell Phone Screener—Child	3,824	1	1/60	64
ACBS Adults	ACBS Adult Consent and Questionnaire.	23,166	1	10/60	3,861
ACBS Parents or Guardians of Children.	ACBS Child Consent and Questionnaire.	3,787	1	10/60	631
State BRFSS Coordinators	ACBS Adult Data Submission Layout.	40	12	155/60	1,240
	ACBS Child Data Submission Layout.	40	12	25/60	200
Total					6,615

Jeffrey M. Zirger,

Lead, Information Collection Review Office, Office of Scientific Integrity, Office of Science, Centers for Disease Control and Prevention.

[FR Doc. 2020–11803 Filed 6–1–20; 8:45 am]

BILLING CODE 4163–18–P

DEPARTMENT OF HEALTH AND HUMAN SERVICES

Centers for Disease Control and Prevention

[30Day–20–1027]

Agency Forms Undergoing Paperwork Reduction Act Review

In accordance with the Paperwork Reduction Act of 1995, the Centers for Disease Control and Prevention (CDC) has submitted the information collection request titled ''Generic Clearance for the Collection of Qualitative Feedback on Agency Service Delivery'' to the Office of Management and Budget (OMB) for review and approval. CDC previously published a ''Proposed Data Collection Submitted for Public Comment and Recommendations'' notice on March 9, 2020 to obtain comments from the public and affected agencies. CDC received one comment related to the previous notice. This notice serves to allow an additional 30 days for public and affected agency comments.

CDC will accept all comments for this proposed information collection project. The Office of Management and Budget is particularly interested in comments that:

(a) Evaluate whether the proposed collection of information is necessary for the proper performance of the functions of the agency, including whether the information will have practical utility;

(b) Evaluate the accuracy of the agencies estimate of the burden of the proposed collection of information, including the validity of the methodology and assumptions used;

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

(d) Minimize the burden of the collection of information on those who are to respond, including, through the use of appropriate automated, electronic, mechanical, or other technological collection techniques or other forms of information technology, *e.g.,* permitting electronic submission of responses; and

(e) Assess information collection costs.

To request additional information on the proposed project or to obtain a copy of the information collection plan and instruments, call (404) 639–7570. Comments and recommendations for the proposed information collection should be sent within 30 days of publication of this notice to *www.reginfo.gov/public/do/PRAMain.* Find this particular information collection by selecting ''Currently under 30-day Review—Open for Public Comments'' or by using the search function. Direct written comments and/or suggestions regarding the items contained in this notice to the Attention: CDC Desk Officer, Office of Management and Budget, 725 17th Street NW, Washington, DC 20503 or by fax to (202) 395–5806. Provide written comments within 30 days of notice publication.

Proposed Project

Generic Clearance for the Collection of Qualitative Feedback on Agency Service Delivery (OMB Control No. 0920–1027, Exp. 7/31/2020)—Extension—National Center for HIV/AIDS, Viral Hepatitis, STD, and TB Prevention (NCHHSTP), Centers for Disease Control and Prevention (CDC).

Background and Brief Description

CDC is requesting a three-year extension of this generic information collection request. During the past three-year approval period, the generic clearance facilitated the approval of seven projects (''GenICs'') involving 13,574 respondents. The projects included web-based surveys, focus groups, and assessments. The information collection activities conducted under this extension will continue to garner qualitative customer and stakeholder feedback in an efficient, timely manner, in accordance with the Administration's commitment to improving service delivery. By qualitative feedback, we mean information that provides useful insights on perceptions and opinions, but are not statistical surveys that yield quantitative results that can be generalized to the population of study. This feedback will provide insights into customer or stakeholder perceptions, experiences and expectations, provide an early warning of issues with service, or focus attention on areas where communication, training, or changes in operations might improve delivery of products or services. These collections will allow for ongoing, collaborative, and actionable communications between the Agency and its customers and stakeholders. It will also allow feedback to contribute directly to the improvement of program management. Feedback collected under this generic clearance will provide useful information, but it will not yield data

that can be generalized to the overall population.

This type of generic clearance for qualitative information will not be used for quantitative information collections that are designed to yield reliably actionable results, such as monitoring trends over time or documenting program performance. Such data uses require more rigorous designs that address: The target population to which generalizations will be made, the sampling frame, the sample design (including stratification and clustering), the precision requirements or power calculations that justify the proposed sample size, the expected response rate, methods for assessing potential non-response bias, the protocols for data collection, and any testing procedures that were or will be undertaken prior to fielding the study. Depending on the degree of influence the results are likely to have, such collections may still be eligible for submission for other generic mechanisms that are designed to yield quantitative results.

Respondents will be screened and selected from individuals and households, businesses, organizations, and/or units of State, Local, Tribal, or Federal Government. Below we provide CDC's projected annualized estimate for the next three years. No changes are proposed. Participation is voluntary and there is no cost to respondents other than their time. The estimated annualized burden hours for this data collection activity are 9,690.

ESTIMATED ANNUALIZED BURDEN HOURS

Type of respondent	Type of collection	Number of respondents	Number of responses per respondent	Average burden per response (in hours)
Agency Customers	Online surveys	10,500	1	30/60
	Discussion Groups	280	1	2
	Focus groups	640	1	2
	Website/app usability testing	2,000	1	30/60
	Interviews	800	1	2

Jeffrey M. Zirger,

Lead, Information Collection Review Office, Office of Scientific Integrity, Office of Science, Centers for Disease Control and Prevention.

[FR Doc. 2020–11797 Filed 6–1–20; 8:45 am]

BILLING CODE 4163–18–P

DEPARTMENT OF HEALTH AND HUMAN SERVICES

Centers for Disease Control and Prevention

[60Day–20–20OJ; Docket No. CDC–2020–0058]

Proposed Data Collection Submitted for Public Comment and Recommendations

AGENCY: Centers for Disease Control and Prevention (CDC), Department of Health and Human Services (HHS).

ACTION: Notice with comment period.

SUMMARY: The Centers for Disease Control and Prevention (CDC), as part of its continuing effort to reduce public burden and maximize the utility of government information, invites the general public and other Federal agencies the opportunity to comment on a proposed and/or continuing information collection, as required by the Paperwork Reduction Act of 1995. This notice invites comment on a proposed information collection project titled National YRBS Test-Retest Reliability Study. This study is designed to test the reliability of the data collected through the Youth Risk Behavior Survey (YRBS) questionnaires. The YRBS is a biennially school-based survey of high school students in the United States.

DATES: CDC must receive written comments on or before August 3, 2020.

ADDRESSES: You may submit comments, identified by Docket No. CDC–2020–0058 by any of the following methods:

- *Federal eRulemaking Portal: Regulations.gov.* Follow the instructions for submitting comments.
- *Mail:* Jeffrey M. Zirger, Information Collection Review Office, Centers for Disease Control and Prevention, 1600 Clifton Road NE, MS–D74, Atlanta, Georgia 30329.

Instructions: All submissions received must include the agency name and Docket Number. CDC will post, without change, all relevant comments to *Regulations.gov.*

Please note: Submit all comments through the Federal eRulemaking portal (regulations.gov) or by U.S. mail to the address listed above.

FOR FURTHER INFORMATION CONTACT: To request more information on the proposed project or to obtain a copy of the information collection plan and instruments, contact Jeffrey M. Zirger, Information Collection Review Office, Centers for Disease Control and Prevention, 1600 Clifton Road NE, MS–D74, Atlanta, Georgia 30329; phone: 404–639–7570; Email: *omb@cdc.gov.*

SUPPLEMENTARY INFORMATION: Under the Paperwork Reduction Act of 1995 (PRA) (44 U.S.C. 3501–3520), Federal agencies must obtain approval from the Office of Management and Budget (OMB) for each collection of information they conduct or sponsor. In addition, the PRA also requires Federal agencies to provide a 60-day notice in the **Federal Register** concerning each proposed collection of information, including each new proposed collection, each proposed extension of existing collection of information, and each reinstatement of previously approved information collection before submitting the collection to the OMB for approval. To comply with this requirement, we are publishing this notice of a proposed data collection as described below.

The OMB is particularly interested in comments that will help:

1. Evaluate whether the proposed collection of information is necessary for the proper performance of the functions of the agency, including whether the information will have practical utility;

2. Evaluate the accuracy of the agency's estimate of the burden of the proposed collection of information, including the validity of the methodology and assumptions used;

3. Enhance the quality, utility, and clarity of the information to be collected; and

4. Minimize the burden of the collection of information on those who are to respond, including through the use of appropriate automated, electronic, mechanical, or other technological collection techniques or other forms of information technology, *e.g.,* permitting electronic submissions of responses.

5. Assess information collection costs.

Proposed Project

The National YRBS Test-Retest Reliability Study—New—National Center for HIV/AIDS, Viral Hepatitis, STD, and TB Prevention (NCHHSTP), Centers for Disease Control and Prevention (CDC).

Background and Brief Description

The purpose of this request is to obtain OMB approval to conduct the National YRBS Test-Retest Reliability Study to establish the reliability of the national Youth Risk Behavior Survey (''YRBS'') questionnaire.

The YRBS assesses priority health risk behaviors related to the major preventable causes of mortality, morbidity, and social problems among both youth and young adults in the United States. Data on health risk behaviors of adolescents are the focus of approximately 65 national health objectives in Healthy People 2030, an initiative of the U.S. Department of Health and Human Services (HHS). The YRBS provides data to measure 13 of the proposed health objectives and one of the Leading Health Indicators currently under public comment to establish Healthy People 2030 objectives. In addition, the YRBS can identify racial and ethnic disparities in health risk behaviors. No other national source of data measures as many of the Healthy People 2030 objectives addressing adolescent health risk behaviors as the YRBS. The data also will have significant implications for policy and program development for school health programs nationwide. CDC seeks a one-year approval to conduct the National YRBS Test-Retest Reliability Study.

Between September and December of 2021, a sample of 2,000 students from 20 regular public secondary schools in the U.S. containing at least one of grades nine through 12 will be selected in no more than 20 districts. This sample is expected to yield at least 1,000 participating students who completed both a Time 1 and Time 2 YRBS questionnaire.

The table below reports the number of respondents annualized over the one-year project period. There are no costs to respondents except their time. The total estimated annualized burden hours are 1,696.

ESTIMATED ANNUALIZED BURDEN HOURS

Respondent	Form name	Number of respondents	Number of responses per respondent	Average burden per response (in hours)	Total burden (in hours)
Preliminary Activities					
District Administrators	District recruitment script (Attachment E).	20	1	30/60	10
School Principals	School recruitment script (Attachment G).	20	1	30/60	10
Data Collection Activities					
Classroom Teachers	Consent form checklist (Attachment N).	80	1	15/60	20
Students	YRBS Questionnaire (Attachment C).	1,000	2	45/60	1,500
Total					1,540

Jeffrey M. Zirger,

Lead, Information Collection Review Office, Office of Scientific Integrity, Office of Science, Centers for Disease Control and Prevention.

[FR Doc. 2020–11800 Filed 6–1–20; 8:45 am]

BILLING CODE 4163–18–P

DEPARTMENT OF HEALTH AND HUMAN SERVICES

Centers for Disease Control and Prevention

[60Day–20–20OG; Docket No. CDC–2020–0057]

Proposed Data Collection Submitted for Public Comment and Recommendations

AGENCY: Centers for Disease Control and Prevention (CDC), Department of Health and Human Services (HHS).

ACTION: Notice with comment period.

SUMMARY: The Centers for Disease Control and Prevention (CDC), as part of its continuing effort to reduce public burden and maximize the utility of government information, invites the general public and other Federal agencies the opportunity to comment on a proposed and/or continuing information collection, as required by the Paperwork Reduction Act of 1995. This notice invites comment on a proposed information collection project titled ''Assessments of adults' professional experiences for improving programs to decrease sexual risk and related behaviors and adverse health outcomes among youth,'' a generic information collection package that supports qualitative and quantitative data collection from adults who help implement programs and services designed to prevent HIV, other sexually transmitted diseases (STDs), and pregnancy or influence related risk and protective factors; data will be collected for needs assessment and program refinement.

DATES: CDC must receive written comments on or before August 3, 2020.

ADDRESSES: You may submit comments, identified by Docket No. CDC–2020–0057 by any of the following methods:

- *Federal eRulemaking Portal: Regulations.gov*. Follow the instructions for submitting comments.
- *Mail:* Jeffrey M. Zirger, Information Collection Review Office, Centers for Disease Control and Prevention, 1600 Clifton Road NE, MS–D74, Atlanta, Georgia 30329.

Instructions: All submissions received must include the agency name and Docket Number. CDC will post, without change, all relevant comments to *Regulations.gov*.

Please note: Submit all comments through the Federal eRulemaking portal (*regulations.gov*) or by U.S. mail to the address listed above.

FOR FURTHER INFORMATION CONTACT: To request more information on the proposed project or to obtain a copy of the information collection plan and instruments, contact Jeffrey M. Zirger, Information Collection Review Office, Centers for Disease Control and Prevention, 1600 Clifton Road NE, MS–D74, Atlanta, Georgia 30329; phone: 404–639–7570; Email: *omb@cdc.gov.*

SUPPLEMENTARY INFORMATION: Under the Paperwork Reduction Act of 1995 (PRA) (44 U.S.C. 3501–3520), Federal agencies must obtain approval from the Office of Management and Budget (OMB) for each collection of information they conduct or sponsor. In addition, the PRA also requires Federal agencies to provide a 60-day notice in the **Federal Register** concerning each proposed collection of information, including each new proposed collection, each proposed extension of existing collection of information, and each reinstatement of previously approved information collection before submitting the collection to the OMB for approval. To comply with this requirement, we are publishing this notice of a proposed data collection as described below.

The OMB is particularly interested in comments that will help:

1. Evaluate whether the proposed collection of information is necessary for the proper performance of the functions of the agency, including whether the information will have practical utility;

2. Evaluate the accuracy of the agency's estimate of the burden of the proposed collection of information, including the validity of the methodology and assumptions used;

3. Enhance the quality, utility, and clarity of the information to be collected; and

4. Minimize the burden of the collection of information on those who are to respond, including through the use of appropriate automated, electronic, mechanical, or other technological collection techniques or other forms of information technology, *e.g.,* permitting electronic submissions of responses.

5. Assess information collection costs.

Proposed Project

Assessments of adults' professional experiences for improving programs to decrease sexual risk and related behaviors and adverse health outcomes among youth—New—Division of Adolescent and School Health (DASH), National Center for HIV/AIDS, Viral Hepatitis, STD, and TB Prevention (NCHHSTP), Centers for Disease Control and Prevention (CDC).

Background and Brief Description

The Centers for Disease Control and Prevention (CDC) requests approval for a new generic information collection package that supports collection of quantitative and qualitative information from adults who help implement programs and services designed to prevent HIV, other sexually transmitted diseases (STDs), and pregnancy or influence related risk and protective factors; data will be collected for needs assessment and program refinement. The National Center for HIV/AIDS, Viral Hepatitis, STD, and TB Prevention (NCHHSTP) conducts the assessment of program practices and health services to reduce sexual risk behaviors among adolescents and reduce adverse health outcomes of those risk behaviors.

NCHHSTP conducts behavioral and health service assessments and research projects as part of its response to the domestic HIV/AIDS epidemic, STD prevention, TB elimination and viral hepatitis control with national, state, and local partners. Adolescents are a population with specific developmental, health and social, and resource needs. Their health risk factors and access to health care is addressed as a primary mission by the Division of Adolescent and School Health (DASH), and adolescents are a population of interest for several other NCHHSTP divisions. The assessment and research conducted by NCHHSTP is one pillar upon which recommendations and guidelines are revised and updated. Recommendations and guidelines for adolescent sexual risk reduction require a foundation of scientific evidence. Assessment of programmatic practices for adolescents helps improve programs through better identification of strategies relevant to adolescents as a population as well as specific sub-groups of adolescents at highest risk for HIV and other STDs so that programs can be better tailored specifically for them.

Participants in data collection include adults (over 18 years old) who help implement or oversee programs to prevent HIV, other sexually transmitted diseases (STDs), and pregnancy among youth or influence related risk and protective factors. These participants may include adults in roles such as:

- School staff and administrators
- Staff in state and local education agencies
- Staff in state and local health agencies
- Staff in youth-serving community and national non-governmental organizations
- Community-based health care providers for adolescents
- School-based health care providers for students

The types of information collection activities included in this generic package are:

(1) Quantitative data collection conducted in-person on remotely through electronic (via computers, tablets, other mobile devices, etc.), telephone, or paper questionnaires to gather information about programmatic and service activities related to sexual risk reduction or related adverse health outcomes among youth. Questions relate to work-related experiences, training, context, duties, activities, and youths' health and service needs. Information may also be gathered on program implementers' demographic and social characteristics, program-related knowledge, attitudes, skills, and implementation practices.

(2) Qualitative data collection in-person or remotely through electronic, telephone, or paper means to gather information about program and service activities related to sexual risk reduction or prevention of related adverse health outcomes among youth. Qualitative data collection may involve focus groups and/or in-depth individual or group interviews. Interview and focus group guides may include questions about work-related experiences, training, context, duties, activities, and youths' health and service needs. Information may also be gathered on program implementers' demographic and social characteristics, program-related knowledge, attitudes, skills, and implementation practices. For adolescents, data collection instruments will include questions on demographic characteristics; experiences with programs and services to reduce the risk of HIV and other STD transmission; and knowledge, attitudes, behaviors, and skills related to sexual risk and protective factors on the individual, interpersonal, and community levels.

The participants for this data collection are considered to be the ''implementers'' of the types of programs that are funded by CDC/DASH. Typically, CDC/DASH programs are intended to have direct impact on proximal indicators such as sexual health-related knowledge, attitudes, perceptions, and behaviors among youth, and although CDC/DASH programs are typically set in schools, they can be implemented by adults who working in a variety of school, community, and health-care roles.

Any data collection request put forward under this generic clearance will identify the programs and/or services to be informed or refined with the information from the collection and will include a cross-walk of data elements to the aspects of the program

the project team seeks to inform or refine. Because this request includes a wide range of possible data collection instruments, specific requests will include items of information to be collected and copies of data collection instruments. It is expected that all data collection instruments will be pilot-tested, and will be culturally appropriate for the intended populations. All data collection procedures will receive review and approval by an Institutional Review Board (IRB) for the Protection of Human Subjects and follow appropriate consent and assent procedures as outlined in the IRB-approved protocols and these will be described in the individual information collection requests put forward under this generic package. Participation of respondents is voluntary. There is no cost to the participants other than their time.

The table below provides the estimated annualized response burden for up to 20 individual data collections per year under this generic clearance at 58,500 hours annually. Average burden per response is based on pilot testing and timing of quantitative and qualitative instrument administration during previous studies. Response times include the time to read and respond to consent forms and to read or listen to instructions. The proposed information collections combine for a total estimated annualized burden of up to 60,000 hours for respondents.

ESTIMATED ANNUALIZED BURDEN HOURS

Type of respondents	Form name	Number of respondents	Number of responses per respondent	Average burden per response (in hours)	Total burden (in hours)
Adults helping with program implementation (e.g., school or district staff, community partners, NGO staff).	Questionnaire	15,000	1	1	15,000
Adults helping with program implementation.	Pre/Post questionnaire	15,000	2	1	30,000
Adults helping with program implementation.	Interview/focus group guide	4,000	1	1.5	6,000
Adults helping with program implementation.	Pre/Post Interview/focus group guide.	3,000	2	1.5	9,000
Total					60,000

Jeffrey M. Zirger,

Lead, Information Collection Review Office, Office of Scientific Integrity, Office of Science, Centers for Disease Control and Prevention.

[FR Doc. 2020–11799 Filed 6–1–20; 8:45 am]

BILLING CODE 4163–18–P

DEPARTMENT OF HEALTH AND HUMAN SERVICES

Centers for Disease Control and Prevention

[60Day–20–0138; Docket No. CDC–2020–0048]

Proposed Data Collection Submitted for Public Comment and Recommendations

AGENCY: Centers for Disease Control and Prevention (CDC), Department of Health and Human Services (HHS).

ACTION: Notice with comment period.

SUMMARY: The Centers for Disease Control and Prevention (CDC), as part of its continuing effort to reduce public burden and maximize the utility of government information, invites the general public and other Federal agencies the opportunity to comment on a proposed and/or continuing information collection, as required by the Paperwork Reduction Act of 1995. This notice invites comment on a proposed information collection project titled Pulmonary Function Test Course Approval Application. The program consists of an application submitted by potential sponsors (universities, hospitals, and private consulting firms) who seek NIOSH approval to conduct courses, and if approved, notification to NIOSH of any course or faculty changes during the approval period, which is limited to five years.

DATES: CDC must receive written comments on or before August 3, 2020.

ADDRESSES: You may submit comments, identified by Docket No. CDC–2020–0048 by any of the following methods:

- *Federal eRulemaking Portal: Regulations.gov*. Follow the instructions for submitting comments.
- *Mail:* Jeffrey M. Zirger, Information Collection Review Office, Centers for Disease Control and Prevention, 1600 Clifton Road NE, MS–D74, Atlanta, Georgia 30329.

Instructions: All submissions received must include the agency name and Docket Number. CDC will post, without change, all relevant comments to *Regulations.gov*.

Please note: Submit all comments through the Federal eRulemaking portal (*regulations.gov*) or by U.S. mail to the address listed above.

FOR FURTHER INFORMATION CONTACT: To request more information on the proposed project or to obtain a copy of the information collection plan and instruments, contact Jeffrey M. Zirger, Information Collection Review Office, Centers for Disease Control and Prevention, 1600 Clifton Road NE, MS–D74, Atlanta, Georgia 30329; phone: 404–639–7570; Email: *omb@cdc.gov.*

SUPPLEMENTARY INFORMATION: Under the Paperwork Reduction Act of 1995 (PRA) (44 U.S.C. 3501–3520), Federal agencies must obtain approval from the Office of Management and Budget (OMB) for each collection of information they conduct or sponsor. In addition, the PRA also requires Federal agencies to provide a 60-day notice in the **Federal Register** concerning each proposed collection of information, including each new proposed collection, each proposed extension of existing collection of information, and each reinstatement of previously approved information collection before submitting the collection to the OMB for approval. To comply with this requirement, we are publishing this notice of a proposed data collection as described below.

The OMB is particularly interested in comments that will help:

1. Evaluate whether the proposed collection of information is necessary for the proper performance of the functions of the agency, including whether the information will have practical utility;

2. Evaluate the accuracy of the agency's estimate of the burden of the proposed collection of information, including the validity of the methodology and assumptions used;

3. Enhance the quality, utility, and clarity of the information to be collected; and

4. Minimize the burden of the collection of information on those who are to respond, including through the use of appropriate automated, electronic, mechanical, or other technological collection techniques or other forms of information technology, *e.g.,* permitting electronic submissions of responses.

5. Assess information collection costs.

Proposed Project

Pulmonary Function Testing Course Approval Program (OMB Control No. 0920–0138, Exp. 11/30/2020)—Revision—National Institute for Occupational Safety and Health (NIOSH), Centers for Disease Control and Prevention (CDC).

Background and Brief Description

NIOSH has the responsibility under the Occupational Safety and Health Administration's Cotton Dust Standard, 29 CFR 1920.1043, for approving courses to train technicians to perform pulmonary function testing in the cotton industry. Successful completion of a NIOSH-approved course is mandatory under this Standard. In addition, regulations at 42 CFR 37.95(a) specify that persons administering spirometry tests for the national Coal Workers 'Health Surveillance Program must successfully complete a NIOSH-approved spirometry training course and maintain a valid certificate by periodically completing NIOSH-approved spirometry refresher training courses. Also, 29 CFR 1910.1053(i)(2)(iv), 29 CFR 1910.1053(i)(3), 29 CFR 1926.1153(h)(2)(iv) and 29 CFR 1926.1153(h)(3) specify that pulmonary function tests for initial and periodic examinations in general industry and construction performed under the respirable crystalline silica standard should be administered by a spirometry technician with a current certificate from a NIOSH-approved spirometry course. NIOSH is requesting a three-year approval.

To carry out its responsibility, NIOSH maintains a Pulmonary Function Testing Course Approval Program. The program consists of an application submitted by potential sponsors (universities, hospitals, and private consulting firms) who seek NIOSH approval to conduct courses, and if approved, notification to NIOSH of any course or faculty changes during the approval period, which is limited to five years.

The application form and added materials, including an agenda, curriculum vitae, and course materials are reviewed by NIOSH to determine if the applicant has developed a program which adheres to the criteria required in the Standard. Following approval, any subsequent changes to the course are submitted by course sponsors via letter or email and reviewed by NIOSH staff to assure that the changes in faculty or course content continue to meet course requirements. Course sponsors also voluntarily submit an annual report to inform NIOSH of their class activity level and any faculty changes. Sponsors who elect to have their approval renewed for an additional five year period submit a renewal application and supporting documentation for review by NIOSH staff to ensure the course curriculum meets all current standard requirements. Approved courses that elect to offer NIOSH-Approved Spirometry Refresher Courses must submit a separate application and supporting documents for review by NIOSH staff. Institutions and organizations throughout the country voluntarily submit applications and materials to become course sponsors and carry out training. Submissions are required for NIOSH to evaluate a course and determine whether it meets the criteria in the Standard and whether technicians will be adequately trained as mandated under the Standard.

Application form changes consist of minor text edits that clarify questions and information, thereby reducing the need for applicants to contact NIOSH for guidance. In addition, parts of the forms were reformatted to reduce redundancy and increase clarity for applicants. Two of the forms have updated titles which reflect the purpose of the applications (initial sponsorship and sponsorship renewal forms).

NIOSH will disseminate a one-time customer satisfaction survey to course directors and sponsor representatives to evaluate our service to courses, the effectiveness of the program changes implemented since 2005, and the usefulness of potential Program enhancements. The annualized figures slightly overestimate the actual burden, due to rounding of the number of respondents for even allocation over the three-year clearance period. The estimated annual burden to respondents is 160 hours. There will be no cost to respondents other than their time.

ESTIMATED ANNUALIZED BURDEN HOURS

Type of respondents	Form name	Number of respondents	Number of responses per respondent	Average burden per response (in hours)	Total burden (in hours)
Potential Sponsors	Initial Application	3	1	8	24
	Annual Report	34	1	28/60	16
	Report for Course Changes	24	1	30/60	12
	Renewal Application	13	1	6	78
	Refresher Course Application	3	1	8	24
	One-time Customer Satisfaction Survey	32	1	12/60	6
Total					160

Jeffrey M. Zirger,

Lead, Information Collection Review Office, Office of Scientific Integrity, Office of Science, Centers for Disease Control and Prevention.

[FR Doc. 2020–11802 Filed 6–1–20; 8:45 am]

BILLING CODE 4163–18–P

DEPARTMENT OF HEALTH AND HUMAN SERVICES

Centers for Disease Control and Prevention

[30Day–20–20JE]

Agency Forms Undergoing Paperwork Reduction Act Review

In accordance with the Paperwork Reduction Act of 1995, the Centers for Disease Control and Prevention (CDC) has submitted the information collection request titled ''Distribution of Traceable Opioid Material (TOM) Kits across U.S. Laboratories'' to the Office of Management and Budget (OMB) for review and approval. CDC previously published a ''Proposed Data Collection Submitted for Public Comment and Recommendations'' notice on February 28, 2020 to obtain comments from the public and affected agencies. CDC received four comments related to the previous notice. This notice serves to allow an additional 30 days for public and affected agency comments.

CDC will accept all comments for this proposed information collection project. The Office of Management and Budget is particularly interested in comments that:

(a) Evaluate whether the proposed collection of information is necessary for the proper performance of the functions of the agency, including whether the information will have practical utility;

(b) Evaluate the accuracy of the agencies estimate of the burden of the proposed collection of information, including the validity of the methodology and assumptions used;

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

(d) Minimize the burden of the collection of information on those who are to respond, including, through the use of appropriate automated, electronic, mechanical, or other technological collection techniques or other forms of information technology, *e.g.,* permitting electronic submission of responses; and

(e) Assess information collection costs.

To request additional information on the proposed project or to obtain a copy of the information collection plan and instruments, call (404) 639–7570. Comments and recommendations for the proposed information collection should be sent within 30 days of publication of this notice to *www.reginfo.gov/public/do/PRAMain* Find this particular information collection by selecting ''Currently under 30-day Review—Open for Public Comments'' or by using the search function. Direct written comments and/or suggestions regarding the items contained in this notice to the Attention: CDC Desk Officer, Office of Management and Budget, 725 17th Street NW, Washington, DC 20503 or by fax to (202) 395–5806. Provide written comments within 30 days of notice publication.

Proposed Project

Distribution of Traceable Opioid Material (TOM) Kits across U.S. Laboratories—New—National Center for Environmental Health (NCEH), Centers for Disease Control and Prevention (CDC).

Background and Brief Description

For the first time in U.S. history, a drug class has been declared a national public health emergency; each day more than 140 Americans die from drug overdoses, 91 specifically because of opioids. Since 2013, there have been significant increases in overdose deaths involving synthetic opioids—particularly those involving illicitly-manufactured fentanyl. The U.S. Drug Enforcement Administration (DEA) estimates that 75% of all opioid identifications are illicit fentanyls. Laboratories are routinely asked to confirm which fentanyl or other opioids are involved in an overdose or encountered by first responders, as it is critical to identify and classify the types of drugs involved in an overdose, how often they are involved, and how that involvement may change over time. By understanding which drugs are present, appropriate prevention and response activities can be implemented.

The Centers for Disease Control and Prevention (CDC) is leading the development of Traceable Opioid Material* Kits (TOM Kits*) to support detection of emerging opioids. CDC maintains the contents of the TOM Kits* based on new needs identified, in part, through DEA Emerging Threat Reports. The DEA 2018 mid-year data indicate that fentanyl and fentanyl-related compounds account for approximately 75% of their opioid identifications. These kits are reference materials and do not eliminate the need to meet analytical method requirements of other federal agencies. TOM Kits* are not intended for diagnostic use. The kits are free to laboratories in the public, private, clinical, law enforcement, research, and public health domains.

To equitably distribute these TOM Kits*, the CDC conducted an emergency information collection, titled ''Distribution of Traceable Opioid Material* Kits (TOM Kits*) across U.S. Laboratories,'' under the Health and Human Services (HHS) Secretary's Public Health Emergency Paperwork Reduction Act (PHE PRA) Waiver mechanism for the period from 03/20/2019 to 05/10/2019. From 05/10/2019, CDC continued distributing kits using a generic information collection (GenIC) under ''Generic Clearance for the Collection of Qualitative Feedback on Agency Service Delivery'' (OMB Control No. 0923–0047; expiration date 01/31/2022). To continue this collection, the CDC is currently requesting a three-year PRA clearance for a new information collection request (ICR) under the same title.

CDC is currently distributing a product line of TOM Kits*. Examples of products in this line include the: (1) Opioid Certified Reference Material Kit (Opioid CRM Kit); and (2) Fentanyl Analog Screening Kit (FAS Kit). Respondent laboratories requesting the TOM Kits* can be from any sector (academic, public, or private), must be located in the U.S., must have a verifiable business address, must have a current DEA registration, must comply with respective state and local regulations, and must submit requests directly to the respective vendor.

As the number of laboratories requesting TOM Kits* is high, the information collection will be used to prioritize which laboratories will receive kits when quantities are limited. The brief six-minute web-based survey will allow the CDC to (1) determine what service the recipient laboratory performs and the volume of samples the laboratory processes, and to (2) equitably distribute TOM Kits* based on the analysis techniques, matrix, and sample size used by the recipient laboratory.

The annual number of respondents (n=1,200) was based on the number of 2019 requests. The total time burden requested is 120 hours per year. There is no burden on the respondents other than their time. **TRACEABLE OPIOID MATERIAL, TOM KITS, and the TOM KITS logo are marks of the U.S. Department of Health and Human Services.*

ESTIMATED ANNUALIZED BURDEN HOURS

Type of respondents	Form name	Number of respondents	Number of responses per respondent	Average burden per response (in hours)
Federal Laboratories	TOM Kits* Questions	400	1	6/60
State, Local, and Tribal Government Laboratories	TOM Kits* Questions	400	1	6/60
Private or Not-for-Profit Institutions	TOM Kits* Questions	400	1	6/60

Jeffrey M. Zirger,

Lead, Information Collection Review Office, Office of Scientific Integrity, Office of Science, Centers for Disease Control and Prevention.

[FR Doc. 2020–11794 Filed 6–1–20; 8:45 am]

BILLING CODE 4163–18–P

DEPARTMENT OF HEALTH AND HUMAN SERVICES

Centers for Disease Control and Prevention

[30Day–20–0260]

Agency Forms Undergoing Paperwork Reduction Act Review

In accordance with the Paperwork Reduction Act of 1995, the Centers for Disease Control and Prevention (CDC) has submitted the information collection request titled Health Hazard Evaluations/Technical Assistance and Emerging Problems to the Office of Management and Budget (OMB) for review and approval. CDC previously published a ''Proposed Data Collection Submitted for Public Comment and Recommendations'' notice on February 10, 2020 to obtain comments from the public and affected agencies. CDC did not receive comments related to the previous notice. This notice serves to allow an additional 30 days for public and affected agency comments.

CDC will accept all comments for this proposed information collection project. The Office of Management and Budget is particularly interested in comments that:

(a) Evaluate whether the proposed collection of information is necessary for the proper performance of the functions of the agency, including whether the information will have practical utility;

(b) Evaluate the accuracy of the agencies estimate of the burden of the proposed collection of information, including the validity of the methodology and assumptions used;

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

(d) Minimize the burden of the collection of information on those who are to respond, including, through the use of appropriate automated, electronic, mechanical, or other technological collection techniques or other forms of information technology, *e.g.,* permitting electronic submission of responses; and

(e) Assess information collection costs.

To request additional information on the proposed project or to obtain a copy of the information collection plan and instruments, call (404) 639–7570. Comments and recommendations for the proposed information collection should be sent within 30 days of publication of this notice to *www.reginfo.gov/public/do/PRAMain.* Find this particular information collection by selecting ''Currently under 30-day Review—Open for Public Comments'' or by using the search function. Direct written comments and/or suggestions regarding the items contained in this notice to the Attention: CDC Desk Officer, Office of Management and Budget, 725 17th Street NW, Washington, DC 20503 or by fax to (202) 395–5806. Provide written comments within 30 days of notice publication.

Proposed Project

Health Hazard Evaluations/Technical Assistance and Emerging Problems (OMB Control No. 0920–0260, Exp. 10/31/2020)—Revision—National Institute for Occupational Safety and Health (NIOSH), Centers for Disease Control and Prevention (CDC).

Background and Brief Description

In accordance with its mandates under the Occupational Safety and Health Act of 1970 and the Federal Mine Safety and Health Act of 1977, NIOSH responds to requests for HHE to identify chemical, biological or physical hazards in workplaces throughout the United States. Each year, NIOSH receives approximately 250 such requests. Most HHE requests come from workplaces in the following industrial sectors: Services, manufacturing, health and social services, transportation, and construction.

A printed HHE request form is available in English and in Spanish. The form is also available on the internet and differs from the printed version only in format and in the fact that it can be submitted directly from the website. The request form takes an estimated 12 minutes to complete. The form provides the mechanism for employees, employers, and other authorized representatives to supply the information required by the regulations governing the NIOSH HHE program (42 CFR 85.3–1). NIOSH reviews the HHE request to determine if an on-site evaluation is needed. The primary purpose of an on-site evaluation is to help employers and employees identify and eliminate occupational health hazards. For 25% of the requests received NIOSH determines an on-site evaluation is needed.

In about 70% of on-site evaluations, employees are interviewed in an informal manner to help further define concerns. Interviews may take approximately 15 minutes per respondent. The interview questions are specific to each workplace and its suspected diseases and hazards. However, interviews are based on standard medical practices. In approximately 30% of on-site evaluations questionnaires are distributed to the employees (averaging about 100 employees per site). Questionnaires may require approximately 30 minutes to complete. The survey questions are specific to each workplace and its suspected diseases and hazards, however, items in the questionnaires are derived from standardized or widely used medical and epidemiologic data collection instruments.

About 70% of the on-site evaluations involve employee exposure monitoring in the workplace. Employees participating in on-site evaluations by wearing a sampler or monitoring device to measure personal workplace exposures are offered the opportunity to get notification of their exposure results. To indicate their preference and, if interested, provide contact information, employees complete a contact information post card. Completing the contact card may take five minutes or less. The number of employees monitored for workplace exposures per

on-site evaluation is estimated to be 25 per site.

NIOSH distributes interim and final reports of health hazard evaluations, excluding personal identifiers, to: Requesters, employers, employee representatives; the Department of Labor (Occupational Safety and Health Administration or Mine Safety and Health Administration, as appropriate); state health departments; and, as needed, other state and federal agencies. NIOSH administers a follow-back program to assess the effectiveness of its HHE program in reducing workplace hazards. This program entails the mailing of follow-back questionnaires to employer and employee representatives at all the workplaces where NIOSH conducted an on-site evaluation. In a small number of instances, a follow-back on-site evaluation may be completed. The first follow-back questionnaire is sent shortly after the first visit for an on-site evaluation and takes about 10 minutes to complete. A second follow-back questionnaire is sent after the final report is completed and requires about 20 minutes to complete. At 12 months, a third follow-back questionnaire is sent which takes about 15 minutes to complete. For requests where NIOSH does not conduct an on-site evaluation, the requestor receives the first follow-back questionnaire after our response letter is sent and a second one 12 months after our response. The first questionnaire takes about 10 minutes to complete and the second questionnaire takes about 15 minutes to complete.

Because of the number of investigations conducted each year; the need to respond quickly to requests for assistance; the diverse and unpredictable nature of these investigations; and its follow-back program to assess evaluation effectiveness, NIOSH requests a consolidated clearance for data collections performed within the domain of its HHE program. The total estimated burden hours is 1715. There is no cost to respondents other than their time.

ESTIMATED ANNUALIZED BURDEN HOURS

Type of respondent	Form	Number of respondents	Number of responses per respondent	Average burden per response in hours
Employees/employee representatives/or employers *.	Health Hazard Evaluation Request Form	250	1	12/60
Employees	Health Hazard Evaluation specific interview example.	1,470	1	15/60
Employees	Health Hazard Evaluation specific questionnaire example.	2,100	1	30/60
Employees	Employee Contact Postcard	1,225	1	5/60
Follow-back for onsite evaluations—employer & employee representative Year 1.	Initial Site Visit Followback Survey form	140	1	10/60
Employer & employee representative Year 1	Closeout for Health Hazard Evaluation Followback Survey with site visit.	140	1	20/60
Employer & employee representative Year 2	1 Year Later for Health Hazard Evaluation Followback Survey with site visit.	140	1	15/60
Follow-back for evaluations without onsite—employer & employee representative Year 1.	Closeout for Health Hazard Evaluation without site visit.	94	1	10/60
Employer & employee representative Year 2	1 Year Later for Health Hazard Evaluation without site visit.	94	1	15/60

Jeffrey M. Zirger,

Lead, Information Collection Review Office, Office of Scientific Integrity, Office of Science, Centers for Disease Control and Prevention.

[FR Doc. 2020–11795 Filed 6–1–20; 8:45 am]

BILLING CODE 4163–18–P

DEPARTMENT OF HEALTH AND HUMAN SERVICES

Centers for Disease Control and Prevention

[30Day–20–20HN]

Agency Forms Undergoing Paperwork Reduction Act Review

In accordance with the Paperwork Reduction Act of 1995, the Centers for Disease Control and Prevention (CDC) has submitted the information collection request titled ''National Outbreak Reporting System (NORS)'' to the Office of Management and Budget (OMB) for review and approval. CDC previously published a ''Proposed Data Collection Submitted for Public Comment and Recommendations'' notice on February 25, 2020 to obtain comments from the public and affected agencies. CDC received two non-substantive, and one substantive comment and replied with a standard CDC response. This notice serves to allow an additional 30 days for public and affected agency comments.

CDC will accept all comments for this proposed information collection project. The Office of Management and Budget is particularly interested in comments that:

(a) Evaluate whether the proposed collection of information is necessary for the proper performance of the functions of the agency, including whether the information will have practical utility;

(b) Evaluate the accuracy of the agencies estimate of the burden of the proposed collection of information, including the validity of the methodology and assumptions used;

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

(d) Minimize the burden of the collection of information on those who are to respond, including, through the use of appropriate automated, electronic, mechanical, or other technological collection techniques or other forms of information technology, *e.g.,* permitting electronic submission of responses; and

(e) Assess information collection costs.

To request additional information on the proposed project or to obtain a copy of the information collection plan and instruments, call (404) 639–7570. Comments and recommendations for the

proposed information collection should be sent within 30 days of publication of this notice to *www.reginfo.gov/public/do/PRAMain* Find this particular information collection by selecting ''Currently under 30-day Review—Open for Public Comments'' or by using the search function. Direct written comments and/or suggestions regarding the items contained in this notice to the Attention: CDC Desk Officer, Office of Management and Budget, 725 17th Street NW, Washington, DC 20503 or by fax to (202) 395–5806. Provide written comments within 30 days of notice publication.

Proposed Project

National Outbreak Reporting System (NORS)—New—National Center for Emerging and Zoonotic Infectious Diseases (NCEZID), Centers for Disease Control and Prevention (CDC).

Background and Brief Description

The National Outbreak Reporting System (NORS) is a web-based platform that is used by local, state, and territorial health departments in the United States to report all waterborne and foodborne disease outbreaks and enteric disease outbreaks transmitted by contact with environmental sources, infected persons or animals, or unknown modes of transmission to the Centers for Disease Control and Prevention (CDC). CDC analyzes outbreak data to determine trends and develop and refine recommendations for prevention and control of foodborne, waterborne, and enteric disease outbreaks. NORS was previously approved as part of OMB Control No. 0920–0004, and is being pulled into its own information collection request to allow for more timely updates to information collection instruments, as necessary for public health surveillance.

CDC request approval for an estimated 747 annual burden hours. There is no cost to respondents other than their time.

ESTIMATED ANNUALIZED BURDEN HOURS

Type of respondents	Form name	Number of respondents	Number of responses per respondent	Average burden per response (in hours)
Epidemiologist	National Outbreak Reporting System, Data Dictionary NORS Foodborne Disease Transmission, Person-to-Person Disease Transmission, Animal Contact, Environmental Contamination, Unknown Transmission Mode, Form 52.13. NORS Waterborne Disease Transmission, Form 52.12.	59	38	20/60

Jeffrey M. Zirger,

Lead, Information Collection Review Office, Office of Scientific Integrity, Office of Science, Centers for Disease Control and Prevention.

[FR Doc. 2020–11793 Filed 6–1–20; 8:45 am]

BILLING CODE 4163–18–P

DEPARTMENT OF HEALTH AND HUMAN SERVICES

Centers for Disease Control and Prevention

[60Day–20–20OM; Docket No. CDC–2020–0059]

Proposed Data Collection Submitted for Public Comment and Recommendations

AGENCY: Centers for Disease Control and Prevention (CDC), Department of Health and Human Services (HHS).

ACTION: Notice with comment period.

SUMMARY: The Centers for Disease Control and Prevention (CDC), as part of its continuing effort to reduce public burden and maximize the utility of government information, invites the general public and other Federal agencies the opportunity to comment on a proposed and/or continuing information collection, as required by the Paperwork Reduction Act of 1995. This notice invites comment on a proposed information collection project titled the Medical Monitoring Project Facility Survey, a one-time survey of the characteristics of HIV care facilities in order to collect information on the nation's existing HIV care infrastructure and the capacity of facilities to implement the strategies of the U.S. Ending the HIV Epidemic Federal Initiative.

DATES: CDC must receive written comments on or before August 3, 2020.

ADDRESSES: You may submit comments, identified by Docket No. CDC–2020–0059 by any of the following methods:

- *Federal eRulemaking Portal: Regulations.gov*. Follow the instructions for submitting comments.
- *Mail:* Jeffrey M. Zirger, Information Collection Review Office, Centers for Disease Control and Prevention, 1600 Clifton Road NE, MS–D74, Atlanta, Georgia 30329.

Instructions: All submissions received must include the agency name and Docket Number. CDC will post, without change, all relevant comments to *Regulations.gov*.

Please note: Submit all comments through the Federal eRulemaking portal (*regulations.gov*) or by U.S. mail to the address listed above.

FOR FURTHER INFORMATION CONTACT: To request more information on the proposed project or to obtain a copy of the information collection plan and instruments, contact Jeffrey M. Zirger, Information Collection Review Office, Centers for Disease Control and Prevention, 1600 Clifton Road NE, MS–D74, Atlanta, Georgia 30329; phone: 404–639–7570; Email: *omb@cdc.gov*.

SUPPLEMENTARY INFORMATION: Under the Paperwork Reduction Act of 1995 (PRA) (44 U.S.C. 3501–3520), Federal agencies must obtain approval from the Office of Management and Budget (OMB) for each collection of information they conduct or sponsor. In addition, the PRA also requires Federal agencies to provide a 60-day notice in the **Federal Register** concerning each proposed collection of information, including each new proposed collection, each proposed extension of existing collection of information, and each reinstatement of previously approved information collection before submitting the collection to the OMB for approval. To comply with this requirement, we are publishing this notice of a proposed data collection as described below.

The OMB is particularly interested in comments that will help:

1. Evaluate whether the proposed collection of information is necessary for the proper performance of the functions of the agency, including whether the information will have practical utility;

2. Evaluate the accuracy of the agency's estimate of the burden of the proposed collection of information, including the

validity of the methodology and assumptions used;

3. Enhance the quality, utility, and clarity of the information to be collected; and

4. Minimize the burden of the collection of information on those who are to respond, including through the use of appropriate automated, electronic, mechanical, or other technological collection techniques or other forms of information technology, *e.g.,* permitting electronic submissions of responses.

5. Assess information collection costs.

Proposed Project

Medical Monitoring Project Facility Survey—New—National Center for HIV/AIDS, Viral Hepatitis, STD, and TB Prevention (NCHHSTP), Centers for Disease Control and Prevention (CDC).

Background and Brief Description

The Centers for Disease Control and Prevention (CDC) requests a three-year approval for a new information collection, ''Medical Monitoring Project Facility Survey'' (MMP). The primary objective of the MMP Facility Survey will be to conduct a one-time survey of the characteristics of HIV care facilities in order to collect information on the nation's existing HIV care infrastructure and the capacity of facilities to implement the strategies of the U.S. Ending the HIV Epidemic Federal Initiative. CDC will also use the findings to guide national and local HIV prevention and care efforts and identify gaps as part of the Division of HIV/AIDS Prevention's Strategic Plan. Specifically, information is needed about the capacity of care facilities to deliver care and prevention services, provide HIV prevention messaging, partner with public health programs, offer services for HIV negative partners of HIV positive persons, engage and retain patients, offer PrEP, medication-assisted therapy (MAT), and substance use treatment/referrals, etc. Information on facility location, key populations served, and workforce capacity is also needed to identify areas in need of expanded support to deliver these services. There is no other data source that comprehensively collects this information.

The participation of respondents is voluntary. There is no cost to the respondents other than their time. Through their participation, respondents will help to improve programs to prevent HIV infection as well as services for those who already have HIV.

ESTIMATED ANNUALIZED BURDEN HOURS

Type of respondents	Form name	Number of respondents	Number of responses per respondent	Average burden per response (in hours)	Total burden (in hours)
Facility administrative staff	MMP Facility Survey	1,200	1	30/60	600
Total					600

Jeffrey M. Zirger,

Lead, Information Collection Review Office, Office of Scientific Integrity, Office of Science, Centers for Disease Control and Prevention.

[FR Doc. 2020–11801 Filed 6–1–20; 8:45 am]

BILLING CODE 4163–18–P

DEPARTMENT OF HEALTH AND HUMAN SERVICES

Centers for Disease Control and Prevention

[30Day–20–0493]

Agency Forms Undergoing Paperwork Reduction Act Review

In accordance with the Paperwork Reduction Act of 1995, the Centers for Disease Control and Prevention (CDC) has submitted the information collection request titled 2021 and 2023 National Youth Risk Behavior Surveys to the Office of Management and Budget (OMB) for review and approval. CDC previously published a ''Proposed Data Collection Submitted for Public Comment and Recommendations'' notice on February 28, 2020 to obtain comments from the public and affected agencies. CDC received five (5) comments related to the previous notice. This notice serves to allow an additional 30 days for public and affected agency comments.

CDC will accept all comments for this proposed information collection project. The Office of Management and Budget is particularly interested in comments that: (a) Evaluate whether the proposed collection of information is necessary for the proper performance of the functions of the agency, including whether the information will have practical utility;

(b) Evaluate the accuracy of the agencies estimate of the burden of the proposed collection of information, including the validity of the methodology and assumptions used;

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

(d) Minimize the burden of the collection of information on those who are to respond, including, through the use of appropriate automated, electronic, mechanical, or other technological collection techniques or other forms of information technology, *e.g.,* permitting electronic submission of responses; and

(e) Assess information collection costs.

To request additional information on the proposed project or to obtain a copy of the information collection plan and instruments, call (404) 639–7570. Comments and recommendations for the proposed information collection should be sent within 30 days of publication of this notice to *www.reginfo.gov/public/do/PRAMain.* Find this particular information collection by selecting ''Currently under 30-day Review—Open for Public Comments'' or by using the search function. Direct written comments and/or suggestions regarding the items contained in this notice to the Attention: CDC Desk Officer, Office of Management and Budget, 725 17th Street NW, Washington, DC 20503 or by fax to (202) 395–5806. Provide written comments within 30 days of notice publication.

Proposed Project

2021 and 2023 National Youth Risk Behavior Surveys (OMB Control No. 0920–0493)—Reinstatement with Change—National Center for HIV/AIDS, Viral Hepatitis, STD, and TB Prevention (NCHHSTP), Centers for Disease Control and Prevention (CDC).

Background and Brief Description

The purpose of this request is to obtain OMB approval to reinstate with change, the data collection for the National Youth Risk Behavior Survey (YRBS), a school-based survey that has been conducted biennially since 1991.

OMB approval for the 2017 YRBS and 2019 YRBS expired September 30, 2019 (OMB Control No. 0920–0493). CDC seeks a three-year approval to conduct the YRBS in Spring 2021 and Spring 2023. Minor changes incorporated into this reinstatement request include: An updated title for the information collection to accurately reflect the years in which the survey will be conducted, minor changes to the data collection instrument, and the use of a tablet-based data collection methodology starting in 2023.

The YRBS assesses priority health risk behaviors related to the major preventable causes of mortality, morbidity, and social problems among both youth and young adults in the United States. Data on health risk behaviors of adolescents are the focus of approximately 65 national health objectives in Healthy People 2030, an initiative of the U.S. Department of Health and Human Services (HHS). The YRBS provides data to measure 13 of the proposed health objectives and one of the Leading Health Indicators currently under public comment to establish Healthy People 2030 objectives. In addition, the YRBS can identify racial and ethnic disparities in health risk behaviors. No other national source of data measures as many of the Healthy People 2030 objectives addressing adolescent health risk behaviors as the YRBS. The data also will have significant implications for policy and program development for school health programs nationwide.

In Spring 2021 and Spring 2023, the YRBS will be conducted among nationally representative samples of students attending public and private schools in grades 9–12. The survey is anonymous and will be conducted using paper-and-pencil questionnaires in 2021 and tablets in 2023. Information supporting the YRBS also will be collected from state-, district-, and school-level administrators and teachers. No individually identifiable information will be collected and only aggregated student data will be published. The table below reports the number of respondents annualized over the three-year project period.

There are no costs to respondents except their time. The total estimated annualized burden hours are 6,259.

ESTIMATED ANNUALIZED BURDEN HOURS

Type of respondent	Form name	Number of respondents	Number of responses per respondent	Average burden per response (in hours)
State Administrators	State-level Recruitment Script for the Youth Risk Behavior Survey.	17	1	30/60
District Administrators	District-level Recruitment Script for the Youth Risk Behavior Survey.	80	1	30/60
School Administrators	School-level Recruitment Script for the Youth Risk Behavior Survey.	133	1	30/60
Teachers	Data Collection Checklist for the Youth Risk Behavior Survey.	440	1	15/60
Students	Youth Risk Behavior Survey	8,045	1	45/60

Jeffrey M. Zirger,

Lead, Information Collection Review Office, Office of Scientific Integrity, Office of Science, Centers for Disease Control and Prevention.

[FR Doc. 2020–11796 Filed 6–1–20; 8:45 am]

BILLING CODE 4163–18–P

DEPARTMENT OF HEALTH AND HUMAN SERVICES

Centers for Disease Control and Prevention

[30Day–20–1198]

Agency Forms Undergoing Paperwork Reduction Act Review

In accordance with the Paperwork Reduction Act of 1995, the Centers for Disease Control and Prevention (CDC) has submitted the information collection request titled ''Use of the Cyclosporiasis National Hypothesis Generating Questionnaire during Investigations of Foodborne Disease Clusters and Outbreaks'' to the Office of Management and Budget (OMB) for review and approval. CDC previously published a ''Proposed Data Collection Submitted for Public Comment and Recommendations'' notice on February 25, 2020 to obtain comments from the public and affected agencies. CDC did not receive comments related to the previous notice. This notice serves to allow an additional 30 days for public and affected agency comments.

CDC will accept all comments for this proposed information collection project. The Office of Management and Budget is particularly interested in comments that:

(a) Evaluate whether the proposed collection of information is necessary for the proper performance of the functions of the agency, including whether the information will have practical utility;

(b) Evaluate the accuracy of the agencies estimate of the burden of the proposed collection of information, including the validity of the methodology and assumptions used;

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

(d) Minimize the burden of the collection of information on those who are to respond, including, through the use of appropriate automated, electronic, mechanical, or other technological collection techniques or other forms of information technology, *e.g.,* permitting electronic submission of responses; and

(e) Assess information collection costs.

To request additional information on the proposed project or to obtain a copy of the information collection plan and instruments, call (404) 639–7570. Comments and recommendations for the proposed information collection should be sent within 30 days of publication of this notice to *www.reginfo.gov/public/do/PRAMain.* Find this particular information collection by selecting ''Currently under 30-day Review—Open for Public Comments'' or by using the search function. Direct written comments and/or suggestions regarding the items contained in this notice to the Attention: CDC Desk Officer, Office of Management and Budget, 725 17th Street NW, Washington, DC 20503 or by fax to (202) 395–5806. Provide written comments within 30 days of notice publication.

Proposed Project

Use of the Cyclosporiasis National Hypothesis Generating Questionnaire

(CNHGQ) During Investigations of Foodborne Disease Clusters and Outbreaks (OMB Control No. 0920–1198, Exp. 9/30/2020)—Revision—Center for Global Health (CGH), Centers for Disease Control and Prevention (CDC).

Background and Brief Description

An estimated one in six Americans per year becomes ill with a foodborne disease. Foodborne outbreaks of cyclosporiasis—caused by the parasite Cyclospora cayetanensis—have been reported in the United States since the mid-1990s and have been linked to various types of fresh produce. During the 15-year period of 2000–2014, 31 U.S. foodborne outbreaks of cyclosporiasis were reported; the total case count was 1,562. It is likely that more cases (and outbreaks) occurred than were reported; in addition, because of insufficient data, many of the reported cases could not be directly linked to an outbreak or to a particular food vehicle. During the intervening years (*i.e.* 2015–2019), the numbers of reported cases have steadily increased and larger multistate outbreaks have been reported. For example, there were an estimated 2,299 laboratory-confirmed, domestically acquired cases among persons who became ill during May to August (the typical timeframe of the cyclosporiasis ''season'' in the United States) reported in 2018. This was markedly higher than the numbers of cases reported for the same time period in 2016 (174) and 2017 (623). In 2019, as of November 13, there were an estimated 2,408 laboratory-confirmed cases reported for the same time period.

Collecting the requisite data for the initial hypothesis-generating phase of investigations of multistate foodborne disease outbreaks is associated with multiple challenges, including the need to have high-quality hypothesis-generating questionnaire(s) that can be used effectively in multijurisdictional investigations. Such a questionnaire was developed in the past for use in the context of foodborne outbreaks caused by bacterial pathogens; that questionnaire is referred to as the Standardized National Hypothesis Generating Questionnaire (SNHGQ) (see OMB No. 0920–0997). However, not all of the data elements in the SNHGQ are relevant to the parasite Cyclospora (*e.g.,* questions about consumption of meat and dairy products); on the other hand, additional data elements (besides those in the SNHGQ) are needed to capture information pertinent to Cyclospora and to fresh produce vehicles of infection. Therefore, in consultation with public health partners at the local, state, and federal level, CDC developed the Cyclosporiasis National Hypothesis Generating Questionnaire (CNHGQ) using core data elements from the SNHGQ and incorporating modifications pertinent to Cyclospora. The CNHGQ facilitates data collection about exposures of potential relevance that an individual had during the period of interest (typically, for ill persons, the two week period before onset of symptoms). The CNHGQ also facilitates information collection about other factors that may be pertinent to multistate outbreaks of cyclosporiasis, including the individual's travel history, hospitalization status, consumption of fresh produce, and points of service for food items consumed at home or away from home. Use of the CNHGQ reduces delays in information collection that would occur if state and local health departments had to develop new forms for each outbreak investigation. The CNHGQ also promotes a common data framework for analysis of pooled data across jurisdictions and better understanding of potential vehicles/sources of Cyclospora infection.

The CNHGQ has been designed for administration over the telephone by public health officials. State or local health departments may use a web-based version of the CNHGQ to facilitate information collection and transmission to CDC. Health departments that prefer to complete a fillable PDF version of the CNHGQ may submit forms to CDC by email.

CDC requests OMB approval to collect information via the CNHGQ from persons who have developed symptomatic cases of Cyclospora infection during periods in which increased numbers of such cases are reported (typically, during spring and summer months). In part because molecular typing methods are not yet available for C. cayetanensis, it is important to interview all case-patients identified during periods of increased reporting, to help determine if their cases could be part of an outbreak(s). In some circumstances, a parent, guardian, household member or other proxy may participate in the interview on behalf of the case-patient.

OMB approval is requested for three years. There are no changes to data collection content, data collection procedures, or the estimated burden per response of 45 minutes per interview. The only change is an increase in the estimated number of respondents based on projected use of the CNHGQ. Participation is voluntary and there are no costs to respondents other than their time. The total estimated annualized burden hours are 1,875.

ESTIMATED ANNUALIZED BURDEN HOURS

Type of respondents	Form name	Number of respondents	Number of responses per respondent	Average burden per response (in hours)
Ill individuals identified as part of an outbreak investigation.	Cyclosporiasis National Hypothesis Generating Questionnaire.	2,500	1	45/60

Jeffrey M. Zirger,

Lead, Information Collection Review Office, Office of Scientific Integrity, Office of Science, Centers for Disease Control and Prevention.

[FR Doc. 2020–11798 Filed 6–1–20; 8:45 am]

BILLING CODE 4163–18–P

DEPARTMENT OF HEALTH AND HUMAN SERVICES

Food and Drug Administration

[Docket No. FDA–2020–N–1338]

Process for Publishing Emergency Use Authorizations for Medical Devices During Coronavirus Disease 2019

AGENCY: Food and Drug Administration, HHS.

ACTION: Notice.

SUMMARY: The Food and Drug Administration (FDA) is announcing the process for publishing FDA Emergency Use Authorizations (EUAs) for medical devices related to the Coronavirus Disease 2019 (COVID–19) public health emergency. FDA believes that this process will allow the Agency to rapidly publish EUAs that have been issued for medical devices under the Federal Food, Drug, and Cosmetic Act.

DATES: This process is effective June 2, 2020.

ADDRESSES: Submit written requests for single copies of an EUA to the Office of Counterterrorism and Emerging Threats, Food and Drug Administration, 10903 New Hampshire Ave., Bldg. 1, Rm. 4338, Silver Spring, MD 20993–0002. Send one self-addressed adhesive label to assist that office in processing your request or include a fax number to which the Authorization may be sent. See the **SUPPLEMENTARY INFORMATION** section for electronic access to the Authorizations.

FOR FURTHER INFORMATION CONTACT: Jennifer J. Ross, Office of Counterterrorism and Emerging Threats, Food and Drug Administration, 10903 New Hampshire Ave., Bldg. 1, Rm. 4332, Silver Spring, MD 20993–0002, 301–796–8510 (this is not a toll free number).

SUPPLEMENTARY INFORMATION:

I. Background

Section 564 of the Federal Food, Drug, and Cosmetic Act (FD&C Act) (21 U.S.C. 360bbb–3) allows FDA to strengthen the public health protections against biological, chemical, radiological, or nuclear agent or agents. Among other things, section 564 of the FD&C Act allows FDA to authorize the use of an unapproved medical product or an unapproved use of an approved medical product in certain situations. With this EUA authority, FDA can help ensure that medical countermeasures may be used in emergencies to diagnose, treat, or prevent serious or life-threatening diseases or conditions caused by biological, chemical, radiological or nuclear agent or agents when there are no adequate, approved, and available alternatives and other criteria are met.

Section 564(b)(1) of the FD&C Act provides that, before an EUA may be issued, the Secretary of Health and Human Services (HHS) must declare that circumstances exist justifying the authorization based on one of the following grounds: (1) A determination by the Secretary of Homeland Security that there is a domestic emergency, or a significant potential for a domestic emergency, involving a heightened risk of attack with a biological, chemical, radiological, or nuclear agent or agents; (2) a determination by the Secretary of Defense that there is a military emergency, or a significant potential for a military emergency, involving a heightened risk to U.S. military forces, including personnel operating under the authority of Title 10 or Title 50, United States Code, of attack with (i) a biological, chemical, radiological, or nuclear agent or agents; or (ii) an agent or agents that may cause, or are otherwise associated with, an imminently life-threatening and specific risk to U.S. military forces [1]; (3) a determination by the Secretary of HHS that there is a public health emergency, or a significant potential for a public health emergency, that affects, or has a significant potential to affect, national security or the health and security of U.S. citizens living abroad, and that involves a biological, chemical, radiological, or nuclear agent or agents, or a disease or condition that may be attributable to such agent or agents; or (4) the identification of a material threat by the Secretary of Homeland Security under section 319F–2 of the Public Health Service (PHS) Act (42 U.S.C. 247d–6b) sufficient to affect national security or the health and security of U.S. citizens living abroad. Once the Secretary of HHS has declared that circumstances exist justifying an authorization under section 564 of the FD&C Act, FDA may authorize the emergency use of a drug, device, or biological product if the Agency concludes that the statutory criteria are satisfied.

Under section 564(h)(1) of the FD&C Act, FDA is required to publish in the **Federal Register** a notice of each authorization, and each termination or revocation of an authorization, and an explanation of the reasons for the action. Additionally, under this provision, the Secretary shall make any revisions to an authorization under section 564 of the FD&C Act available on FDA's website.

[1] In the case of a determination by the Secretary of Defense, the Secretary of HHS shall determine within 45 calendar days of such determination, whether to make a declaration under section 564(b)(1) of the FD&C Act, and, if appropriate, shall promptly make such a declaration.

II. Medical Devices for Which the Secretary Has Declared That Circumstances Exist Justifying Their Emergency Use

On February 4, 2020, the Secretary of HHS determined that there is a public health emergency that has a significant potential to affect national security or the health and security of U.S. citizens living abroad, and that involves the SARS–CoV–2. Pursuant to this determination, the Secretary has made the following declarations that circumstances exist justifying the authorization of emergency use of the following products:

- On February 4, 2020, under section 564(b)(1) of the FD&C Act, the Secretary of HHS declared that circumstances exist justifying the authorization of emergency use of in vitro diagnostics for detection and/or diagnosis of the virus (SARS–CoV–2), subject to the terms of any authorization issued under section 564 of the FD&C Act. Notice of the determination and declaration of the Secretary was published in the **Federal Register** on February 7, 2020 (85 FR 7316).
- On March 2, 2020, under section 564(b)(1) of the FD&C Act, the Secretary of HHS declared that circumstances exist justifying the authorization of emergency use of personal respiratory protective devices during the COVID–19 outbreak, subject to the terms of any authorization issued under section 564 of the FD&C Act. Notice of the declaration of the Secretary was published in the **Federal Register** on March 10, 2020 (85 FR 13907).
- On March 24, 2020, under section 564(b)(1) of the FD&C Act, the Secretary of HHS declared that circumstances exist justifying the authorization of emergency use of medical devices, including alternative products use as medical devices, due to shortages during the COVID–19 outbreak, subject to the terms of any authorization issued under section 564 of the FD&C Act. Notice of the declaration of the Secretary was published in the **Federal Register** on March 27, 2020 (85 FR 17335).

III. Electronic Access

An electronic version of this document and the full text of the Authorizations are available on the internet at *https://www.fda.gov/emergency-preparedness-and-response/mcm-legal-regulatory-and-policy-framework/emergency-use-authorization.*

IV. Process for Publishing EUAs for Medical Devices During COVID–19

To facilitate publication of each EUA, and each termination or revocation of an EUA under section 564, in accordance with section 564(h)(1) of the FD&C Act, the Agency intends to use the following process:

• Rather than publishing a separate Notice of Availability (NOA) for each COVID–19 related EUA for a medical device, FDA intends to publish periodically a consolidated NOA. This periodic NOA will announce the availability of all the COVID–19 related EUAs for medical devices that issued during the relevant period. The consolidated NOA will provide instructions to the public on how to view the EUAs, and instructions for persons interested in obtaining a copy of the COVID–19 related EUAs.

• COVID–19 related EUAs for medical devices will be accessible on the internet at the FDA web page entitled ''Emergency Use Authorization,'' available at *https://www.fda.gov/emergency-preparedness-and-response/mcm-legal-regulatory-and-policy-framework/emergency-use-authorization.*

• COVID–19 related EUAs for medical devices are also currently accessible on the internet from the FDA web page entitled ''Emergency Use Authorizations,'' available at *https://www.fda.gov/medical-devices/emergency-situations-medical-devices/emergency-use-authorizations#covid19ivd.*

Dated: May 28, 2020.

Lowell J. Schiller,

Principal Associate Commissioner for Policy.

[FR Doc. 2020–11898 Filed 6–1–20; 8:45 am]

BILLING CODE 4164–01–P

DEPARTMENT OF HEALTH AND HUMAN SERVICES

Food and Drug Administration

[Docket No. FDA–2020–N–1302]

Pediatric Oncology Subcommittee of the Oncologic Drugs Advisory Committee; Notice of Meeting; Establishment of a Public Docket; Request for Comments

AGENCY: Food and Drug Administration, HHS.

ACTION: Notice; establishment of a public docket; request for comments.

SUMMARY: The Food and Drug Administration (FDA) announces a forthcoming public advisory committee meeting of the Pediatric Oncology Subcommittee of the Oncologic Drugs Advisory Committee. The general function of the committee is to provide advice and recommendations to FDA on regulatory issues. The meeting will be open to the public. FDA is establishing a docket for public comment on this document.

DATES: The meeting will be held on June 17, 2020, from 10 a.m. to 3:30 p.m. and June 18, 2020, from 10 a.m. to 3:30 p.m.

ADDRESSES: Please note that due to the impact of this COVID–19 public health emergency, all meeting participants will be joining this advisory committee meeting via an online teleconferencing platform. Answers to commonly asked questions about FDA advisory committee meetings may be accessed at: *https://www.fda.gov/AdvisoryCommittees/AboutAdvisoryCommittees/ucm408555.htm.*

FDA is establishing a docket for public comment on this meeting. The docket number is FDA–2020–N–1302. The docket will close on June 16, 2020. Submit either electronic or written comments on this public meeting by June 16, 2020. Please note that late, untimely filed comments will not be considered. Electronic comments must be submitted on or before June 16, 2020. The *https://www.regulations.gov* electronic filing system will accept comments until 11:59 p.m. Eastern Time at the end of June 16, 2020. Comments received by mail/hand delivery/courier (for written/paper submissions) will be considered timely if they are postmarked or the delivery service acceptance receipt is on or before that date.

Comments received on or before June 10, 2020, will be provided to the subcommittee. Comments received after that date will be taken into consideration by FDA. In the event that the meeting is cancelled, FDA will continue to evaluate any relevant applications or information, and consider any comments submitted to the docket, as appropriate.

You may submit comments as follows:

Electronic Submissions

Submit electronic comments in the following way:

• *Federal eRulemaking Portal: https://www.regulations.gov.* Follow the instructions for submitting comments. Comments submitted electronically, including attachments, to *https://www.regulations.gov* will be posted to the docket unchanged. Because your comment will be made public, you are solely responsible for ensuring that your comment does not include any confidential information that you or a third party may not wish to be posted, such as medical information, your or anyone else's Social Security number, or confidential business information, such as a manufacturing process. Please note that if you include your name, contact information, or other information that identifies you in the body of your comments, that information will be posted on *https://www.regulations.gov.*

• If you want to submit a comment with confidential information that you do not wish to be made available to the public, submit the comment as a written/paper submission and in the manner detailed (see ''Written/Paper Submissions'' and ''Instructions'').

Written/Paper Submissions

Submit written/paper submissions as follows:

• *Mail/Hand delivery/Courier (for written/paper submissions):* Dockets Management Staff (HFA–305), Food and Drug Administration, 5630 Fishers Lane, Rm. 1061, Rockville, MD 20852.

• For written/paper comments submitted to the Dockets Management Staff, FDA will post your comment, as well as any attachments, except for information submitted, marked and identified, as confidential, if submitted as detailed in ''Instructions.''

Instructions: All submissions received must include the Docket No. FDA–2020–N–1302 for ''Pediatric Oncology Subcommittee of the Oncologic Drugs Advisory Committee; Notice of Meeting; Establishment of a Public Docket; Request for Comments.'' Received comments, those filed in a timely manner (see **ADDRESSES**), will be placed in the docket and, except for those submitted as ''Confidential Submissions,'' publicly viewable at *https://www.regulations.gov* or at the Dockets Management Staff between 9

a.m. and 4 p.m., Monday through Friday. Please call 240–402–7500 ahead of the meeting time to verify access.

• Confidential Submissions—To submit a comment with confidential information that you do not wish to be made publicly available, submit your comments only as a written/paper submission. You should submit two copies total. One copy will include the information you claim to be confidential with a heading or cover note that states ''THIS DOCUMENT CONTAINS CONFIDENTIAL INFORMATION.'' FDA will review this copy, including the claimed confidential information, in its consideration of comments. The second copy, which will have the claimed confidential information redacted/blacked out, will be available for public viewing and posted on *https://www.regulations.gov.* Submit both copies to the Dockets Management Staff. If you do not wish your name and contact information be made publicly available, you can provide this information on the cover sheet and not in the body of your comments and you must identify the information as ''confidential.'' Any information marked as ''confidential'' will not be disclosed except in accordance with 21 CFR 10.20 and other applicable disclosure law. For more information about FDA's posting of comments to public dockets, see 80 FR 56469, September 18, 2015, or access the information at: *https://www.govinfo.gov/content/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, 240–402–7500.

FOR FURTHER INFORMATION CONTACT: LaToya Bonner, Center for Drug Evaluation and Research, Food and Drug Administration, 10903 New Hampshire Ave., Bldg. 31, Rm. 2417, Silver Spring, MD 20993–0002, 301–796–9001, Fax: 301–847–8533, email: *ODAC@fda.hhs.gov,* or FDA Advisory Committee Information Line, 1–800–741–8138 (301–443–0572 in the Washington, DC area). A notice in the **Federal Register** about last minute modifications that impact a previously announced advisory committee meeting cannot always be published quickly enough to provide timely notice. Therefore, you should always check the FDA's website at *https://www.fda.gov/AdvisoryCommittees/default.htm* and scroll down to the appropriate advisory committee meeting link, or call the advisory committee information line to learn about possible modifications before coming to the meeting.

SUPPLEMENTARY INFORMATION:

Agenda: The meeting presentations will be heard, viewed, captioned, and recorded through an online teleconferencing platform. On June 17, 2020, information will be presented regarding pediatric development plans for two products that are in development for an adult oncology indication. The subcommittee will consider and discuss issues relating to the development of each product for pediatric use and provide guidance to facilitate the formulation of written requests for pediatric studies, if appropriate. The two products under consideration are: (1) SP 2577 presentation by Salarius Pharmaceuticals, Inc. and (2) Marizomib, presentation by Celgene International II Sàrl, a wholly owned subsidiary of Bristol-Myers Squibb.

On June 18, 2020, information will be presented regarding pediatric development plans for two products that are in development for an adult oncology indication. The subcommittee will consider and discuss issues relating to the development of each product for pediatric use and provide guidance to facilitate the formulation of written requests for pediatric studies, if appropriate. The two products under consideration are: (1) CD30.CAR–T, presentation by Tessa Therapeutics and (2) SNDX–5613, presentation by Syndax Pharmaceuticals, Inc.

FDA intends to make background material available to the public no later than 2 business days before the meeting. If FDA is unable to post the background material on its website prior to the meeting, the background material will be made publicly available on FDA's website at the time of the advisory committee meeting. Background material and the link to the online teleconferencing platform will be available at *https://www.fda.gov/AdvisoryCommittees/Calendar/default.htm.* Scroll down to the appropriate advisory committee meeting link. The meeting will include slide presentations with audio components to allow the presentation of materials in a manner that most closely resembles an in-person advisory committee meeting.

Procedure: Interested persons may present data, information, or views, orally or in writing, on issues pending before the subcommittee. All electronic and written submissions submitted to the Docket (see **ADDRESSES**) on or before June 10, 2020, will be provided to the subcommittee. Oral presentations from the public will be scheduled between approximately 10:50 a.m. to 11:20 a.m. and 1:55 p.m. to 2:25 p.m. on June 17, 2020. Oral presentations from the public will also be scheduled between approximately 10:50 a.m. to 11:20 a.m. and 1:55 p.m. to 2:25 p.m. on June 18, 2020. Those individuals interested in making formal oral presentations should notify the contact person and submit a brief statement of the general nature of the evidence or arguments they wish to present, the names and addresses of proposed participants, and an indication of the approximate time requested to make their presentation on or before June 5, 2020. Time allotted for each presentation may be limited. If the number of registrants requesting to speak is greater than can be reasonably accommodated during the scheduled open public hearing session, FDA may conduct a lottery to determine the speakers for the scheduled open public hearing session. The contact person will notify interested persons regarding their request to speak by June 8, 2020.

For press inquiries, please contact the Office of Media Affairs at *fdaoma@fda.hhs.gov* or 301–796–4540.

FDA welcomes the attendance of the public at its advisory committee meetings and will make every effort to accommodate persons with disabilities. If you require accommodations due to a disability, please contact LaToya Bonner (see **FOR FURTHER INFORMATION CONTACT**) at least 7 days in advance of the meeting.

FDA is committed to the orderly conduct of its advisory committee meetings. Please visit our website at *https://www.fda.gov/AdvisoryCommittees/AboutAdvisoryCommittees/ucm111462.htm* for procedures on public conduct during advisory committee meetings.

Notice of this meeting is given under the Federal Advisory Committee Act (5 U.S.C. app. 2).

Dated: May 28, 2020.

Lowell J. Schiller,

Principal Associate Commissioner for Policy.

[FR Doc. 2020–11883 Filed 6–1–20; 8:45 am]

BILLING CODE 4164–01–P

DEPARTMENT OF HEALTH AND HUMAN SERVICES

Health Resources and Services Administration

Meeting of the Advisory Committee on Infant Mortality

AGENCY: Health Resources and Services Administration (HRSA), Department of Health and Human Services (HHS).

ACTION: Notice; correction.

SUMMARY: This notice announces a correction to the time of the Secretary's Advisory Committee on Infant Mortality (ACIM) scheduled public meeting. The ACIM meeting, originally scheduled for June 17, 2020, 11:00 a.m.–6:00 p.m. Eastern Time (ET) and June 18, 2020, 11:00 a.m.–3:00 p.m. ET, has been extended by 30 minutes on June 18, 2020. The meeting will now end at 3:30 p.m. on June 18, 2020. This meeting was originally announced in the **Federal Register**, Vol. 85, No. 95, on Friday, May 15, 2020 (FR Doc. 2020–10447 Filed 5–14–20; 8:45 a.m.). The location and agenda for the re-scheduled ACIM meeting remains the same as posted. Information about ACIM and the agenda for this meeting will be available on the ACIM website at *https://www.hrsa.gov/advisory-committees/infant-mortality/index.html.*

DATE AND CORRECTED TIME: June 17, 2020, 11:00 a.m.–6:00 p.m. Eastern Time (ET) and June 18, 2020, 11:00 a.m.–3:30 p.m. ET.

ADDRESSES: This meeting will be held via webinar.

- *The webinar link will be available at ACIM's website before the meeting: https://www.hrsa.gov/advisory-committees/infant-mortality/index.html.*
- *The conference call-in number will be available at ACIM's website before the meeting: https://www.hrsa.gov/advisory-committees/infant-mortality/index.html.*

FOR FURTHER INFORMATION CONTACT: Juliann DeStefano, RN, MPH, at Maternal and Child Health Bureau (MCHB), HRSA, 5600 Fishers Lane, Rockville, Maryland 20857; 301–443–0883; or *SACIM@hrsa.gov.*

Correction: The end time of the second day of the virtual meeting was changed from 3:00 p.m. ET to 3:30 p.m. ET.

Maria G. Button,

Director, Executive Secretariat.

[FR Doc. 2020–11774 Filed 6–1–20; 8:45 am]

BILLING CODE 4165–15–P

DEPARTMENT OF HEALTH AND HUMAN SERVICES

Health Resources and Services Administration

Agency Information Collection Activities: Submission to OMB for Review and Approval; Information Collection Request Title: Ryan White HIV/AIDS Program Part F Dental Services Report, OMB No. 0915–0151—Extension

AGENCY: Health Resources and Services Administration (HRSA), Department of Health and Human Services.

ACTION: Notice.

SUMMARY: In compliance with of the Paperwork Reduction Act of 1995, HRSA has submitted an Information Collection Request (ICR) to the Office of Management and Budget (OMB) for review and approval. Comments submitted during the first public review of this ICR will be provided to OMB. OMB will accept further comments from the public during the review and approval period. OMB may act on HRSA's ICR only after the 30 day comment period for this notice has closed.

DATES: Comments on this ICR should be received no later than July 2, 2020.

ADDRESSES: Written comments and recommendations for the proposed information collection should be sent within 30 days of publication of this notice to *www.reginfo.gov/public/do/PRAMain.* Find this particular information collection by selecting ''Currently under Review—Open for Public Comments'' or by using the search function.

FOR FURTHER INFORMATION CONTACT: To request a copy of the clearance requests submitted to OMB for review, email Lisa Wright-Solomon, the HRSA Information Collection Clearance Officer at *paperwork@hrsa.gov* or call (301) 443–1984.

SUPPLEMENTARY INFORMATION:

Information Collection Request Title: HRSA's Ryan White HIV/AIDS Program Part F Dental Services Report, OMB No. 0915–0151—Extension.

Abstract: The Dental Reimbursement Program (DRP) and the Community Based Dental Partnership Program (CBDPP) under Part F of the Ryan White HIV/AIDS Program (RWHAP) offer funding to accredited dental education programs to support the education and training of oral health providers in HIV oral health care, and reimbursement for the provision of oral health services for people eligible for the RWHAP. Institutions eligible for these RWHAP DRP and CBDPP are accredited schools of dentistry and other accredited dental education programs, such as dental hygiene programs or those sponsored by a school of dentistry, a hospital, or a public or private institution that offers postdoctoral training in the specialties of dentistry, advanced education in general dentistry, or a dental general practice residency. The DRP Application for the Notice of Funding Opportunity includes the Dental Services Report (DSR) that applicants use to apply for funding of non-reimbursed costs incurred in providing oral health care to patients with HIV and to report annual program data. Awards are authorized under section 2692(b) of the Public Health Service Act (42 U.S.C. 300ff–111(b). The DSR collects data on program information, client demographics, oral health services, funding, and training. It also requests applicants to provide narrative descriptions of their services and facilities, as well as their links and collaboration with community-based providers of oral health services.

There are minor revisions to 12 data elements in the DSR to be consistent with other HRSA RWHAP grant recipient data that are submitted. For example, the response options for the data element for gender would be expanded to include transgender options; and the age ranges for the data element for age would be changed to align with how data are submitted for the Ryan White HIV/AIDS Program Services Report. In addition, response options for three other data elements would be reworded or deleted for alignment. These changes will not affect burden as they are minor.

A 60-day notice published in the **Federal Register** on February 3, 2020, vol. 85, No. 22; pp. 5969–70. There were no public comments.

Need and Proposed Use of the Information: The primary purpose of collecting this information annually is to verify applicant eligibility and determine reimbursement amounts for DRP applicants, as well as to document the program accomplishments of CBDDP grant recipients. This information also allows HRSA to learn about (1) the extent of the involvement of dental schools and programs in treating patients with HIV, (2) the number and characteristics of clients who receive RWHAP supported oral health services, (3) the types and frequency of the provision of these services, (4) the non-reimbursed costs of oral health care provided to patients with HIV, and (5) the scope of grant recipients' community-based

collaborations and training of providers. In addition to meeting the goal of accountability to Congress, clients, public and community groups, and the general public, information collected in the DSR is critical for HRSA and for recipients to help assess the status of existing HIV-related health service delivery systems.

Likely Respondents: Accredited schools of dentistry and other accredited dental education programs, such as dental hygiene programs or those sponsored by a school of dentistry, a hospital, or a public or private institution that offers postdoctoral training in the specialties of dentistry, advanced education in general dentistry, or a dental general practice residency.

Burden Statement: Burden in this context means the time expended by persons to generate, maintain, retain, disclose or provide the information requested. This includes the time needed to review instructions; to develop, acquire, install, and utilize technology and systems for the purpose of collecting, validating, and verifying information, processing and maintaining information, and disclosing and providing information; to train personnel and respond to a collection of information; to search data sources; to complete and review the collection of information; and to transmit or otherwise disclose the information. The total annual burden hours estimated for this ICR are summarized in the table below.

TOTAL ESTIMATED ANNUALIZED BURDEN HOURS

Form name	Type of respondent	Number of respondents	Number of responses per respondent	Total responses	Average burden per response (in hours)	Total burden hours
Dental Services Report	DRP	56	1	56	45	2,520
	CBDPP	12	1	12	39	468
Total	.....	68	.....	68	.....	2,988

Maria G. Button,

Director, Executive Secretariat.

[FR Doc. 2020–11834 Filed 6–1–20; 8:45 am]

BILLING CODE 4165–15–P

DEPARTMENT OF HEALTH AND HUMAN SERVICES

[Document Identifier OS–0990–0438]

Agency Information Collection Request. 30-Day Public Comment Request

AGENCY: Office of the Secretary, HHS.

ACTION: Notice.

SUMMARY: In compliance with the requirement of the Paperwork Reduction Act of 1995, the Office of the Secretary (OS), Department of Health and Human Services, is publishing the following summary of a proposed collection for public comment.

DATES: Comments on the ICR must be received on or before July 2, 2020.

ADDRESSES: Written comments and recommendations for the proposed information collection should be sent within 30 days of publication of this notice to *www.reginfo.gov/public/do/PRAMain.* Find this particular information collection by selecting ''Currently under 30-day Review—Open for Public Comments'' or by using the search function.

FOR FURTHER INFORMATION CONTACT: Sherrette Funn, *Sherrette.Funn@hhs.gov* or (202) 795–7714. When submitting comments or requesting information, please include the document identifier 0990–0438–30D and project title for reference.

SUPPLEMENTARY INFORMATION: Interested persons are invited to send comments regarding this burden estimate or any other aspect of this collection of information, including any of the following subjects: (1) The necessity and utility of the proposed information collection for the proper performance of the agency's functions; (2) the accuracy of the estimated burden; (3) ways to enhance the quality, utility, and clarity of the information to be collected; and (4) the use of automated collection techniques or other forms of information technology to minimize the information collection burden.

Title of the Collection: Teen Pregnancy Prevention Performance Measures for FY2020.

Type of Collection: Revision.

OMB No.: 0990–0438.

Abstract: The Office of Population Affairs (OPA), U.S. Department of Health and Human Services (HHS), is requesting a revision of the performance measures for collecting data from new Teen Pregnancy Prevention Program grantees to be awarded in FY2020. In FY2020, OPA expects to award 3-year TPP cooperative agreements to up to 90 organizations across three funding announcements. Collection of performance measures is a requirement of all TPP grant awards and is included in the funding announcements. The measures include dissemination, partners, training, sustainability, reach, dosage, fidelity, quality, Tier 1 supportive services referrals, stakeholder engagement, and Tier 2 project type. To reflect the priorities of the new funding announcements, some of the measures and forms have been revised. The data collection will allow OPA to comply with federal accountability and performance requirements, inform stakeholders of grantee progress in meeting TPP program goals, provide OPA with metrics for monitoring FY2020 TPP grantees, and facilitate individual grantees' continuous quality improvement efforts within their projects.

Clearance is requested for three years.

Type of Respondent: TPP grantees and their staff.

ESTIMATED ANNUALIZED BURDEN TABLE

Type of respondent	Number of respondents	Number responses per respondent	Average burden per response (in hours)	Total burden hours
TPP grantees (partners and sustainability)	90	2	15/60	45

ESTIMATED ANNUALIZED BURDEN TABLE—Continued

Type of respondent	Number of respondents	Number responses per respondent	Average burden per response (in hours)	Total burden hours
TPP Grantees (training)	90	2	15/60	45
TPP Grantees (dissemination)	90	2	30/60	90
TPP Grantees Stakeholder Engagement	90	2	15/60	45
Tier 1 and Tier 2 Phase II grantees (Reach and Demographics)	64	2	3	384
Tier 1 and Tier 2 Phase II grantees (Dosage)	64	2	2	256
Tier 1 and Tier 2 Phase II grantees (Fidelity and Quality)	64	2	2	256
Tier 2 Innovation Network Item	14	2	15/60	7
Tier 1 Grantees (Supportive Services)	54	2	15/60	27
Total	90	2		1155

Sherrette A. Funn,

Office of the Secretary, Paperwork Reduction Act Reports Clearance Officer.

[FR Doc. 2020–11862 Filed 6–1–20; 8:45 am]

BILLING CODE 4150–34–P

DEPARTMENT OF HEALTH AND HUMAN SERVICES

National Institutes of Health

National Institute on Drug Abuse; Notice of Closed Meeting

Pursuant to section 10(d) of the Federal Advisory Committee Act, as amended, notice is hereby given of the following meeting.

The meeting will be closed to the public in accordance with the provisions set forth in sections 552b(c)(4) and 552b(c)(6), Title 5 U.S.C., as amended. The grant applications and the discussions could disclose confidential trade secrets or commercial property such as patentable material, and personal information concerning individuals associated with the grant applications, the disclosure of which would constitute a clearly unwarranted invasion of personal privacy.

Name of Committee: National Institute on Drug Abuse Special Emphasis Panel; HEAL Initiative: America's Startups and Small Businesses Build Technologies to Stop the Opioid Epidemic.

Date: July 15–16, 2020.

Time: 9:00 a.m. to 6:00 p.m.

Agenda: To review and evaluate grant applications.

Place: National Institutes of Health, Neurosciences Center Building, 6001 Executive Boulevard, Rockville, MD 20852 (Telephone Conference Call).

Contact Person: Gerald L. McLaughlin, Ph.D., Scientific Review Officer, Office of Extramural Policy and Review, National Institute on Drug Abuse, NIH, Room 4235, MSC 9550, 6001 Executive Boulevard, Bethesda, MD 20892–9550, (301) 827–5819, *gm145a@nih.gov.*

(Catalogue of Federal Domestic Assistance Program Nos. 93.277, Drug Abuse Scientist Development Award for Clinicians, Scientist Development Awards, and Research Scientist Awards; 93.278, Drug Abuse National Research Service Awards for Research Training; 93.279, Drug Abuse and Addiction Research Programs, National Institutes of Health, HHS)

Dated: May 27, 2020.

Tyeshia M. Roberson,

Program Analyst, Office of Federal Advisory Committee Policy.

[FR Doc. 2020–11804 Filed 6–1–20; 8:45 am]

BILLING CODE 4140–01–P

DEPARTMENT OF HEALTH AND HUMAN SERVICES

National Institutes of Health

Center for Scientific Review; Notice of Closed Meetings

Pursuant to section 10(d) of the Federal Advisory Committee Act, as amended, notice is hereby given of the following meetings.

The meetings will be closed to the public in accordance with the provisions set forth in sections 552b(c)(4) and 552b(c)(6), Title 5 U.S.C., as amended. The grant applications and the discussions could disclose confidential trade secrets or commercial property such as patentable material, and personal information concerning individuals associated with the grant applications, the disclosure of which would constitute a clearly unwarranted invasion of personal privacy.

Name of Committee: Healthcare Delivery and Methodologies Integrated Review Group; Biomedical Computing and Health Informatics Study Section.

Date: June 25–26, 2020.

Time: 8:00 a.m. to 6:00 p.m.

Agenda: To review and evaluate grant applications.

Place: National Institutes of Health, Rockledge II, 6701 Rockledge Drive, Bethesda, MD 20892 (Virtual Meeting).

Contact Person: Chittari V. Shivakumar, Ph.D., Scientific Review Officer, National Institutes of Health, Center for Scientific Review, 6701 Rockledge Drive, Bethesda, MD 20892, (301) 408–9098, *chittari.shivakumar@nih.gov.*

Name of Committee: Center for Scientific Review Special Emphasis Panel; Small Business Applications: Drug Discovery and Development.

Date: June 29–30, 2020.

Time: 8:00 a.m. to 7:00 p.m.

Agenda: To review and evaluate grant applications.

Place: National Institutes of Health, Rockledge II, 6701 Rockledge Drive, Bethesda, MD 20892 (Virtual Meeting).

Contact Person: Sergei Ruvinov, Ph.D., Scientific Review Officer, Center for Scientific Review, National Institutes of Health, 6701 Rockledge Drive, Room 4158, MSC 7806, Bethesda, MD 20892, (301) 435–1180, *ruvinser@csr.nih.gov.*

Name of Committee: Biobehavioral and Behavioral Processes Integrated Review Group; Motor Function, Speech and Rehabilitation Study Section.

Date: June 29–30, 2020.

Time: 8:00 a.m. to 5:00 p.m.

Agenda: To review and evaluate grant applications.

Place: National Institutes of Health, Rockledge II, 6701 Rockledge Drive, Bethesda, MD 20892 (Virtual Meeting).

Contact Person: Biao Tian, Ph.D., Scientific Review Officer, Center for Scientific Review, National Institutes of Health, 6701 Rockledge Drive, Room 3166, MSC 7848, Bethesda, MD 20892, (301) 402–4411, *tianbi@csr.nih.gov.*

Name of Committee: Oncology 1—Basic Translational Integrated Review Group; Cancer Molecular Pathobiology Study Section.

Date: June 29–30, 2020.

Time: 8:00 a.m. to 5:00 p.m.

Agenda: To review and evaluate grant applications.

Place: National Institutes of Health, Rockledge I,I 6701 Rockledge Drive, Bethesda, MD 20892 (Virtual Meeting).

Contact Person: Manzoor Zarger, Ph.D., Scientific Review Officer, Center for Scientific Review, National Institutes of Health, 6701 Rockledge Drive, Room 6208, MSC 7804, Bethesda, MD 20892, (301) 435–2477, *zargerma@csr.nih.gov.*

Name of Committee: Cardiovascular and Respiratory Sciences Integrated Review

Group; Cardiac Contractility, Hypertrophy, and Failure Study Section.

Date: June 29–30, 2020.

Time: 9:00 a.m. to 6:00 p.m.

Agenda: To review and evaluate grant applications.

Place: National Institutes of Health, Rockledge II, 6701 Rockledge Drive, Bethesda, MD 20892 (Virtual Meeting).

Contact Person: Abdelouahab Aitouche, Ph.D., Scientific Review Officer, Center for Scientific Review, National Institutes of Health, 6701 Rockledge Drive, Room 4222, MSC 7814, Bethesda, MD 20892, (301) 435–2365, *aitouchea@csr.nih.gov.*

Name of Committee: Risk, Prevention and Health Behavior Integrated Review Group; Psychosocial Risk and Disease Prevention Study Section.

Date: June 29–July 1, 2020.

Time: 9:00 a.m. to 6:00 p.m.

Agenda: To review and evaluate grant applications.

Place: National Institutes of Health, Rockledge II, 6701 Rockledge Drive, Bethesda, MD 20892 (Virtual Meeting).

Contact Person: Stacey FitzSimmons, Ph.D., Scientific Review Officer, Center for Scientific Review, National Institutes of Health, 6701 Rockledge Drive, Room 3114, MSC 7808, Bethesda, MD 20892, (301) 451–9956, *fitzsimmonss@csr.nih.gov.*

Name of Committee: Genes, Genomes, and Genetics Integrated Review Group; Genetics of Health and Disease Study Section.

Date: June 29–30, 2020.

Time: 9:00 a.m. to 7:00 p.m.

Agenda: To review and evaluate grant applications.

Place: National Institutes of Health, Rockledge II, 6701 Rockledge Drive, Bethesda, MD 20892 (Virtual Meeting).

Contact Person: Christopher Payne, Ph.D., Scientific Review Officer, Center for Scientific Review, 6701 Rockledge Drive, Bethesda, MD 20892, (301) 402–3702, *christopher.payne@nih.gov.*

Name of Committee: Oncology 2—Translational Clinical Integrated Review Group; Clinical Oncology Study Section.

Date: June 29, 2020.

Time: 9:00 a.m. to 7:00 p.m.

Agenda: To review and evaluate grant applications.

Place: National Institutes of Health, Rockledge II, 6701 Rockledge Drive, Bethesda, MD 20892 (Virtual Meeting).

Contact Person: Malaya Chatterjee, Ph.D., Scientific Review Officer, Center for Scientific Review, National Institutes of Health, 6701 Rockledge Drive, Room 6192, MSC 7804, Bethesda, MD 20892, (301) 806–2515, *chatterm@csr.nih.gov.*

Name of Committee: Center for Scientific Review Special Emphasis Panel; Small Business: Drug Discovery for Aging, Neuropsychiatric and Neurologic Disorders.

Date: June 30–July 1, 2020.

Time: 9:00 a.m. to 7:30 p.m.

Agenda: To review and evaluate grant applications.

Place: National Institutes of Health, Rockledge II, 6701 Rockledge Drive, Bethesda, MD 20892 (Virtual Meeting).

Contact Person: Aurea D. De Sousa, Ph.D., Scientific Review Officer, National Institutes of Health, Center for Scientific Review, 6701 Rockledge Drive, Room 5186, Bethesda, MD 20892, (301) 827–6829, *aurea.desousa@nih.gov.*

Name of Committee: Center for Scientific Review Special Emphasis Panel; Member Conflict: Radiation Therapeutics and Biology.

Date: June 30, 2020.

Time: 12:00 p.m. to 3:30 p.m.

Agenda: To review and evaluate grant applications.

Place: National Institutes of Health, Rockledge II, 6701 Rockledge Drive, Bethesda, MD 20892 (Telephone Conference Call).

Contact Person: Syed M.Quadri, Ph.D., Scientific Review Officer, Center for Scientific Review, National Institutes of Health, 6701 Rockledge Drive, Room 6210, MSC 7804, Bethesda, MD 20892, (301) 435–1211, *quadris@csr.nih.gov.*

(Catalogue of Federal Domestic Assistance Program Nos. 93.306, Comparative Medicine; 93.333, Clinical Research, 93.306, 93.333, 93.337, 93.393–93.396, 93.837–93.844, 93.846–93.878, 93.892, 93.893, National Institutes of Health, HHS)

Dated: May 28, 2020.

Miguelina Perez,

Program Analyst, Office of Federal Advisory Committee Policy.

[FR Doc. 2020–11879 Filed 6–1–20; 8:45 am]

BILLING CODE 4140–01–P

DEPARTMENT OF HEALTH AND HUMAN SERVICES

National Institutes of Health

National Eye Institute; Notice of Closed Meeting

Pursuant to section 10(d) of the Federal Advisory Committee Act, as amended, notice is hereby given of the following meeting.

The meeting will be closed to the public in accordance with the provisions set forth in sections 552b(c)(4) and 552b(c)(6), Title 5 U.S.C., as amended. The grant applications and the discussions could disclose confidential trade secrets or commercial property such as patentable material, and personal information concerning individuals associated with the grant applications, the disclosure of which would constitute a clearly unwarranted invasion of personal privacy.

Name of Committee: National Eye Institute Special Emphasis Panel; NEI Individual Training Grant (K) Applications.

Date: June 24, 2020.

Time: 9:00 a.m. to 4:00 p.m.

Agenda: To review and evaluate grant applications.

Place: National Eye Institute, National Institutes of Health, 6700 B Rockledge Drive, Suite 3400 Bethesda, MD 20892 (Virtual Meeting).

Contact Person: Jeanette M. Hosseini, Ph.D., Scientific Review Officer, National Eye Institute, National Institutes of Health, 6700 B Rockledge Drive, Suite 3400, Bethesda, MD 20892, 301–451–2020, *jeanetteh@mail.nih.gov.*

(Catalogue of Federal Domestic Assistance Program Nos. 93.867, Vision Research, National Institutes of Health, HHS)

Dated: May 27, 2020.

Melanie J. Pantoja,

Program Analyst, Office of Federal Advisory Committee Policy.

[FR Doc. 2020–11811 Filed 6–1–20; 8:45 am]

BILLING CODE 4140–01–P

DEPARTMENT OF HEALTH AND HUMAN SERVICES

National Institutes of Health

Office of the Director, National Institutes of Health; Notice of Meeting

Pursuant to section 10(d) of the Federal Advisory Committee Act, as amended, notice is hereby given of a meeting of the Advisory Committee to the Director, National Institutes of Health.

These meetings will be held as virtual meetings and are open to the public. Individuals who plan to view the virtual meeting and need special assistance or other reasonable accommodations to view the meeting, should notify the Contact Person listed below in advance of the meeting. The meetings will be videocast and can be accessed from the NIH Videocasting and Podcasting website (*http://videocast.nih.gov/*).

Name of Committee: Advisory Committee to the Director, National Institutes of Health.

Date: June 11, 2020.

Time: 1:00 p.m. to 4:00 p.m.

Agenda: NIH Director's Report, COVID–19 Science, Other Business of the Committee.

Place: National Institutes of Health, Building 1, One Center Drive, Bethesda, MD 20892 (Virtual Meeting).

Name of Committee: Advisory Committee to the Director, National Institutes of Health.

Date: June 12, 2020.

Time: 1:00 p.m. to 4:00 p.m.

Agenda: COVID–19 Science, ACD Working Group Updates, Other Business of the Committee.

Place: National Institutes of Health, Building 1, One Center Drive, Bethesda, MD 20892 (Virtual Meeting).

Contact Person: Gretchen Wood, Staff Assistant, National Institutes of Health, Office of the Director, One Center Drive, Building 1, Room 126, Bethesda, MD 20892, 301–496–4272, *Woodgs@od.nih.gov.*

Any interested person may file written comments with the committee by forwarding the statement to the Contact Person listed on this notice. The statement should include the name, address, telephone number and when applicable, the business or professional affiliation of the interested person.

Information is also available on the Institute's/Center's home page: *http://acd.od.nih.gov,* where an agenda and any additional information for the meeting will be posted when available.

(Catalogue of Federal Domestic Assistance Program Nos. 93.14, Intramural Research Training Award; 93.22, Clinical Research Loan Repayment Program for Individuals from Disadvantaged Backgrounds; 93.232, Loan Repayment Program for Research Generally; 93.39, Academic Research Enhancement Award; 93.936, NIH Acquired Immunodeficiency Syndrome Research Loan Repayment Program; 93.187, Undergraduate Scholarship Program for Individuals from Disadvantaged Backgrounds, National Institutes of Health, HHS)

Dated: May 27, 2020.

Natasha M. Copeland,

Deputy Director Office of Federal Advisory Committee Policy.

[FR Doc. 2020–11808 Filed 6–1–20; 8:45 am]

BILLING CODE 4140–01–P

DEPARTMENT OF HEALTH AND HUMAN SERVICES

National Institutes of Health

National Cancer Institute; Notice of Meeting

Pursuant to section 10(d) of the Federal Advisory Committee Act, as amended, notice is hereby given of a meeting of the National Cancer Advisory Board and NCI Board of Scientific Advisors.

The meeting will be held as a virtual meeting and is open to the public as indicated below. Individuals who plan to view the virtual meeting and need special assistance or other reasonable accommodations to view the meeting, should notify the Contact Person listed below in advance of the meeting. The meeting will be videocast and can be accessed from the NIH Videocasting and Podcasting website (*http://videocast.nih.gov/*).

A portion of the National Cancer Advisory Board meeting will be closed to the public in accordance with the provisions set forth in sections 552b(c)(4) and 552b(c)(6), Title 5 U.S.C., as amended. The grant applications and the discussions could disclose confidential trade secrets or commercial property such as patentable material, and personal information concerning individuals associated with the grant applications, the disclosure of which would constitute a clearly unwarranted invasion of personal privacy.

Name of Committee: National Cancer Advisory Board and NCI Board of Scientific Advisors.

Date: June 15, 2020.

Open: 10:00 a.m. to 5:00 p.m.

Agenda: Joint meeting of the National Cancer Advisory Board and NCI Board of Scientific Advisors, NCI Director's report and presentations, NCI Board of Scientific Advisors Concepts Review.

Closed: 5:00 p.m. to 6:00 p.m.

Agenda: To review and evaluate grant applications.

Place: National Cancer Institute—Shady Grove, 9609 Medical Center Drive, Rockville, MD 20850, (Virtual Meeting).

Contact Person: Paulette S. Gray, Ph.D., Executive Secretary, Division of Extramural Activities, National Cancer Institute—Shady Grove, National Institutes of Health, 9609 Medical Center Drive, 7th Floor, Room. 7W444, Bethesda, MD 20892, 240–276–6340, *grayp@mail.nih.gov*.

Any interested person may file written comments with the committee by forwarding the statement to the Contact Person listed on this notice. The statement should include the name, address, telephone number and when applicable, the business or professional affiliation of the interested person.

Information is also available on the Institute's/Center's home page: NCAB: *https://deainfo.nci.nih.gov/advisory/ncab/ncabmeetings.htm,* BSA: *https://deainfo.nci.nih.gov/advisory/bsa/bsameetings.htm,* where an agenda and any additional information for the meeting will be posted when available.

This notice is being published less than 15 days prior to the meeting due to scheduling difficulties.

(Catalogue of Federal Domestic Assistance Program Nos. 93.392, Cancer Construction; 93.393, Cancer Cause and Prevention Research; 93.394, Cancer Detection and Diagnosis Research; 93.395, Cancer Treatment Research; 93.396, Cancer Biology Research; 93.397, Cancer Centers Support; 93.398, Cancer Research Manpower; 93.399, Cancer Control, National Institutes of Health, HHS)

Dated: May 27, 2020.

Melanie J. Pantoja,

Program Analyst, Office of Federal Advisory Committee Policy.

[FR Doc. 2020–11810 Filed 6–1–20; 8:45 am]

BILLING CODE 4140–01–P

DEPARTMENT OF HEALTH AND HUMAN SERVICES

National Institutes of Health

National Heart, Lung, and Blood Institute; Notice of Meeting

Pursuant to section 10(a) of the Federal Advisory Committee Act, as amended, notice is hereby given of a meeting of the Sleep Disorders Research Advisory Board.

The meeting will be open to the public, with attendance limited to space available. Individuals who plan to attend virtually and will need special assistance, such as sign language interpretation or other reasonable accommodations, should notify the Contact Person listed below in advance of the meeting.

Name of Committee: Sleep Disorders Research Advisory Board.

Date: June 11, 2020.

Time: 2:00 p.m. to 5:00 p.m.

Agenda: Summary of sleep and circadian research activities at NIH and coordination with other federal agencies; discussion of NIH Sleep Disorders Research Plan Revision.

Place: National Institutes of Health, Rockledge I, 6705 Rockledge Blvd., Bethesda, MD 20892 (Virtual Meeting).

Telephone Access: 1–650–479–3208, Access Code: 627 590 305

Virtual Access: https://nih.webex.com/webappng/sites/nih/dashboard?siteurl=nih, Access Code: 627 590 305.

Contact Person: Michael J. Twery, Ph.D., Director, National Center on Sleep Disorders Research, Division of Lung Diseases, National Heart, Lung, and Blood Institute, National Institutes of Health, 6705 Rockledge Drive, Suite 10042, Bethesda, MD 20892–7952, 301–435–0199 *ncsdr@nih.gov*.

This notice is being published less than 15 days prior to the meeting due to the timing limitations imposed by the review and funding cycle.

Any interested person may file written comments with the committee by forwarding the statement to the Contact Person listed on this notice. The statement should include the name, address, telephone number and when applicable, the business or professional affiliation of the interested person.

(Catalogue of Federal Domestic Assistance Program Nos. 93.233, National Center for Sleep Disorders Research; 93.837, Heart and Vascular Diseases Research; 93.838, Lung Diseases Research; 93.839, Blood Diseases and Resources Research, National Institutes of Health, HHS)

Dated: May 28, 2020.

Ronald J. Livingston, Jr.,

Program Analyst, Office of Federal Advisory Committee Policy.

[FR Doc. 2020–11880 Filed 6–1–20; 8:45 am]

BILLING CODE 4140–01–P

DEPARTMENT OF HEALTH AND HUMAN SERVICES

National Institutes of Health

National Institute of Allergy and Infectious Diseases; Notice of Closed Meeting

Pursuant to section 10(d) of the Federal Advisory Committee Act, as amended, notice is hereby given of the following meeting.

The meeting will be closed to the public in accordance with the provisions set forth in sections 552b(c)(4) and 552b(c)(6), Title 5 U.S.C., as amended. The grant applications and the discussions could disclose confidential trade secrets or commercial

property such as patentable material, and personal information concerning individuals associated with the grant applications, the disclosure of which would constitute a clearly unwarranted invasion of personal privacy.

Name of Committee: National Institute of Allergy and Infectious Diseases Special Emphasis Panel; Emergency Awards: Rapid Investigation of Severe Acute Respiratory Syndrome Coronavirus 2 (SARS–CoV–2) and Coronavirus Disease 2019 (COVID–19).

Date: June 19, 2020.

Time: 11:00 a.m. to 4:00 p.m.

Agenda: To review and evaluate grant applications.

Place: National Institute of Allergy and Infectious Diseases, National Institutes of Health, 5601 Fishers Lane, Room 3E71, Rockville, MD 20892 (Telephone Conference Call).

Contact Person: Ann Marie M. Brighenti, Ph.D., Scientific Review Officer, National Institute of Allergy and Infectious Diseases, National Institutes of Health, 5601 Fishers Lane, Room 3E71 Rockville, MD 20852, 301–761–3100, *ann-marie.brighenti@nih.gov.*

This notice is being published less than 15 days prior to the meeting due to the timing limitations imposed by the review and funding cycle.

(Catalogue of Federal Domestic Assistance Program Nos. 93.855, Allergy, Immunology, and Transplantation Research; 93.856, Microbiology and Infectious Diseases Research, National Institutes of Health, HHS)

Dated: May 27, 2020.

Tyeshia M. Roberson,

Program Analyst, Office of Federal Advisory Committee Policy.

[FR Doc. 2020–11812 Filed 6–1–20; 8:45 am]

BILLING CODE 4140–01–P

DEPARTMENT OF HEALTH AND HUMAN SERVICES

National Institutes of Health

National Institute of Allergy and Infectious Diseases; Notice of Closed Meeting

Pursuant to section 10(d) of the Federal Advisory Committee Act, as amended, notice is hereby given of the following meeting.

The meeting will be closed to the public in accordance with the provisions set forth in sections 552b(c)(4) and 552b(c)(6), Title 5 U.S.C., as amended. The grant applications and the discussions could disclose confidential trade secrets or commercial property such as patentable material, and personal information concerning individuals associated with the grant applications, the disclosure of which would constitute a clearly unwarranted invasion of personal privacy.

Name of Committee: National Institute of Allergy and Infectious Diseases Special Emphasis Panel NIAID Investigator Initiated Program Project Applications (P01 Clinical Trial Not Allowed).

Date: July 8, 2020.

Time: 12:00 p.m. to 4:00 p.m.

Agenda: To review and evaluate grant applications.

Place: National Institute of Allergy and Infectious Diseases, National Institutes of Health, 5601 Fishers Lane, Room 3G53, Rockville, MD 20892, (Telephone Conference Call).

Contact Person: Konrad Krzewski, Ph.D., Scientific Review Officer, Scientific Review Program, Division of Extramural Activities, National Institute of Allergy and Infectious Diseases, National Institutes of Health, 5601 Fishers Lane, Room 3G53, Rockville, MD 20852, 240–747–7526, *konrad.krzewski@nih.gov.*

(Catalogue of Federal Domestic Assistance Program Nos. 93.855, Allergy, Immunology, and Transplantation Research; 93.856, Microbiology and Infectious Diseases Research, National Institutes of Health, HHS)

Dated: May 27, 2020.

Tyeshia M. Roberson,

Program Analyst, Office of Federal Advisory Committee Policy.

[FR Doc. 2020–11814 Filed 6–1–20; 8:45 am]

BILLING CODE 4140–01–P

DEPARTMENT OF HEALTH AND HUMAN SERVICES

National Institutes of Health

National Institute of Dental & Craniofacial Research; Notice of Closed Meeting

Pursuant to section 10(d) of the Federal Advisory Committee Act, as amended, notice is hereby given of the following meeting.

The meeting will be closed to the public in accordance with the provisions set forth in sections 552b(c)(4) and 552b(c)(6), Title 5 U.S.C., as amended. The grant applications and the discussions could disclose confidential trade secrets or commercial property such as patentable material, and personal information concerning individuals associated with the grant applications, the disclosure of which would constitute a clearly unwarranted invasion of personal privacy.

Name of Committee: National Institute of Dental and Craniofacial Research Special Emphasis Panel; NIDCR Fellowship and Conference Grants.

Date: July 14, 2020.

Time: 10:00 a.m. to 5:00 p.m.

Agenda: To review and evaluate grant applications.

Place: National Institute of Dental and Craniofacial Research, National Institutes of Health, 6701 Democracy Boulevard, Suite 670, Bethesda, MD 20892 (Virtual Meeting).

Contact Person: Yun Mei, MD, Scientific Review Officer, Scientific Review Branch, National Institute of Dental and Craniofacial, Research National Institutes of Health, 6701 Democracy Boulevard, Suite 670, Bethesda, MD 20817, (301) 827–4639, *yun.mei@nih.gov.*

(Catalogue of Federal Domestic Assistance Program Nos. 93.121, Oral Diseases and Disorders Research, National Institutes of Health, HHS)

Dated: May 28, 2020.

Melanie J. Pantoja,

Program Analyst, Office of Federal Advisory Committee Policy.

[FR Doc. 2020–11875 Filed 6–1–20; 8:45 am]

BILLING CODE 4140–01–P

DEPARTMENT OF HEALTH AND HUMAN SERVICES

National Institutes of Health

Center for Scientific Review; Notice of Closed Meetings

Pursuant to section 10(d) of the Federal Advisory Committee Act, as amended, notice is hereby given of the following meetings.

The meetings will be closed to the public in accordance with the provisions set forth in sections 552b(c)(4) and 552b(c)(6), Title 5 U.S.C., as amended. The grant applications and the discussions could disclose confidential trade secrets or commercial property such as patentable material, and personal information concerning individuals associated with the grant applications, the disclosure of which would constitute a clearly unwarranted invasion of personal privacy.

Name of Committee: Center for Scientific Review Special Emphasis Panel Small Business: Non-HIV Anti-Infective Therapeutics Overflow.

Date: June 24, 2020.

Time: 1:00 p.m. to 6:30 p.m.

Agenda: To review and evaluate grant applications.

Place: National Institutes of Health, Rockledge II, 6701 Rockledge Drive, Bethesda, MD 20892 (Virtual Meeting).

Contact Person: Bidyottam Mittra, Ph.D., Scientific Review Officer, Center for Scientific Review, National Institutes of Health, 6701 Rockledge Drive, Bethesda, MD 20892, (301) 435–4057, *bidyottam.mittra@nih.gov.*

Name of Committee: Brain Disorders and Clinical Neuroscience Integrated Review Group Chronic Dysfunction and Integrative Neurodegeneration Study Section.

Date: June 25–26, 2020.

Time: 8:00 a.m. to 7:00 p.m.

Agenda: To review and evaluate grant applications.

Place: National Institutes of Health, 6701 Rockledge Drive, Bethesda, MD 20892 (Virtual Meeting).

Contact Person: Jenny R Browning, Ph.D., Scientific Review Officer, Center for Scientific Review, National Institutes of Health, 6701 Rockledge Drive, Rm. 5207, Bethesda, MD 20892, (301) 402–8197, *jenny.browning@nih.gov.*

Name of Committee: Vascular and Hematology Integrated Review Group Vascular Cell and Molecular Biology Study Section.

Date: June 25–26, 2020.

Time: 8:30 a.m. to 6:00 p.m.

Agenda: To review and evaluate grant applications.

Place: National Institutes of Health, Rockledge II, 6701 Rockledge Drive, Bethesda, MD 20892 (Virtual Meeting).

Contact Person: Larry Pinkus, Ph.D., Scientific Review Officer, Center for Scientific Review, National Institutes of Health, 6701 Rockledge Drive, Room 4132, MSC 7802, Bethesda, MD 20892, (301) 435–1214, *pinkusl@csr.nih.gov.*

Name of Committee: Center for Scientific Review Special Emphasis Panel PAR19–367: Maximizing Investigators' Research Award (R35—Clinical Trial Optional).

Date: June 26, 2020.

Time: 9:00 a.m. to 1:00 p.m.

Agenda: To review and evaluate grant applications.

Place: National Institutes of Health, Rockledge II, 6701 Rockledge Drive, Bethesda, MD 20892 (Virtual Meeting).

Contact Person: Maqsood A Wani, Ph.D., Scientific Review Officer, Center for Scientific Review, National Institutes of Health, 6701 Rockledge Drive, Room 2114, MSC 7814, Bethesda, MD 20892, 301–435–2270, *wanimaqs@csr.nih.gov.*

Name of Committee: Center for Scientific Review Special Emphasis Panel Small Business: HIV/AIDS Innovative research Applications.

Date: June 26, 2020.

Time: 9:30 a.m. to 10:30 a.m.

Agenda: To review and evaluate grant applications.

Place: National Institutes of Health, Rockledge II, 6701 Rockledge Drive, Bethesda, MD 20892 (Virtual Meeting).

Contact Person: Jingsheng Tuo, Ph.D., Scientific Review Officer, Center for Scientific Review, National Institutes of Health, 6701 Rockledge Drive, Room 5207, Bethesda, MD 20892, 301–451–8754, *tuoj@nei.nih.gov.*

Name of Committee: Center for Scientific Review Special Emphasis Panel Small Business: HIV/AIDS Innovative research Applications.

Date: June 26, 2020.

Time: 10:00 a.m. to 5:00 p.m.

Agenda: To review and evaluate grant applications.

Place: National Institutes of Health, Rockledge II, 6701 Rockledge Drive, Bethesda, MD 20892 (Virtual Meeting).

Contact Person: Barna Dey, Ph.D., Scientific Review Officer, Center for Scientific Review, National Institutes of Health, 6701 Rockledge Drive, Room 3184, Bethesda, MD 20892, 301–451–2796, *bdey@mail.nih.gov.*

Name of Committee: Center for Scientific Review Special Emphasis Panel Member Conflict: Mechanisms of Memory and Sound Processing.

Date: June 26, 2020.

Time: 11:00 a.m. to 5:00 p.m.

Agenda: To review and evaluate grant applications.

Place: National Institutes of Health, Rockledge II, 6701 Rockledge Drive, Bethesda, MD 20892 (Virtual Meeting).

Contact Person: Sepandarmaz Aschrafi, Ph.D., Scientific Review Officer, Center for Scientific Review, National Institutes of Health, 6701 Rockledge Drive, Room 4040D, Bethesda, MD 20892, (301) 451–4251, *Armaz.aschrafi@nih.gov.*

(Catalogue of Federal Domestic Assistance Program Nos. 93.306, Comparative Medicine; 93.333, Clinical Research, 93.306, 93.333, 93.337, 93.393–93.396, 93.837–93.844, 93.846–93.878, 93.892, 93.893, National Institutes of Health, HHS)

Dated: May 27, 2020.

Tyeshia M. Roberson,

Program Analyst, Office of Federal Advisory Committee Policy.

[FR Doc. 2020–11813 Filed 6–1–20; 8:45 am]

BILLING CODE 4140–01–P

DEPARTMENT OF HEALTH AND HUMAN SERVICES

National Institutes of Health

National Institute of Allergy and Infectious Diseases; Notice of Closed Meeting

Pursuant to section 10(d) of the Federal Advisory Committee Act, as amended, notice is hereby given of the following meeting.

The meeting will be closed to the public in accordance with the provisions set forth in sections 552b(c)(4) and 552b(c)(6), Title 5 U.S.C., as amended. The grant applications and the discussions could disclose confidential trade secrets or commercial property such as patentable material, and personal information concerning individuals associated with the grant applications, the disclosure of which would constitute a clearly unwarranted invasion of personal privacy.

Name of Committee: National Institute of Allergy and Infectious Diseases Special Emphasis Panel; NIAID Clinical Trial Implementation Cooperative Agreement (U01) and Investigator Initiated Extended Clinical Trial (R01).

Date: June 26, 2020.

Time: 11:00 a.m. to 3:30 p.m.

Agenda: To review and evaluate grant applications.

Place: National Institute of Allergy and Infectious Diseases, National Institutes of Health, 5601 Fishers Lane, Room 3E71, Rockville, MD 20892 (Virtual Meeting).

Contact Person: Lee G. Klinkenberg, Ph.D., Scientific Review Program, Division of Extramural Activities, National Institute of Allergy and Infectious Diseases, National Institutes of Health, 5601 Fishers Lane, Room 3E71, Rockville, MD 20852, 301–761–7749, *lee.klinkenberg@nih.gov.*

(Catalogue of Federal Domestic Assistance Program Nos. 93.855, Allergy, Immunology, and Transplantation Research; 93.856, Microbiology and Infectious Diseases Research, National Institutes of Health, HHS)

Dated: May 27, 2020.

Tyeshia M. Roberson,

Program Analyst, Office of Federal Advisory Committee Policy.

[FR Doc. 2020–11815 Filed 6–1–20; 8:45 am]

BILLING CODE 4140–01–P

DEPARTMENT OF HEALTH AND HUMAN SERVICES

National Institutes of Health

National Institute of Mental Health; Notice of Closed Meetings

Pursuant to section 10(d) of the Federal Advisory Committee Act, as amended, notice is hereby given of the following meetings.

The meetings will be closed to the public in accordance with the provisions set forth in sections 552b(c)(4) and 552b(c)(6), Title 5 U.S.C., as amended. The grant applications and the discussions could disclose confidential trade secrets or commercial property such as patentable material, and personal information concerning individuals associated with the grant applications, the disclosure of which would constitute a clearly unwarranted invasion of personal privacy.

Name of Committee: National Institute of Mental Health Special Emphasis Panel; Invasive Recording and Stimulating in Humans to Advance Neural Circuitry Understanding of Mental Health Disorders (R01, R21).

Date: June 24, 2020.

Time: 12:00 p.m. to 4:00 p.m.

Agenda: To review and evaluate grant applications.

Place: National Institutes of Health, Neuroscience Center, 6001 Executive Blvd., Rockville, MD 20852 (Telephone Conference Call).

Contact Person: Erin E. Gray, Ph.D., Scientific Review Officer, Division of Extramural Activities, National Institute of Mental Health, National Institutes of Health, 6001 Executive Boulevard, NSC 6152B, Bethesda, MD 20892, 301–402–8152, *erin.gray@nih.gov.*

Name of Committee: National Institute of Mental Health Special Emphasis Panel; NIMH R01/R01 Clinical Trials to Test the Effectiveness of Treatment, Preventive, and Services Interventions.

Date: June 29, 2020.

Time: 8:30 a.m. to 12:30 p.m.

Agenda: To review and evaluate grant applications.

Place: National Institutes of Health, Neuroscience Center, 6001 Executive Blvd., Rockville, MD 20852 (Telephone Conference Call).

Contact Person: Karen Gavin-Evans, Ph.D., Scientific Review Officer, Division of Extramural Activities, National Institute of Mental Health, NIH, Neuroscience Center, 6001 Executive Boulevard, Room 6153, MSC 9606, Bethesda, MD 20892, 301–451–2356 *gavinevanskm@mail.nih.gov.*

Name of Committee: National Institute of Mental Health Special Emphasis Panel; NIMH R34 Pilot Effectiveness Trials for Treatment, Preventive and Services Interventions.

Date: June 29, 2020.

Time: 1:00 p.m. to 5:00 p.m.

Agenda: To review and evaluate grant applications.

Place: National Institutes of Health, Neuroscience Center, 6001 Executive Blvd., Rockville, MD 20852 (Telephone Conference Call).

Contact Person: Karen Gavin-Evans, Ph.D., Scientific Review Officer, Division of Extramural Activities, National Institute of Mental Health, NIH, Neuroscience Center, 6001 Executive Boulevard, Room 6153, MSC 9606, Bethesda, MD 20892, 301–451–2356, *gavinevanskm@mail.nih.gov.*

Name of Committee: National Institute of Mental Health Special Emphasis Panel; BRAIN Initiative: Data Integration and Analysis (R01).

Date: June 29, 2020.

Time: 12:00 p.m. to 3:00 p.m.

Agenda: To review and evaluate grant applications.

Place: National Institutes of Health, Neuroscience Center, 6001 Executive Blvd., Rockville, MD 20852 (Telephone Conference Call).

Contact Person: Erin E. Gray, Ph.D., Scientific Review Officer, Division of Extramural Activities, National Institute of Mental Health, National Institutes of Health, 6001 Executive Boulevard, NSC 6152B, Bethesda, MD 20892, 301–402–8152, *erin.gray@nih.gov.*

Name of Committee: National Institute of Mental Health Special Emphasis Panel; Early Phase Clinical Trials—Pharmacological and Device-based Interventions.

Date: June 30, 2020.

Time: 11:00 a.m. to 4:00 p.m.

Agenda: To review and evaluate grant applications.

Place: National Institutes of Health, Neuroscience Center, 6001 Executive Blvd., Rockville, MD 20852 (Telephone Conference Call).

Contact Person: Nicholas Gaiano, Ph.D., Review Branch Chief, Division of Extramural Activities, National Institute of Mental Health, NIH, Neuroscience Center/Room 6150/MSC 9606, 6001 Executive Boulevard, Bethesda, MD 20892–9606, 301–443–2742, *nick.gaiano@nih.gov.*

(Catalogue of Federal Domestic Assistance Program No. 93.242, Mental Health Research Grants, National Institutes of Health, HHS)

Dated: May 27, 2020.

Melanie J. Pantoja,

Program Analyst, Office of Federal Advisory Committee Policy.

[FR Doc. 2020–11809 Filed 6–1–20; 8:45 am]

BILLING CODE 4140–01–P

DEPARTMENT OF HEALTH AND HUMAN SERVICES

National Institutes of Health

Center for Scientific Review; Amended Notice of Meeting

Notice is hereby given of a change in the meeting of the Center for Scientific Review Special Emphasis Panel, June 15, 2020, 10:00 a.m. to June 15, 2020, 06:00 p.m., National Institutes of Health, Rockledge II, 6701 Rockledge Drive, Bethesda, MD, 20892 which was published in the **Federal Register** on May 12, 2020, 85 FR 28020.

This notice is being amended to change the meeting format from Virtual Meeting to Video Assisted Meeting. The meeting is closed to the public.

Dated: May 28, 2020.

Miguelina Perez,

Program Analyst, Office of Federal Advisory Committee Policy.

[FR Doc. 2020–11878 Filed 6–1–20; 8:45 am]

BILLING CODE 4140–01–P

DEPARTMENT OF HEALTH AND HUMAN SERVICES

National Institutes of Health

Center for Scientific Review; Notice of Closed Meetings

Pursuant to section 10(d) of the Federal Advisory Committee Act, as amended, notice is hereby given of the following meetings.

The meetings will be closed to the public in accordance with the provisions set forth in sections 552b(c)(4) and 552b(c)(6), Title 5 U.S.C., as amended. The grant applications and the discussions could disclose confidential trade secrets or commercial property such as patentable material, and personal information concerning individuals associated with the grant applications, the disclosure of which would constitute a clearly unwarranted invasion of personal privacy.

Name of Committee: Center for Scientific Review Special Emphasis Panel; Clinical Informatics and Digital Health.

Date: June 25, 2020.

Time: 8:00 a.m. to 6:00 p.m.

Agenda: To review and evaluate grant applications.

Place: National Institutes of Health, Rockledge II, 6701 Rockledge Drive, Bethesda, MD 20892 (Virtual Meeting).

Contact Person: Wenchi Liang, Ph.D., Scientific Review Officer, Center for Scientific Review, National Institutes of Health, 6701 Rockledge Drive, Room 3150, MSC 7770, Bethesda, MD 20892, 301–435–0681, *liangw3@csr.nih.gov.*

Name of Committee: Center for Scientific Review Special Emphasis Panel; Small Business: Neuroscience Assay, Diagnostics and Animal Model Development.

Date: June 29–30, 2020.

Time: 8:00 a.m. to 7:00 p.m.

Agenda: To review and evaluate grant applications.

Place: National Institutes of Health, Rockledge II, 6701 Rockledge Drive, Bethesda, MD 20892 (Virtual Meeting).

Contact Person: Joseph G. Rudolph, Ph.D., Chief and Scientific Review Officer, Center for Scientific Review, National Institutes of Health, 6701 Rockledge Drive, Room 5186, MSC 7844, Bethesda, MD 20892, 301–408–9098, *josephru@csr.nih.gov.*

Name of Committee: Center for Scientific Review Special Emphasis Panel; PAR Panel: Academic Industrial Partnerships for Translation of Medical Technologies.

Date: June 29, 2020.

Time: 8:30 a.m. to 5:30 p.m.

Agenda: To review and evaluate grant applications.

Place: National Institutes of Health, Rockledge II, 6701 Rockledge Drive, Bethesda, MD 20892 (Virtual Meeting).

Contact Person: Guo Feng Xu, Ph.D., Scientific Review Officer, Center for Scientific Review, National Institutes of Health, 6701 Rockledge Drive, Room 5122, MSC 7854, Bethesda, MD 20892, 301–237–9870, *xuguofen@csr.nih.gov.*

Name of Committee: Center for Scientific Review Special Emphasis Panel; Small Business: Instrumentation, Environmental and Occupational Safety.

Date: June 29–30, 2020.

Time: 9:00 a.m. to 6:00 p.m.

Agenda: To review and evaluate grant applications.

Place: National Institutes of Health, Rockledge II, 6701 Rockledge Drive, Bethesda, MD 20892 (Virtual Meeting).

Contact Person: Marie-Jose Belanger, Ph.D., Scientific Review Officer, Center for Scientific Review, National Institutes of Health, 6701 Rockledge Drive, Rm 6188, MSC 7804, Bethesda, MD 20892, 301–435–1267, *belangerm@csr.nih.gov.*

Name of Committee: Center for Scientific Review Special Emphasis Panel; Infectious Diseases and Microbiology Fellowship Review.

Date: June 29–30, 2020.

Time: 9:00 a.m. to 6:00 p.m.

Agenda: To review and evaluate grant applications.

Place: National Institutes of Health. Rockledge II. 6701 Rockledge Drive. Bethesda, MD 20892 (Virtual Meeting).

Contact Person: Tamara Lyn McNealy, Ph.D., Scientific Review Officer, Center for Scientific Review, National Institutes of Health, 6701 Rockledge Drive, Room 3188,

Bethesda, MD 20892, 301–827–2372, *tamara.mcnealy@nih.gov.*

Name of Committee: Center for Scientific Review Special Emphasis Panel; Cancer Biotherapeutics Development.

Date: June 29–30, 2020.

Time: 9:30 a.m. to 6:30 p.m.

Agenda: To review and evaluate grant applications.

Place: National Institutes of Health, Rockledge II, 6701 Rockledge Drive, Bethesda, MD 20892 (Virtual Meeting).

Contact Person: Laura Asnaghi, Ph.D., Scientific Review Officer, National Institutes of Health, Center for Scientific Review, 6701 Rockledge Drive, Room 6200, Bethesda, MD 20892, 301–443–1196, *laura.asnaghi@nih.gov.*

Name of Committee: Center for Scientific Review Special Emphasis Panel; Pulmonary Host Defense.

Date: June 29, 2020.

Time: 10:00 a.m. to 6:00 p.m.

Agenda: To review and evaluate grant applications.

Place: National Institutes of Health, Rockledge II, 6701 Rockledge Drive, Bethesda, MD 20892 (Virtual Meeting).

Contact Person: Scott Jakes, Ph.D., Scientific Review Officer, Center for Scientific Review, National Institutes of Health, 6701 Rockledge Drive, Room 4198, MSC 7812, Bethesda, MD 20892, 301–495–1506, *jakesse@mail.nih.gov.*

Name of Committee: Center for Scientific Review Special Emphasis Panel; Infectious Diseases, Reproductive Health, Asthma and Pulmonary Conditions: Infectious Disease Epidemiology.

Date: June 30, 2020.

Time: 8:00 a.m. to 7:00 p.m.

Agenda: To review and evaluate grant applications.

Place: National Institutes of Health, Rockledge II, 6701 Rockledge Drive, Bethesda, MD 20892 (Virtual Meeting).

Contact Person: Lisa Steele, Ph.D., Scientific Review Officer, PSE IRG Center for Scientific Review, National Institutes of Health, 6701 Rockledge Drive, Room 3139, MSC 7770, Bethesda, MD 20892, 301–594–6594, *steeleln@csr.nih.gov.*

Name of Committee: Digestive, Kidney and Urological Systems Integrated Review Group; Systemic Injury by Environmental Exposure.

Date: June 30–July 1, 2020.

Time: 9:00 a.m. to 5:00 p.m.

Agenda: To review and evaluate grant applications.

Place: National Institutes of Health, Rockledge II, 6701 Rockledge Drive, Bethesda, MD 20892 (Virtual Meeting).

Contact Person: Yunshang Piao, Ph.D., Scientific Review Officer, Center for Scientific Review, National Institute of Health, 6701 Rockledge Drive, Room 6184, Bethesda, MD 20892, (301) 402–8402, *piaoy3@mail.nih.gov.*

(Catalogue of Federal Domestic Assistance Program Nos. 93.306, Comparative Medicine; 93.333, Clinical Research, 93.306, 93.333, 93.337, 93.393–93.396, 93.837–93.844, 93.846–93.878, 93.892, 93.893, National Institutes of Health, HHS)

Dated: May 28, 2020.

Ronald J. Livingston, Jr.,

Program Analyst, Office of Federal Advisory Committee Policy.

[FR Doc. 2020–11876 Filed 6–1–20; 8:45 am]

BILLING CODE 4140–01–P

DEPARTMENT OF HEALTH AND HUMAN SERVICES

Substance Abuse and Mental Health Services Administration

Current List of HHS-Certified Laboratories and Instrumented Initial Testing Facilities Which Meet Minimum Standards To Engage in Urine and Oral Fluid Drug Testing for Federal Agencies

AGENCY: Substance Abuse and Mental Health Services Administration, HHS.

ACTION: Notice.

SUMMARY: The Department of Health and Human Services (HHS) notifies federal agencies of the laboratories and Instrumented Initial Testing Facilities (IITFs) currently certified to meet the standards of the Mandatory Guidelines for Federal Workplace Drug Testing Programs using Urine or Oral Fluid (Mandatory Guidelines).

FOR FURTHER INFORMATION CONTACT: Anastasia Donovan, Division of Workplace Programs, SAMHSA/CSAP, 5600 Fishers Lane, Room 16N06B, Rockville, Maryland 20857; 240–276–2600 (voice); *Anastasia.Donovan@samhsa.hhs.gov* (email).

SUPPLEMENTARY INFORMATION: A notice listing all currently HHS-certified laboratories and IITFs is published in the **Federal Register** during the first week of each month. If any laboratory or IITF certification is suspended or revoked, the laboratory or IITF will be omitted from subsequent lists until such time as it is restored to full certification under the Mandatory Guidelines.

If any laboratory or IITF has withdrawn from the HHS National Laboratory Certification Program (NLCP) during the past month, it will be listed at the end and will be omitted from the monthly listing thereafter.

This notice is also available on the internet at *https://www.samhsa.gov/workplace/resources/drug-testing/certified-lab-list.*

The Department of Health and Human Services (HHS) notifies federal agencies of the laboratories and Instrumented Initial Testing Facilities (IITFs) currently certified to meet the standards of the Mandatory Guidelines for Federal Workplace Drug Testing Programs (Mandatory Guidelines) using Urine and of the laboratories currently certified to meet the standards of the Mandatory Guidelines using Oral Fluid.

The Mandatory Guidelines using Urine were first published in the **Federal Register** on April 11, 1988 (53 FR 11970), and subsequently revised in the **Federal Register** on June 9, 1994 (59 FR 29908); September 30, 1997 (62 FR 51118); April 13, 2004 (69 FR 19644); November 25, 2008 (73 FR 71858); December 10, 2008 (73 FR 75122); April 30, 2010 (75 FR 22809); and on January 23, 2017 (82 FR 7920).

The Mandatory Guidelines using Oral Fluid were first published in the **Federal Register** on October 25, 2019 (84 FR 57554) with an effective date of January 1, 2020.

The Mandatory Guidelines were initially developed in accordance with Executive Order 12564 and section 503 of Public Law 100–71 and allowed urine drug testing only. The Mandatory Guidelines using Urine have since been revised, and new Mandatory Guidelines allowing for oral fluid drug testing have been published. The Mandatory Guidelines require strict standards that laboratories and IITFs must meet in order to conduct drug and specimen validity tests on specimens for federal agencies. HHS does not allow IITFs for oral fluid testing.

To become certified, an applicant laboratory or IITF must undergo three rounds of performance testing plus an on-site inspection. To maintain that certification, a laboratory or IITF must participate in a quarterly performance testing program plus undergo periodic, on-site inspections.

Laboratories and IITFs in the applicant stage of certification are not to be considered as meeting the minimum requirements described in the HHS Mandatory Guidelines using Urine and/or Oral Fluid. An HHS-certified laboratory or IITF must have its letter of certification from HHS/SAMHSA (formerly: HHS/NIDA), which attests that the test facility has met minimum standards. HHS does not allow IITFs for oral fluid testing.

HHS-Certified Laboratories Certified To Conduct Oral Fluid Drug Testing

In accordance with the Mandatory Guidelines using Oral Fluid dated October 25, 2019 (84 FR 57554), the following HHS-certified laboratories meet the minimum standards to conduct drug and specimen validity tests on oral fluid specimens:

At this time, there are no laboratories certified to conduct drug and specimen validity tests on oral fluid specimens.

HHS-Certified Instrumented Initial Testing Facilities Certified To Conduct Urine Drug Testing

In accordance with the Mandatory Guidelines using Urine dated January 23, 2017 (82 FR 7920), the following HHS-certified IITFs meet the minimum standards to conduct drug and specimen validity tests on urine specimens:

Dynacare, 6628 50th Street NW, Edmonton, AB Canada T6B 2N7, 780–784–1190, (Formerly: Gamma-Dynacare Medical Laboratories)

HHS-Certified Laboratories Certified To Conduct Urine Drug Testing

In accordance with the Mandatory Guidelines using Urine dated January 23, 2017 (82 FR 7920), the following HHS-certified laboratories meet the minimum standards to conduct drug and specimen validity tests on urine specimens:

Alere Toxicology Services, 1111 Newton St., Gretna, LA 70053, 504–361–8989/800–433–3823, (Formerly: Kroll Laboratory Specialists, Inc., Laboratory Specialists, Inc.)

Alere Toxicology Services, 450 Southlake Blvd., Richmond, VA 23236, 804–378–9130, (Formerly: Kroll Laboratory Specialists, Inc., Scientific Testing Laboratories, Inc.; Kroll Scientific Testing Laboratories, Inc.)

Clinical Reference Laboratory, Inc., 8433 Quivira Road, Lenexa, KS 66215–2802, 800–445–6917

Cordant Health Solutions, 2617 East L Street, Tacoma, WA 98421, 800–442–0438, (Formerly: STERLING Reference Laboratories)

Desert Tox, LLC, 5425 E Bell Rd, Suite 125, Scottsdale, AZ, 85254, 602–457–5411/623–748–5045

DrugScan, Inc., 200 Precision Road, Suite 200, Horsham, PA 19044, 800–235–4890

Dynacare*, 245 Pall Mall Street, London, ONT, Canada N6A 1P4, 519–679–1630, (Formerly: Gamma-Dynacare Medical Laboratories)

ElSohly Laboratories, Inc., 5 Industrial Park Drive, Oxford, MS 38655, 662–236–2609

Laboratory Corporation of America Holdings, 7207 N. Gessner Road, Houston, TX 77040, 713–856–8288/800–800–2387

Laboratory Corporation of America Holdings, 69 First Ave., Raritan, NJ 08869, 908–526–2400/800–437–4986, (Formerly: Roche Biomedical Laboratories, Inc.)

Laboratory Corporation of America Holdings, 1904 TW Alexander Drive, Research Triangle Park, NC 27709, 919–572–6900/800–833–3984, (Formerly: LabCorp Occupational Testing Services, Inc., CompuChem Laboratories, Inc.; CompuChem Laboratories, Inc., A Subsidiary of Roche Biomedical Laboratory; Roche CompuChem Laboratories, Inc., A Member of the Roche Group)

Laboratory Corporation of America Holdings, 1120 Main Street, Southaven, MS 38671, 866–827–8042/800–233–6339, (Formerly: LabCorp Occupational Testing Services, Inc.; MedExpress/National Laboratory Center)

LabOne, Inc. d/b/a Quest Diagnostics, 10101 Renner Blvd., Lenexa, KS 66219, 913–888–3927/800–873–8845, (Formerly: Quest Diagnostics Incorporated; LabOne, Inc.; Center for Laboratory Services, a Division of LabOne, Inc.)

Legacy Laboratory Services Toxicology, 1225 NE 2nd Ave., Portland, OR 97232, 503–413–5295/800–950–5295

MedTox Laboratories, Inc., 402 W County Road D, St. Paul, MN 55112, 651–636–7466/800–832–3244

Minneapolis Veterans Affairs Medical Center, Forensic Toxicology Laboratory, 1 Veterans Drive, Minneapolis, MN 55417, 612–725–2088, Testing for Veterans Affairs (VA) Employees Only

Pacific Toxicology Laboratories, 9348 DeSoto Ave., Chatsworth, CA 91311, 800–328–6942, (Formerly: Centinela Hospital Airport Toxicology Laboratory)

Pathology Associates Medical Laboratories, 110 West Cliff Dr., Spokane, WA 99204, 509–755–8991/800–541–7891x7

Phamatech, Inc., 15175 Innovation Drive, San Diego, CA 92128, 888–635–5840

Quest Diagnostics Incorporated, 1777 Montreal Circle, Tucker, GA 30084, 800–729–6432, (Formerly: SmithKline Beecham Clinical Laboratories; SmithKline Bio-Science Laboratories)

Quest Diagnostics Incorporated, 400 Egypt Road, Norristown, PA 19403, 610–631–4600/877–642–2216, (Formerly: SmithKline Beecham Clinical Laboratories; SmithKline Bio-Science Laboratories)

Redwood Toxicology Laboratory, 3700 Westwind Blvd., Santa Rosa, CA 95403, 800–255–2159

U.S. Army Forensic Toxicology Drug Testing Laboratory, 2490 Wilson St., Fort George G. Meade, MD 20755–5235, 301–677–7085, Testing for Department of Defense (DoD) Employees Only

* The Standards Council of Canada (SCC) voted to end its Laboratory Accreditation Program for Substance Abuse (LAPSA) effective May 12, 1998. Laboratories certified through that program were accredited to conduct forensic urine drug testing as required by U.S. Department of Transportation (DOT) regulations. As of that date, the certification of those accredited Canadian laboratories will continue under DOT authority. The responsibility for conducting quarterly performance testing plus periodic on-site inspections of those LAPSA-accredited laboratories was transferred to the U.S. HHS, with the HHS' NLCP contractor continuing to have an active role in the performance testing and laboratory inspection processes. Other Canadian laboratories wishing to be considered for the NLCP may apply directly to the NLCP contractor just as U.S. laboratories do.

Upon finding a Canadian laboratory to be qualified, HHS will recommend that DOT certify the laboratory (**Federal Register**, July 16, 1996) as meeting the minimum standards of the Mandatory Guidelines published in the **Federal Register** on January 23, 2017 (82 FR 7920). After receiving DOT certification, the laboratory will be included in the monthly list of HHS-certified laboratories and participate in the NLCP certification maintenance program.

Anastasia Marie Donovan,

Policy Analyst.

[FR Doc. 2020–11695 Filed 6–1–20; 8:45 am]

BILLING CODE 4160–20–P

DEPARTMENT OF THE INTERIOR

Office of the Secretary

[LLWO210000.L1610000]

National Environmental Policy Act Implementing Procedures for the Bureau of Land Management (516 DM 11)

AGENCY: Office of the Secretary, Interior.

ACTION: Notice.

SUMMARY: This notice announces the Department of the Interior's (Department) proposal to revise the National Environmental Policy Act (NEPA) implementing procedures for the Bureau of Land Management (BLM) at Chapter 11 of Part 516 of the Departmental Manual (DM) with a proposed new categorical exclusion (CX) for authorization of the salvage harvest of dead or dying trees.

DATES: Comments must be postmarked (for mailed comments), delivered (for personal or messenger delivery comments), or filed (for electronic comments) no later than July 2, 2020.

ADDRESSES: The public can review the proposed changes to the DM and the new proposed CX Verification Report online at: *https://tinyurl.com/w8t4jx2.* Comments can be submitted using:

—*BLM National NEPA Register: https://go.usa.gov/xvPfT.* Follow the instruction at this website.

—*Mail:* U.S. Department of the Interior, Bureau of Land Management, Attention: WO–210–SLVGCX, 2850 Youngfield Street, Lakewood, CO 80215.

—*Personal or messenger delivery:* U.S. Department of the Interior, Bureau of Land Management, Attention: W0–210–SLVGCX, 2850 Youngfield Street, Lakewood, CO 80215.

FOR FURTHER INFORMATION CONTACT: Heather Bernier, Acting Division Chief, Decision Support, Planning, and NEPA, at (202) 912–7282, or *hbernier@blm.gov.* Persons who use a telecommunications device for the deaf (TDD) may call the Federal Relay Service (FRS) at 1–800–877–8339. The FRS is available 24 hours a day, 7 days a week, to leave a message or question with the above individual. You will receive a reply during normal business hours.

SUPPLEMENTARY INFORMATION:

Background

Compliance with NEPA requires Federal agencies to consider the potential environmental consequences of their decisions before deciding whether and how to proceed. The Council on Environmental Quality (CEQ) encourages Federal agencies to use CXs to protect the environment more efficiently by reducing the resources spent analyzing proposals which normally do not have potentially significant environmental impacts, thereby allowing those resources to be focused on proposals that may have significant environmental impacts. The appropriate use of CXs allows NEPA compliance to be concluded, in the absence of extraordinary circumstances that merit further consideration, without preparing either an environmental assessment (EA) or an environmental impact statement (EIS) (40 CFR 1500.4(p) and 40 CFR 1508.4).

The Department's revised NEPA procedures were published in the **Federal Register** on October 15, 2008 (73 FR 61292), and are codified at 43 CFR part 46. These procedures address policy as well as procedure in order to assure compliance with the spirit and intent of NEPA. Additional Department-wide NEPA policy may be found in the DM, in chapters 1 through 4 of part 516. The procedures for the Department's bureaus are published as chapters 7 through 15 of this DM part 516. Chapter 11 of 516 DM covers the BLM's procedures. The BLM's current procedures can be found at: *https://elips.doi.gov/ELIPS/DocView.aspx?id=1721.* These procedures address policy as well as procedure in order to assure compliance with the spirit and intent of NEPA.

Rationale

Proposed CX number C (10) covers harvest of dead or dying trees impacted by biotic or abiotic disturbances commonly referred to as ''salvage harvest'' on harvest areas of up to 5,000 acres. Salvage harvest can help to recover economic value from timber, contribute to rural economies, accelerate reestablishment of native resilient forest tree species, and reduce future wildfire fuel loads and hazards to wildland firefighters, the public, and infrastructure from dead and dying trees. This CX would allow the BLM more flexibility to quickly respond to disturbances across larger areas to provide for public and infrastructure safety, reduce hazardous fuel loads that impact firefighter and public safety, and contribute to one of the six principal or major uses of the public lands identified in the Federal Land Policy and Management Act of 1976, which recognizes ''the Nation's need for domestic sources of timber and fiber.'' In addition to analysis through EAs and EISs, the BLM already relies upon its existing CX (C.8) that addresses salvage harvest not to exceed 250 acres and intends to retain that CX; the BLM is proposing this additional CX to increase its flexibility to respond to disturbances across larger areas. Based on review of the existing CX C.8 as part of this process, the BLM does not intend to pursue removal of the 250-acre CX nor revise that CX to encompass the proposed scope of actions described in this proposal. The BLM sees a need for both CX categories. The 250-acre CX provides a more limited scope of actions that are useful, and the BLM has used the CX about 10 times a year for the last 5 years. The BLM expects existing CX C.8 would still be used for smaller areas where the BLM has no need for the additional tools this proposed CX would provide. Following years of experience in conducting salvage harvest without significant effects, the BLM has identified that establishing a CX for the action is necessary to increase the BLM's flexibility to respond to disturbances across larger areas, while keeping the tailored focus of the action. The BLM has completed review of scientific literature and previously analyzed and implemented actions in the *Verification Report on the results of a Bureau of Land Management analysis of NEPA records and field verification for salvage harvest of timber* (Salvage CX Verification Report), which is incorporated by reference here and summarized in Justification for Change below, and has found that the establishment of a CX is appropriate because of the evidence of no significant effects from salvage harvest at the parameters proposed. Establishing the new proposed CX would enable the BLM to ensure a timely process for a timber salvage project prior to a new fire season and in preparation for the subsequent fire season.

Description of Change

The Department proposes to add one CX to the BLM chapter of the Departmental Manual 516 DM 11 at Section, C. Forestry. The language of the proposed new CX citation at 516 DM 11.9 C. (10) Forestry is:

(10) Harvesting dead or dying trees resulting from fire, insects, disease, drought, or other disturbances not to exceed 1,000 acres for disturbances of 3,000 acres or less. For disturbances greater than 3,000 acres, harvesting shall not exceed ⅓ of a disturbance area but not to exceed 5,000 acres total harvest.

(a) Covered actions:

(i) Cutting, yarding, and removal of dead or dying trees and live trees needed for landings, skid trails, and road clearing. Includes chipping/grinding and removal of residual slash.

(ii) Jackpot burning, pile burning, or underburning.

(iii) Seeding or planting necessary to accelerate native species re-establishment.

(b) Such actions:

(i) May include construction of permanent roads not to exceed 1 mile in order to facilitate the covered actions. Permanent roads are routes intended to be part of the BLM's permanent transportation system.

(ii) If a permanent road is constructed to facilitate the covered actions, the segments shall conform to all applicable land use planning decisions for permanent road construction in the land use plan; and if travel management planning has been completed, the route specific designations related to the new segments shall be disclosed.

(iii) May include temporary roads, which are defined as roads authorized by contract, permit, lease, other written authorization, or emergency operation not intended to be part of the BLM's permanent transportation system and not necessary for long-term resource management. Temporary roads shall be designed to standards appropriate for

the intended uses, considering safety, cost of transportation, and impacts on land and resources.

(iv) Shall require the treatment of temporary roads constructed or used so as to permit the reestablishment, by artificial or natural means, or vegetative cover on the roadway and areas where the vegetative cover was disturbed by the construction or use of the road, as necessary to minimize erosion from the disturbed area. Such treatment shall be designed to reestablish vegetative cover as soon as practicable, but at least within 10 years after the termination of the contract.

(v) Shall require inclusion of project design features pertaining to the land use plan decisions providing for protections of the following resources and resource uses in the documentation of the CX:

(1) Level of snag and downed wood creation/retention, and retention level of live trees;

(2) Specifications for erosion control features such as water bars, dispersed slash;

(3) Criteria for minimizing or remedying soil compaction;

(4) Types and extents of logging system constraints (*e.g.,* seasonal, location, extent, etc.);

(5) Extent and purpose of seasonal operating constraints or restrictions;

(6) Criteria to limit spread of weeds;

(7) Size of riparian buffers and/or riparian zone operating restrictions;

(8) Operating constraints and restrictions for underburning or pile burning; and

(9) Revegetation standards for temporary roads.

(c) For this CX, a dying tree is defined as a standing tree that has been severely damaged by forces such as fire, wind, ice, insects, or disease, and that in the judgement of an experienced forest professional or someone technically trained for the work, is likely to die within a few years. Examples include, but are not limited to:

(i) Harvesting a portion of a stand damaged by a wind or ice event.

(ii) Harvesting fire damaged trees.

The intent of this CX is to improve the efficiency of routine environmental review processes for the harvest of dead or dying trees impacted by biotic or abiotic disturbances. Each proposed action must be reviewed for extraordinary circumstances that would preclude the use of this CX. The Department's list of extraordinary circumstances under which a normally excluded action would require further analysis and documentation in an EA or EIS is found at 43 CFR 46.215. If a timber salvage project is within the activity described in this CX, then these ''extraordinary circumstances'' will be considered in the context of the proposed project to determine if they indicate the potential for effects that merit additional consideration in an EA or EIS. If any of the extraordinary circumstances indicate such potential, the CX would not be used, and an EA or EIS would be prepared.

The public is asked to review and comment on the newly proposed CX. To be considered, any comments on this proposed addition to the list of CXs in the DM must be received by the date listed in the **DATES** section of this notice at the location listed in the **ADDRESSES** section. Comments received after that date will be considered only to the extent practicable. Comments, including names and addresses of respondents, will be part of the public record and available for public review at the BLM address shown in the **ADDRESSES** section, during business hours, 8 a.m. to 4:30 p.m., Monday through Friday, except holidays. Before including your address, telephone number, email address, or other personal identifying information in your comment, you should be aware that your entire comment—including your personal identifying information—may be made publicly available at any time. While you can ask us in your comment to withhold your personal identifying information from public review, we cannot guarantee that we will be able to do so.

Justification for Change

The BLM proposes CX C (10) after reviewing existing NEPA analysis and available scientific research on the effects of these types of routine actions over time and over different geographic areas. The BLM has documented in detail the justification for establishing this new CX in the Verification Report, which is incorporated by reference here and available to review in full at the websites shown in **ADDRESSES**.

As described in the Verification Report, over the past three decades, forests in the western United States have experienced landscape-scale mortality events caused by wildfire, insect infestation and disease, drought, and other disturbances. From 2000 to 2017, an average of 6.8 million acres has burned annually in the U.S. (*https://www.nifc.gov/fireInfo/fireInfo_stats_totalFires.html*). For BLM-managed forests, fire has affected an average of 279,630 acres annually from 2009 to 2018. Insect and disease survey data collected in 2015 by the Forest Health Protection Program of the U.S. Forest Service identified 70 different mortality-causing agents and complexes on 5.2 million acres in the conterminous United States (Potter and Conkling 2017). The BLM assembled data from the U.S. Forest Service Aerial Detection Survey from 2008 to 2017 and found nearly two million acres of forest mortality were observed over that period on BLM lands.

Responsive to these larger, landscape-scale mortalities, the BLM has determined a need to be able to harvest dead and dying trees at larger scales than is currently authorized by the existing CX C.8. Salvage harvest is essential on portions of BLM-administered lands to provide for safety, meet legal mandates for land management, and conform to applicable land use plans. The BLM is pursuing the addition of this proposed CX to serve as a complement to the existing CX, and to provide the suite of actions often necessary when conducting salvage harvest at the scale the proposed CX would allow. This new proposed CX includes higher acreage limitations, but also includes actions to more comprehensively manage salvage harvest operations at a larger acreage scale, including permanent road construction, temporary road construction, and fuels management of harvested areas through jackpot burning and underburning. By including these additional actions for the larger scale of this proposed CX, the BLM would be able to address the full range of needs, including access and post-harvest fuels management, associated with salvage harvesting. Permanent roads are sometimes needed in salvage projects for the reforestation and forest development activities that occur over the years following the harvest activity. The effects of a permanent road are the same whether the road is transporting salvage wood or green wood in a thinning or a regeneration harvest. Since the salvage EAs reviewed for this analysis contained only one project describing a permanent road, the BLM looked at additional timber harvest EAs where permanent roads were included and resulted in findings of no significant impacts. As summarized below, and described in more detail in the Verification Report, the BLM used existing NEPA analysis and peer-reviewed research to determine the extent of both the actions to include and acreage on which to allow those actions that would ensure significance would not occur.

The BLM's review of the available literature demonstrates that the activities proposed for this new CX would not cause significant environmental effects, whether the

activities were to be implemented individually or in combination. As discussed in detail in the Verification Report Methods section, the research informed the development of this CX by providing evidence to suggest the need for the CX, both to facilitate the timely authorization of projects that can realize the long-term benefits that salvage harvest can provide, as well as to take advantage of the effectiveness of project design features to minimize adverse impacts. For example, several studies evaluate post-fire salvage harvest for soil disturbance, soil compaction, soil movement and soil deposition into stream systems. James and Krumland (2018) found that salvage logging with proper practices can reduce erosion when implemented immediately post fire. Research also demonstrates that soil disturbance during salvage operations can be minimized through effective project design. For example, partial harvest and skid trail layout can limit the extent of soil disturbance. Soil microbes have been shown to have no significant difference between sites that were post-fire logged and not logged (Smith et al. 2001).

As discussed in the Methods section of the Verification Report, the BLM currently implements timber salvage sales supported by EAs, EISs, and (since 2007) the existing timber salvage CX (C.8), and conducts post-harvest monitoring on all sales. The BLM has implemented salvage sales in response to insects and disease, windthrow, drought, and wildfires through commercial harvest using helicopter, cable yarding, and ground-based methods. A sampling of associated NEPA documents were reviewed to determine the scope of environmental consequences anticipated to result from the proposed actions. In the EAs reviewed, no significant individual or cumulative impacts were predicted to result from the kinds of activities included in the proposed CX for salvage harvest, nor were any unanticipated impacts observed after treatments were implemented. Actual impacts were the same as predicted impacts in all cases. There were no instances where any of the projects evaluated in EAs would have required completion of an EIS had these measures not been applied as a feature of the proposed action or alternatives.

The BLM has implemented elements of the salvage actions proposed for this new CX in the current salvage CX and has not found significant impacts or instances where the presence of extraordinary circumstances prevented reliance on the existing salvage CX. In the two circumstances where the BLM completed EISs for salvage harvest, the specific combination of actions proposed and the scale of the proposals warranted analysis through EISs. The scale and scope of the actions proposed for categorical exclusion here are readily distinguishable from those evaluated in the EISs.

All proposed actions and alternatives evaluated in the EAs reviewed included project design features that minimize environmental consequences. Often, through application of locally appropriate project design features, environmental effects are minimized to the level of non-significant, whereby resource issues were eliminated from further analysis due to application of these elements incorporated into project design. Development of lists of standard project design features as required components of this proposed CX would not be appropriate given the variability in specifications by region and land use planning area. The BLM identifies actions required to manage BLM-administered lands for specific purposes through land use planning as appropriate to the resource conditions and legal framework specific to the planning area and region. The BLM will often also identify project design features in the development of environmental analysis documents that are appropriate to consider when designing actions implementing the land use plan's direction in land use planning documents. All actions approved or authorized by the BLM must conform to the existing land use plan (43 CFR 1610.5–3), including those relying on a CX to comply with NEPA. To capture the project design features appropriate to working in a particular region or planning area, this proposed CX requires specific inclusion of project design features pertaining to the specific environmental considerations that the applicable land use plans require for forestry treatments. Reinforcing that activities covered by the proposed CX must conform to the applicable land use plan and requiring application of the protections specified by the land use plan through project design features developed for the areas required by the CX (section (b)(v) of proposed text) allows the CX to be applied as appropriate in varying site conditions. The BLM proposes through the establishment of this CX to require inclusion of project design features pertaining to the land use planning decisions related to the resources and activities listed in part (b)(v) of the proposed CX to both ensure documentation of conformance and that protective measures required to meet land use planning decisions applicable to the planning/action area are incorporated into the design of any project supported by the proposed CX.

While there are long-term benefits of conducting salvage harvest to reduce fuel loads that result in neutral or no-effect findings, there are documented instances of adverse, residual environmental consequences associated with implementation of these actions. However, as discussed in the Methods section of the Verification Report, these adverse environmental consequences are not considered individually or cumulatively significant due to low to moderate intensity of the treatments, as discussed, and the limited extent of treatment area relative to the extent and intensity of the disturbed area. The BLM's post-implementation observations align with the literature reviewed and summarized in the Methods section of the Verification Report.

As described in the Verification Report, the BLM has experience analyzing and implementing the harvest of salvage timber in an environmentally sustainable manner and considers the activities described in this proposal to be routine and non-significant. Expediting the immediate removal of dead and dying trees is essential to maximize economic returns as wood deterioration and value begins to drop immediately after the disturbance occurs. Establishment of a new CX covering these actions associated with salvage harvest will facilitate implementation of other BLM land management priorities and will contribute economic benefit to communities by providing timber for the forest product manufacturing sector.

The BLM's experience with implementing and monitoring these types of projects mirrors the scientific literature; taken together, they support establishment of this proposed CX, providing the evidence that this type and scope of action can be categorically excluded from further detailed analysis. As described in detail in the Verification Report, establishment of this proposed new CX would not individually or cumulatively have significant impacts on the human environment, and its use, like that of other administratively established CXs, would be subject to extraordinary circumstances review. Salvage harvest on the scale and scope that would be supported by this proposed CX is a common, effective tool that BLM uses to meet multiple forest and fuels management objectives as well as human health and safety and economic objectives.

Authorities: NEPA, the National Environmental Policy Act of 1969, as amended (42 U.S.C. 4321 *et seq.*); E.O. 11514, March 5, 1970, as amended by E.O. 11991, May 24, 1977; and CEQ regulations (40 CFR 1507.3).

Stephen G. Tryon,

Acting Director, Office of Environmental Policy and Compliance.

[FR Doc. 2020–11888 Filed 6–1–20; 8:45 am]

BILLING CODE 4331–84–P

DEPARTMENT OF THE INTERIOR

Office of the Secretary

[DOI–2019–0013; 201D0102DM, DS6CS00000, DLSN00000.000000, DX6CS25]

Privacy Act of 1974; System of Records

AGENCY: Office of the Secretary, Interior.

ACTION: Notice of a new system of records.

SUMMARY: Pursuant to the provisions of the Privacy Act of 1974, as amended, the Department of the Interior (DOI) is issuing a public notice of its intent to create a DOI Privacy Act system of records titled, ''INTERIOR/DOI–21, eRulemaking Program.'' This system of records helps DOI manage an eRulemaking Program and the associated rulemaking documents, public comments, and supporting materials submitted on its rulemakings and **Federal Register** notices. This newly established system will be included in DOI's inventory of record systems.

DATES: This new system will take effect upon publication. New routine uses will take effect July 2, 2020. Submit comments on or before July 2, 2020.

ADDRESSES: You may submit comments identified by docket number [DOI–2019–0013] by any of the following methods:

- *Federal eRulemaking Portal: http://www.regulations.gov.* Follow the instructions for sending comments.
- *Email: DOI_Privacy@ios.doi.gov.* Include docket number [DOI–2019–0013] in the subject line of the message.
- *U.S. mail or hand-delivery:* Teri Barnett, Departmental Privacy Officer, U.S. Department of the Interior, 1849 C Street NW, Room 7112, Washington, DC 20240.

Instructions: All submissions received must include the agency name and docket number [DOI–2019–0013]. All comments received will be posted without change to *http://www.regulations.gov,* including any personal information provided.

Docket: For access to the docket to read background documents or comments received, go to *http://www.regulations.gov.*

FOR FURTHER INFORMATION CONTACT: Teri Barnett, Departmental Privacy Officer, U.S. Department of the Interior, 1849 C Street NW, Room 7112, Washington, DC 20240, *DOI_Privacy@ios.doi.gov* or (202) 208–1605.

SUPPLEMENTARY INFORMATION:

I. Background

The DOI Office of the Executive Secretariat and Regulatory Affairs manages regulatory policy for the Department and is establishing the INTERIOR/DOI–21, eRulemaking Program, system of records to process, analyze and manage documents, comments and supporting materials submitted by members of the public in response to proposed rulemakings and notices. The system is comprised of public comments and documents received from the public that contain personally identifiable information that may include names, mailing addresses, email addresses, or other information received as part of the public comment and regulatory review process.

Public comments are published on *Regulations.gov*, a public facing website that provides public users ease of access to Federal regulatory content and a way to submit comments on regulatory documents published in the **Federal Register**. On *Regulations.gov*, the public can search, view, download, and comment on publicly available regulatory materials and post comments or provide supporting documents on rulemakings or **Federal Register** notices. Public comments published on *Regulations.gov* are maintained in the Federal Docket Management System (FDMS), a government-wide system that provides a platform for agencies to manage their rulemaking and content in *Regulations.gov*. FDMS allows Federal agencies to search, view, download, and review the public comments or supporting materials submitted on rulemakings and notices.

Regulations.gov and FDMS are managed by the General Services Administration (GSA) as the managing partner and government shared services provider to Federal partner agencies. Although GSA manages *Regulations.gov* and FDMS and provides assistance to Federal partner agencies, each Federal partner agency accesses and manages its own rulemaking documents and comments in FDMS. Therefore, DOI is publishing this INTERIOR/DOI–21, eRulemaking Program, system of records notice to cover records collected, used and maintained by DOI in support of Federal rulemakings through FDMS and *Regulations.gov*, as well as, DOI bureau and office eRulemaking Programs that may include administrative records and comments, information, and documents received from the public as part of the public comment process through email correspondence, postal mail, or other methods. Each DOI bureau and office is responsible for managing its own docket and the comments or supporting materials submitted on its own rulemakings.

II. Privacy Act

The Privacy Act of 1974, as amended, embodies fair information practice principles in a statutory framework governing the means by which Federal agencies collect, maintain, use, and disseminate individuals' records. The Privacy Act applies to records about individuals that are maintained in a ''system of records.'' A ''system of records'' is a group of any records under the control of an agency from which information is retrieved by the name of an individual or by some identifying number, symbol, or other identifying particular assigned to the individual. The Privacy Act defines an individual as a United States citizen or lawful permanent resident. Individuals may request access to their own records that are maintained in a system of records in the possession or under the control of DOI by complying with DOI Privacy Act regulations at 43 CFR part 2, subpart K, and following the procedures outlined in the Records Access, Contesting Record, and Notification Procedures sections of this notice.

The Privacy Act requires each agency to publish in the **Federal Register** a description denoting the existence and character of each system of records that the agency maintains and the routine uses of each system. The INTERIOR/DOI–21, eRulemaking Program, system of records notice is published in its entirety below. In accordance with 5 U.S.C. 552a(r), DOI has provided a report of this system of records to the Office of Management and Budget and to Congress.

III. Public Participation

You should be aware that your entire comment including your personal identifying information, such as your address, phone number, email address, or any other personal identifying information in your comment, may be made publicly available at any time. While you may request to withhold your personal identifying information from public review, we cannot guarantee we will be able to do so.

SYSTEM NAME AND NUMBER:

INTERIOR/DOI–21, eRulemaking Program.

SECURITY CLASSIFICATION:

Unclassified.

SYSTEM LOCATION:

Office of the Executive Secretariat, U.S. Department of the Interior, 1849 C Street NW, Mail Stop 7314 MIB, Washington, DC 20240; DOI bureaus and offices managing eRulemaking Program records; and General Services Administration servers located in the National Computer Center, Research Triangle Park, North Carolina.

SYSTEM MANAGER(S):

Director, Office of the Executive Secretariat and Regulatory Affairs, U.S. Department of the Interior, 1849 C Street NW, Mail Stop 7314 MIB, Washington, DC 20240.

AUTHORITY FOR MAINTENANCE OF THE SYSTEM:

E-Government Act of 2002, Public Law 107–347, 206(d); 44 U.S.C. Ch 36; 5 U.S.C. 301.

PURPOSE(S) OF THE SYSTEM:

The eRulemaking Program helps DOI manage a central, electronic repository for all DOI rulemaking materials and dockets, which include the rulemaking itself, **Federal Register** notices, supporting materials such as scientific or economic analyses, and public comments. The electronic repository also includes non-rulemaking dockets. DOI uses *Regulations.gov* to accept public comments electronically and FDMS for comment analysis. Each DOI bureau and office manages its own docket and can only access the comments or supporting materials submitted on its own rulemakings.

CATEGORIES OF INDIVIDUALS COVERED BY THE SYSTEM:

Individuals covered by the system are any individuals—including public citizens; representatives of Federal, state, Tribal, or local governments; businesses; and industries—who provide personal information while submitting a comment or supporting materials on a Federal agency rulemaking.

CATEGORIES OF RECORDS IN THE SYSTEM:

Public comments and any supporting materials received in response to DOI rulemakings and **Federal Register** notices. Records may include names, mailing addresses, email addresses and other information about members of the public submitting comments in response to DOI rulemakings and notices. This system may also include administrative records, comment analyses, correspondence and other records related to the management of the eRulemaking Program that may contain personal information.

RECORD SOURCE CATEGORIES:

Any individual who submits a comment or supporting materials on a DOI rulemaking.

ROUTINE USES OF RECORDS MAINTAINED IN THE SYSTEM, INCLUDING CATEGORIES OF USERS AND THE PURPOSES OF SUCH USES:

In addition to those disclosures generally permitted under 5 U.S.C. 552a(b) of the Privacy Act, all or a portion of the records or information contained in this system may be disclosed outside DOI as a routine use pursuant to 5 U.S.C. 552a(b)(3) as follows:

A. To the Department of Justice (DOJ), including Offices of the U.S. Attorneys, or other Federal agency conducting litigation or in proceedings before any court, adjudicative, or administrative body, when it is relevant or necessary to the litigation and one of the following is a party to the litigation or has an interest in such litigation:

(1) DOI or any component of DOI;

(2) Any other Federal agency appearing before the Office of Hearings and Appeals;

(3) Any DOI employee or former employee acting in his or her official capacity;

(4) Any DOI employee or former employee acting in his or her individual capacity when DOI or DOJ has agreed to represent that employee or pay for private representation of the employee; or

(5) The United States Government or any agency thereof, when DOJ determines that DOI is likely to be affected by the proceeding.

B. To a congressional office when requesting information on behalf of, and at the request of, the individual who is the subject of the record.

C. To the Executive Office of the President in response to an inquiry from that office made at the request of the subject of a record or a third party on that person's behalf, or for a purpose compatible with the reason for which the records are collected or maintained.

D. To any criminal, civil, or regulatory law enforcement authority (whether Federal, state, territorial, local, Tribal or foreign) when a record, either alone or in conjunction with other information, indicates a violation or potential violation of law—criminal, civil, or regulatory in nature, and the disclosure is compatible with the purpose for which the records were compiled.

E. To an official of another Federal agency to provide information needed in the performance of official duties related to reconciling or reconstructing data files, or to enable that agency to respond to an inquiry by the individual to whom the record pertains.

F. To Federal, state, territorial, local, Tribal, or foreign agencies that have requested information relevant or necessary to the hiring, firing or retention of an employee or contractor, or the issuance of a security clearance, license, contract, grant or other benefit, when the disclosure is compatible with the purpose for which the records were compiled.

G. To representatives of the National Archives and Records Administration (NARA) to conduct records management inspections under the authority of 44 U.S.C. 2904 and 2906.

H. To state, territorial, Tribal and local governments to provide information needed in response to court order and/or discovery purposes related to litigation, when the disclosure is compatible with the purpose for which the records were compiled.

I. To an expert, consultant, grantee, or contractor (including employees of the contractor) of DOI that performs services requiring access to these records on DOI's behalf to carry out the purposes of the system.

J. To appropriate agencies, entities, and persons when:

(1) DOI suspects or has confirmed that there has been a breach of the system of records;

(2) DOI has determined that as a result of the suspected or confirmed breach there is a risk of harm to individuals, DOI (including its information systems, programs, and operations), the Federal Government, or national security; and

(3) the disclosure made to such agencies, entities, and persons is reasonably necessary to assist in connection with DOI's efforts to respond to the suspected or confirmed breach or to prevent, minimize, or remedy such harm.

K. To another Federal agency or Federal entity, when DOI determines that information from this system of

records is reasonably necessary to assist the recipient agency or entity in:

(1) responding to a suspected or confirmed breach; or

(2) preventing, minimizing, or remedying the risk of harm to individuals, the recipient agency or entity (including its information systems, programs, and operations), the Federal Government, or national security, resulting from a suspected or confirmed breach.

L. To the Office of Management and Budget (OMB) during the coordination and clearance process in connection with legislative affairs as mandated by OMB Circular A–19.

M. To the Department of the Treasury to recover debts owed to the United States.

N. To the news media and the public, with the approval of the Public Affairs Officer in consultation with counsel and the Senior Agency Official for Privacy, where there exists a legitimate public interest in the disclosure of the information, except to the extent it is determined that release of the specific information in the context of a particular case would constitute an unwarranted invasion of personal privacy.

O. To the General Services Administration (GSA) or other Federal agency operating under a shared service provider cross-servicing agreement with DOI for purposes relating to the processing and maintenance of records, to reconstitute the system in case of system failure or helpdesk request, and to ensure the integrity of the system and the effective management of the eRulemaking Program.

P. To OMB, the Government Accountability Office (GAO), or other organization for the purpose of performing audit or oversight operations as authorized by law in accordance with their responsibilities for evaluating Federal programs, but only such information as is necessary and relevant to such audit or oversight function.

POLICIES AND PRACTICES FOR STORAGE OF RECORDS:

Paper records are contained in file folders stored in file cabinets in secure DOI controlled facilities. Electronic records are contained in removable drives, computers, email, electronic databases, backups maintained by DOI, and on secure servers maintained by GSA that are only accessed by authorized personnel.

POLICIES AND PRACTICES FOR RETRIEVAL OF RECORDS:

Records, comments and supporting materials submitted for DOI rulemakings may be retrieved by various data elements and key word searches, including: Name, docket type, docket sub-type, agency docket ID, docket title, docket category, document type, CFR part, date comment received, and **Federal Register** publication date.

POLICIES AND PRACTICES FOR RETENTION AND DISPOSAL OF RECORDS:

Retention periods may vary depending on the program, notice or purpose of the rulemaking or publication. Records of public comments are retained and disposed of in accordance with applicable DOI records schedules that have been approved by NARA based on the subject or function and records series. The majority of public comments related to **Federal Register** notices fall under the DOI Departmental Records Schedule (DRS). Records related to **Federal Register** notices are covered by DRS 1, Short-term Administration Records (DAA–0048–2013–0001–0001), which have a temporary disposition and are destroyed 3 years after cut-off. Records related to rulemaking are covered by DRS 3, Policy Records (DAA–0048–2013–0008–0010), Final Regulations, which have a Permanent disposition and are transferred to NARA 15 years after cut-off.

Records of public comments are disposed of in accordance with the applicable DOI records retention schedules and policy based on the program area and agency needs. When approved for destruction, paper records are disposed of by shredding or pulping, and records contained on electronic media are degaussed or erased in accordance with NARA guidelines and 384 Departmental Manual 1.

ADMINISTRATIVE, TECHNICAL, AND PHYSICAL SAFEGUARDS:

The records contained in this system are safeguarded in accordance with 43 CFR 2.226 and other applicable security and privacy rules and policies. During normal hours of operation, paper records such as the original or scanned copies of the supporting materials received in response to DOI rulemakings and **Federal Register** notices are maintained in file cabinets under the control of authorized personnel.

Computer servers on which electronic records are stored are located in secured DOI-controlled facilities with physical, technical, and administrative levels of security to prevent unauthorized access to the DOI network and information assets. Access granted to authorized personnel is password-protected, and each person granted access to the system must be individually authorized to use the system. A Privacy Act Warning Notice appears on the computer monitor screens when records containing information on individuals are first displayed. Data exchanged between the servers and the system is encrypted. Backup tapes are encrypted and stored in a locked and controlled room in a secure, off-site location.

Computerized records systems follow the National Institute of Standards and Technology privacy and security standards as developed to comply with the Privacy Act of 1974 as amended, 5 U.S.C. 552a; the Paperwork Reduction Act of 1995, Public Law 104–13, as codified at 44 U.S.C. 3501 *et seq.;* the Federal Information Security Modernization Act of 2014, Public Law 113–283, as codified at 44 U.S.C. 3551, *et seq.;* and the Federal Information Processing Standard 199, ''Standards for Security Categorization of Federal Information and Information Systems.'' Security controls include user identification, passwords, database permissions, encryption, firewalls, audit logs, network system security monitoring, and software controls.

Access to records in the system is limited to authorized personnel who have a need to access the records in the performance of their official duties, and each user's access is restricted to only the functions and data necessary to perform that person's job responsibilities. System administrators and authorized users are trained and required to follow established internal security protocols and must complete all security, privacy, and records management training and sign the DOI Rules of Behavior.

The GSA information technology system that hosts *Regulations.gov* and FDMS is located in a facility protected by physical walls, security guards, and requiring identification badges. Rooms housing the information technology system infrastructure are locked, as are the individual server racks. All security controls are reviewed on a periodic basis by external assessors. The controls themselves include measures for access control, security awareness training, audits, configuration management, contingency planning, incident response, and maintenance. Records in FDMS are maintained in a secure, password protected electronic system that utilizes security hardware and software to include multiple firewalls, active intrusion detection, encryption, identification and authentication of users.

As a partner agency, DOI manages access to FDMS through designated account managers in order to establish, manage, and terminate DOI user

accounts. DOI bureaus and offices have access to comments and supporting materials submitted on their own rulemakings and are responsible for managing those records in accordance with DOI policies and regulations.

RECORD ACCESS PROCEDURES:

An individual requesting records on himself or herself should send a signed, written inquiry to the applicable System Manager identified above. The request must include the specific bureau or office that maintains the record to facilitate the location of the applicable records. The request envelope and letter should both be clearly marked ''PRIVACY ACT REQUEST FOR ACCESS.'' A request for access must meet the requirements of 43 CFR 2.238.

CONTESTING RECORD PROCEDURES:

An individual requesting corrections or the removal of material from his or her records should send a signed, written request to the applicable System Manager as identified above. The request must include the specific bureau or office that maintains the record to facilitate the location of the applicable records. A request for corrections or removal must meet the requirements of 43 CFR 2.246.

NOTIFICATION PROCEDURES:

An individual requesting notification of the existence of records on himself or herself should send a signed, written inquiry to the applicable System Manager as identified above. The request must include the specific bureau or office that maintains the record to facilitate the location of the applicable records. The request envelope and letter should both be clearly marked ''PRIVACY ACT INQUIRY.'' A request for notification must meet the requirements of 43 CFR 2.235.

EXEMPTIONS PROMULGATED FOR THE SYSTEM:

None.

HISTORY:

None.

Teri Barnett,

Departmental Privacy Officer, Department of the Interior.

[FR Doc. 2020–11770 Filed 6–1–20; 8:45 am]

BILLING CODE 4334–63–P

DEPARTMENT OF THE INTERIOR

Bureau of Safety and Environmental Enforcement

[Docket ID BSEE–2020–0006; EEEE500000 20XE1700DX EX1SF0000.EAQ000; OMB Control Number 1014–0018]

Agency Information Collection Activities; Oil and Gas Drilling Operations

AGENCY: Bureau of Safety and Environmental Enforcement, Interior.

ACTION: Notice of information collection; request for comment.

SUMMARY: In accordance with the Paperwork Reduction Act (PRA) of 1995, the Bureau of Safety and Environmental Enforcement (BSEE) proposes to renew an information collection.

DATES: Interested persons are invited to submit comments on or before August 3, 2020.

ADDRESSES: Send your comments on this information collection request (ICR) by either of the following methods listed below:

- Electronically go to *http://www.regulations.gov.* In the Search box, enter BSEE–2020–0006 then click search. Follow the instructions to submit public comments and view all related materials. We will post all comments.
- Email *kye.mason@bsee.gov,* fax (703) 787–1546, or mail or hand-carry comments to the Department of the Interior; Bureau of Safety and Environmental Enforcement; Regulations and Standards Branch; ATTN: Nicole Mason; 45600 Woodland Road, Sterling, VA 20166. Please reference OMB Control Number 1014–0018 in the subject line of your comments.

FOR FURTHER INFORMATION CONTACT: To request additional information about this ICR, contact Nicole Mason by email at *kye.mason@bsee.gov* or by telephone at (703) 787–1607.

SUPPLEMENTARY INFORMATION: In accordance with the PRA and 5 CFR 1320.8(d)(1), all information collections require approval under the PRA. We may not conduct, or sponsor and you are not required to respond to a collection of information unless it displays a currently valid OMB control number.

As part of our continuing effort to reduce paperwork and respondent burdens, we invite the public and other Federal agencies to comment on new, proposed, revised, and continuing collections of information. This helps us assess the impact of our information collection requirements and minimize the public's reporting burden. It also helps the public understand our information collection requirements and provide the requested data in the desired format.

We are especially interested in public comment addressing the following:

(1) Whether or not the collection of information is necessary for the proper performance of the functions of the agency, including whether or not the information will have practical utility;

(2) The accuracy of our estimate of the burden for this 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) How might the agency 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.

Comments that you submit in response to this notice are a matter of public record. We will include or summarize each comment in our request to OMB to approve this ICR. Before including your address, phone number, email address, or other personal identifying information in your comment, you should be aware that your entire comment—including your personal identifying information—may be made publicly available at any time. While you can ask us in your comment to withhold your personal identifying information from public review, we cannot guarantee that we will be able to do so.

Abstract: The BSEE uses the information to ensure safe drilling operations and to protect the human, marine, and coastal environment. Among other things, BSEE specifically uses the information to ensure: The drilling unit is fit for the intended purpose; the lessee or operator will not encounter geologic conditions that present a hazard to operations; equipment is maintained in a state of readiness and meets safety standards; each drilling crew is properly trained and able to promptly perform well-control activities at any time during well operations; compliance with safety standards; and the current regulations will provide for safe and proper field or reservoir development, resource evaluation, conservation, protection of correlative rights, safety, and environmental protection. We also

review well records to ascertain whether drilling operations have encountered hydrocarbons or H2S and to ensure that H2S detection equipment, personnel protective equipment, and training of the crew are adequate for safe operations in zones known to contain H2S and zones where the presence of H2S is unknown.

This ICR includes three forms. The forms use and information consist of the following:

End of Operations Report, BSEE–0125

This information is used to ensure that industry has accurate and up-to-date data and information on wells and leasehold activities under their jurisdiction and to ensure compliance with approved plans and any conditions placed upon a suspension or temporary probation. It is also used to evaluate the remedial action in the event of well equipment failure or well control loss. The Form BSEE–0125 is updated and resubmitted in the event the well status changes. In addition, except for proprietary data, BSEE is required by the Outer Continental Shelf (OCS) Lands Act to make available to the public certain information submitted on BSEE–0125.

Well Activity Report, BSEE–0133 and –0133S

The BSEE uses this information to monitor the conditions of a well and status of drilling operations. We review the information to be aware of the well conditions and current drilling activity (*i.e.,* well depth, drilling fluid weight, casing types and setting depths, completed well logs, and recent safety equipment tests and drills). The engineer uses this information to determine how accurately the lessee anticipated well conditions and if the lessee or operator is following the other approved forms that were submitted. With the information collected on BSEE–0133 available, the reviewers can analyze the proposed revisions (*e.g.,* revised grade of casing or deeper casing setting depth) and make a quick and informed decision on the request.

In addition, except for proprietary data, BSEE is required by the OCS Lands Act to make available to the public certain information submitted on Forms BSEE–0133 and –0133S.

Title of Collection: 30 CFR 250, Subpart D, *Oil and Gas Drilling Operations.*

OMB Control Number: 1014–0018.

Form Number: BSEE–0125, BSEE–0133, and BSEE–0133S.

Type of Review: Extension of a currently approved collection.

Respondents/Affected Public: Potential respondents include Federal OCS oil, gas, and sulfur lessees and/or operators and holders of pipeline rights-of-way.

Total Estimated Number of Annual Respondents: Not all the potential respondents will submit information in any given year, and some may submit multiple times.

Total Estimated Number of Annual Responses: 63,367.

Estimated Completion Time per Response: 15 minutes to 40 hours, depending on the activity.

Total Estimated Number of Annual Burden Hours: 83,528.

Respondent's Obligation: Responses are mandatory.

Frequency of Collection: Submissions are generally on occasion.

Total Estimated Annual Nonhour Burden Cost: $16,000.

An agency may not conduct, or sponsor and a person is not required to respond to a collection of information unless it displays a currently valid OMB control number.

The authority for this action is the Paperwork Reduction Act of 1995 (44 U.S.C. 3501 *et seq.*).

Amy White,

Acting Chief, Regulations and Standards Branch.

[FR Doc. 2020–11839 Filed 6–1–20; 8:45 am]

BILLING CODE 4310–VH–P

INTERNATIONAL TRADE COMMISSION

[Investigation No. 337–TA–1169]

Certain Fish-Handling Pliers and Packaging Thereof; Commission Determination To Review-in-Part an Initial Determination Finding a Violation of Section 337; Schedule for Filing Written Submissions on the Issues Under Review and on Remedy, the Public Interest, and Bonding

AGENCY: U.S. International Trade Commission.

ACTION: Notice.

SUMMARY: Notice is hereby given that the U.S. International Trade Commission (''Commission'') has determined to review-in-part an initial determination (''ID'') (Order No. 14) of the presiding administrative law judge (''ALJ''). The Commission requests briefing from the parties on certain issues under review, as indicated in this notice. The Commission also requests briefing from the parties, interested government agencies, and interested persons on the issues of remedy, the public interest, and bonding.

FOR FURTHER INFORMATION CONTACT: Robert Needham, Esq., Office of the General Counsel, U.S. International Trade Commission, 500 E Street SW, Washington, DC 20436, telephone (202) 205–2392. Copies of non-confidential documents filed in connection with this investigation may be viewed on the Commission's electronic docket (EDIS) at *https://edis.usitc.gov.* For help accessing EDIS, please email *EDIS3Help@usitc.gov.* General information concerning the Commission may also be obtained by accessing its internet server at *https://www.usitc.gov.* The public record for this investigation may be viewed on the Commission's electronic docket (EDIS) at *https://edis.usitc.gov.* Hearing-impaired persons are advised that information on this matter can be obtained by contacting the Commission's TDD terminal on (202) 205–1810.

SUPPLEMENTARY INFORMATION: The Commission instituted this investigation on July 29, 2020, based on a complaint filed by complainant United Plastic Molders, Inc. of Jackson, Mississippi (''UPM''). 84 FR 36620–21 (July 29, 2020). The complaint, as supplemented, alleges violations of section 337 of the Tariff Act of 1930, as amended, 19 U.S.C. 1337, in the importation into the United States, the sale for importation, or the sale within the United States after importation of certain fish-handling pliers and packaging thereof by reason of infringement of claims 1–11 of U.S. Patent No. 6,256,923 (''the '923 patent'') and U.S. Trademark Registration Nos. 4,980,923 (''the '923 mark'') and 5,435,944 (''the '944 mark''). *Id.* The complaint further alleges that a domestic industry exists. *Id.* The Commission's notice of investigation named as respondents Yixing Five Union Industry & Trade Co., Ltd. of Yixing City, China (''Five Union''); NOEBY Fishing Tackle Co., Ltd. of Weihai, China (''NOEBY''); Weihai iLure Fishing Tackle Co., Ltd. of Weihai, China (''iLure''); SamsFX of Yangzhou City, China (''SamsFX''); and Weihai Lotus Outdoor Co., Ltd. of Weihai, China (''Lotus'') (collectively, ''Respondents''). *Id.* The Office of Unfair Import Investigations (''OUII'') is participating in the investigation. *Id.*

All five Respondents defaulted. On December 18, 2019, the Commission found NOEBY, iLure, Weihai Lotus, and Five Union in default for failing to respond to the complaint and notice of investigation. Order No. 11 (Nov. 19, 2019), *not reviewed* Notice (Dec. 18, 2019). Also on December 18, 2019, the Commission found SamsFX in default for failing to respond to the complaint

and notice of investigation. Order No. 12 (Nov. 25, 2019), *not reviewed* Notice (Dec. 18, 2019).

On December 5, 2019, UPM moved for a summary determination of violation based on infringement of the '923 patent, the '923 mark, and the '944 mark and for a recommendation for the issuance of a general exclusion order (''GEO''). In its motion, UPM withdrew its infringement allegations with respect to claims 2–6 and 8–11 of the '923 patent, but continued to assert claims 1 and 7 of the '923 patent. On January 3, 2020, OUII filed a response that largely supported UPM's motion.

On April 10, 2020, the ALJ issued the subject ID, Order No. 14, granting-in-part UPM's motion. Specifically, the ALJ issued a summary of determination of violation finding that SamsFX, Lotus, and NOEBY violated section 337 with respect to claims 1 and 7 of the '923 patent, as well as the '923 and '944 marks; that iLure violated section 337 with respect to claims 1 and 7 of the '923 patent; and that Five Union violated section 337 with respect to the '923 mark. The ALJ also found that UPM failed to show that iLure violated section 337 with respect to the '923 and '944 marks, as the only evidence of importation predates the registration of those marks. No petitions for review of the ID were filed.

The Commission has determined to review the subject ID in part. Specifically, the Commission has determined to review the ID's finding of violation with respect to the '923 patent; the ID's findings of trademark infringement; the ID's finding that UPM satisfied the economic prong of the domestic industry requirement; and the ID's finding of violation with respect to Lotus and Five Union. The Commission has not determined to review any other findings in the ID.

In connection with its review, the Commission is interested in briefing on the following issues:

1. In view of UPM's acknowledgment that the '923 patent expired on February 25, 2020 (Complaint ¶ 23), how does that expiration impact the findings in the ID? Please specifically address any impact on the ID's findings on the economic prong of the domestic industry requirement.

2. Please identify all evidence in the record that demonstrates that Lotus and Five Union are involved in ''the importation into the United States, the sale for importation, or the sale within the United States after importation by the owner, importer, or consignee'' of infringing articles. 19 U.S.C. 1337(a)(1)(C). Please explain how that evidence constitutes ''substantial, reliable, and probative evidence.''

19 U.S.C. 1337(g)(2)(B).

The parties are invited to brief only the discrete issues described above, with reference to the applicable law and evidentiary record. The parties are not to brief other issues on review, which are adequately presented in the parties' existing filings.

In connection with the final disposition of this investigation, the statute authorizes issuance of (1) an order that could result in the exclusion of the subject articles from entry into the United States, and/or (2) cease and desist orders that could result in the respondents being required to cease and desist from engaging in unfair acts in the importation and sale of such articles. Accordingly, the Commission is interested in receiving written submissions that address the form of remedy, if any, that should be ordered. If a party seeks exclusion of an article from entry into the United States for purposes other than entry for consumption, the party should so indicate and provide information establishing that activities involving other types of entry either are adversely affecting it or likely to do so. For background, see *Certain Devices for Connecting Computers via Telephone Lines,* Inv. No. 337–TA–360, USITC Pub. No. 2843, Comm'n Op. at 7–10 (December 1994).

The statute requires the Commission to consider the effects of any remedy upon the public interest. The public interest factors the Commission will consider include the effect that an exclusion order and/or a cease and desist order would have on (1) the public health and welfare, (2) competitive conditions in the U.S. economy, (3) U.S. production of articles that are like or directly competitive with those that are subject to investigation, and (4) U.S. consumers. The Commission is therefore interested in receiving written submissions that address the aforementioned public interest factors in the context of this investigation.

If the Commission orders some form of remedy, the U.S. Trade Representative, as delegated by the President, has 60 days to approve, disapprove, or take no action on the Commission's determination. *See* Presidential Memorandum of July 21, 2005, 70 FR 43251 (July 26, 2005). During this period, the subject articles would be entitled to enter the United States under bond, in an amount determined by the Commission and prescribed by the Secretary of the Treasury. The Commission is therefore interested in receiving submissions concerning the amount of the bond that should be imposed if a remedy is ordered.

Written Submissions: The Commission requests that the parties to the investigation file written submissions on the issues identified in this notice. Parties to the investigation, interested government agencies, and any other interested parties are encouraged to file written submissions on the issues of remedy, the public interest, and bonding. Such initial submissions should include views on the recommended determination by the ALJ on remedy and bonding.

In their initial submissions, Complainant and OUII are also requested to identify the remedy sought and to submit proposed remedial orders for the Commission's consideration. Complainant is also requested to state the HTSUS subheadings under which the accused products are imported and to supply the identification information for all known importers of the products at issue in this investigation. The initial written submissions and proposed remedial orders must be filed no later than close of business on June 10, 2020. Reply submissions must be filed no later than the close of business on June 17, 2020. No further submissions on these issues will be permitted unless otherwise ordered by the Commission.

Persons filing written submissions must file the original document electronically on or before the deadlines stated above. The Commission's paper filing requirements in 19 CFR 210.4(f) are currently waived. 85 FR 15798 (March 19, 2020). Submissions should refer to the investigation number (Inv. No. 337–TA–1169) in a prominent place on the cover page and/or the first page. (*See* Handbook for Electronic Filing Procedures, *https://www.usitc.gov/documents/handbook_on_filing_procedures.pdf*). Persons with questions regarding filing should contact the Secretary, (202) 205–2000.

Any person desiring to submit a document to the Commission in confidence must request confidential treatment. All such requests should be directed to the Secretary to the Commission and must include a full statement of the reasons why the Commission should grant such treatment. See 19 CFR 201.6. Documents for which confidential treatment by the Commission is properly sought will be treated accordingly. A redacted non-confidential version of the document must also be filed simultaneously with any confidential filing. All information, including confidential business information and documents for which confidential treatment is properly sought, submitted to the Commission for

purposes of this investigation may be disclosed to and used: (i) By the Commission, its employees and Offices, and contract personnel (a) for developing or maintaining the records of this or a related proceeding, or (b) in internal investigations, audits, reviews, and evaluations relating to the programs, personnel, and operations of the Commission including under 5 U.S.C. Appendix 3; or (ii) by U.S. government employees and contract personnel, solely for cybersecurity purposes. All contract personnel will sign appropriate nondisclosure agreements. All nonconfidential written submissions will be available for public inspection on EDIS.

The Commission vote for these determinations took place on May 27, 2020.

The authority for the Commission's determination is contained in section 337 of the Tariff Act of 1930, as amended (19 U.S.C. 1337), and in Part 210 of the Commission's Rules of Practice and Procedure (19 CFR part 210).

By order of the Commission.

Issued: May 27, 2020.

Lisa Barton,

Secretary to the Commission.

[FR Doc. 2020–11761 Filed 6–1–20; 8:45 am]

BILLING CODE 7020–02–P

INTERNATIONAL TRADE COMMISSION

[Investigation No. 337–TA–1148]

Certain Integrated Circuits and Products Containing the Same; Notice of Request for Submissions on the Public Interest

AGENCY: U.S. International Trade Commission.

ACTION: Notice.

SUMMARY: Notice is hereby given that on May 22, 2020, the presiding administrative law judge (''ALJ'') issued an Initial Determination on Violation of Section 337. The ALJ also issued a Recommended Determination on remedy and bonding should a violation be found in the above-captioned investigation. The Commission is soliciting submissions on public interest issues raised by the recommended relief should the Commission find a violation. This notice is soliciting comments from the public only.

FOR FURTHER INFORMATION CONTACT: Michael Liberman, Esq., Office of the General Counsel, U.S. International Trade Commission, 500 E Street SW, Washington, DC 20436, telephone (202) 205–3115. Copies of non-confidential documents filed in connection with this investigation may be viewed on the Commission's electronic docket (EDIS) at *https://edis.usitc.gov.* For help accessing EDIS, please email *EDIS3Help@usitc.gov.* General information concerning the Commission may also be obtained by accessing its internet server at *https://www.usitc.gov.* Hearing-impaired persons are advised that information on this matter can be obtained by contacting the Commission's TDD terminal on (202) 205–1810.

SUPPLEMENTARY INFORMATION: Parties are to file public interest submissions pursuant to 19 CFR 210.50(a)(4). Section 337 of the Tariff Act of 1930 provides that, if the Commission finds a violation, it shall exclude the articles concerned from the United States:

> unless, after considering the effect of such exclusion upon the public health and welfare, competitive conditions in the United States economy, the production of like or directly competitive articles in the United States, and United States consumers, it finds that such articles should not be excluded from entry.

19 U.S.C. 1337(d)(1). A similar provision applies to cease and desist orders. 19 U.S.C. 1337(f)(1).

The Commission is soliciting submissions on public interest issues raised by the recommended relief should the Commission find a violation, specifically: A limited exclusion order directed to certain integrated circuits and products containing the same imported, sold for importation, and/or sold after importation by respondents Acer, Inc., Acer America Corporation, AsusTek Computer Inc., Asus Computer International, Intel Corporation, Lenovo Group Ltd., Lenovo (United States) Inc., Micro-Star International Co., Ltd., and MSI Computer Corp. (collectively, ''Respondents''); and cease and desist orders directed to each Respondent.

The Commission is interested in further development of the record on the public interest in this investigation. Accordingly, members of the public are invited to file submissions of no more than five (5) pages, inclusive of attachments, concerning the public interest in light of the ALJ's Recommended Determination on Remedy and Bonding issued in this investigation on May 22, 2020. Comments should address whether issuance of the recommended remedial orders in this investigation, should the Commission find a violation, would affect the public health and welfare in the United States, competitive conditions in the United States economy, the production of like or directly competitive articles in the United States, or United States consumers.

In particular, the Commission is interested in comments that:

(i) Explain how the articles potentially subject to the recommended remedial orders are used in the United States;

(ii) identify any public health, safety, or welfare concerns in the United States relating to the recommended orders;

(iii) identify like or directly competitive articles that complainant, its licensees, or third parties make in the United States which could replace the subject articles if they were to be excluded;

(iv) indicate whether complainant, complainant's licensees, and/or third-party suppliers have the capacity to replace the volume of articles potentially subject to the recommended orders within a commercially reasonable time; and

(v) explain how the recommended orders would impact consumers in the United States.

Written submissions must be filed no later than by close of business on June 25, 2020.

Persons filing written submissions must file the original document electronically on or before the deadlines stated above. The Commission's paper filing requirements in 19 CFR 210.4(f) are currently waived. 85 FR 15798 (March 19, 2020). Submissions should refer to the investigation number (''Inv. No. 337–TA–1148'') in a prominent place on the cover page and/or the first page. (*See Handbook for Electronic Filing Procedures, https://www.usitc.gov/documents/handbook_on_filing_procedures.pdf.*) Persons with questions regarding filing should contact the Secretary (202–205–2000).

Any person desiring to submit a document to the Commission in confidence must request confidential treatment. All such requests should be directed to the Secretary to the Commission and must include a full statement of the reasons why the Commission should grant such treatment. *See* 19 CFR 201.6. Documents for which confidential treatment by the Commission is properly sought will be treated accordingly. All information, including confidential business information and documents for which confidential treatment is properly sought, submitted to the Commission for purposes of this Investigation may be disclosed to and used: (i) By the Commission, its employees and Offices, and contract personnel (a) for developing or maintaining the records

of this or a related proceeding, or (b) in internal investigations, audits, reviews, and evaluations relating to the programs, personnel, and operations of the Commission including under 5 U.S.C. Appendix 3; or (ii) by U.S. government employees and contract personnel, solely for cybersecurity purposes. All contract personnel will sign appropriate nondisclosure agreements. All nonconfidential written submissions will be available for public inspection at the Office of the Secretary and on EDIS.

This action is taken under the authority of section 337 of the Tariff Act of 1930, as amended (19 U.S.C. 1337), and in Part 210 of the Commission's Rules of Practice and Procedure (19 CFR part 210).

By order of the Commission.

Issued: May 27, 2020.

Lisa Barton,

Secretary to the Commission.

[FR Doc. 2020–11824 Filed 6–1–20; 8:45 am]

BILLING CODE 7020–02–P

INTERNATIONAL TRADE COMMISSION

[Investigation No. 337–TA–1155]

Certain Luxury Vinyl Tile and Components Thereof; Notice of Request for Statements on the Public Interest

AGENCY: U.S. International Trade Commission.

ACTION: Notice.

SUMMARY: Notice is hereby given that the presiding administrative law judge (''ALJ'') has issued an Initial Determination Granting Complainants' Motion for Summary Determination of Violation of Section 337 by certain defaulting respondents and Recommended Determination on Remedy and Bonding in the above-captioned investigation. The Commission is soliciting comments on public interest issues raised by the recommended relief, should the Commission find a violation. This notice is soliciting public interest comments from the public only. Parties are to file public interest submissions pursuant to Commission rules.

FOR FURTHER INFORMATION CONTACT: Lynde Herzbach, Office of the General Counsel, U.S. International Trade Commission, 500 E Street SW, Washington, DC 20436, telephone (202) 205–3228. Copies of non-confidential documents filed in connection with this investigation may be viewed on the Commission's electronic docket (EDIS) at *https://edis.usitc.gov.* For help accessing EDIS, please email *EDIS3Help@usitc.gov.* General information concerning the Commission may also be obtained by accessing its internet server at *https://www.usitc.gov.* Hearing-impaired persons are advised that information on this matter can be obtained by contacting the Commission's TDD terminal, telephone 202–205–1810.

SUPPLEMENTARY INFORMATION: Section 337 of the Tariff Act of 1930 provides that, if the Commission finds a violation, it shall exclude the articles concerned from the United States:

> unless, after considering the effect of such exclusion upon the public health and welfare, competitive conditions in the United States economy, the production of like or directly competitive articles in the United States, and United States consumers, it finds that such articles should not be excluded from entry.

19 U.S.C. 1337(d)(1). A similar provision applies to cease and desist orders. 19 U.S.C. 1337(f)(1).

The Commission is soliciting comments on public interest issues raised by the recommended relief should the Commission find a violation, specifically whether the Commission should issue:

(1) A general exclusion order (''GEO'') with respect to the three asserted patents; U.S. Patent Nos. 9,200,460, 10,208,490, and 10,233,655; and/or

(2) cease and desist orders (''CDOs'') against the five domestic defaulting respondents: ABK Trading Corp. of Katy, Texas; Aurora Flooring LLC of Kennesaw, Georgia; Maxwell Flooring Distribution LLC of Houston, Texas; Mr. Hardwood Inc. of Acworth, Georgia; and Sam Houston Hardwood Inc. of Houston, Texas.

The Commission is interested in further development of the record on the public interest in this investigation. Accordingly, members of the public are invited to file submissions of no more than five (5) pages, inclusive of attachments, concerning the public interest in light of the ALJ's Recommended Determination on Remedy and Bonding issued in this investigation on May 15, 2020. Comments should address whether issuance of the GEO and/or CDOs in this investigation, should the Commission find a violation, would affect the public health and welfare in the United States, competitive conditions in the United States economy, the production of like or directly competitive articles in the United States, or United States consumers.

In particular, the Commission is interested in comments that:

(i) Explain how the articles potentially subject to the recommended orders are used in the United States;

(ii) identify any public health, safety, or welfare concerns in the United States relating to the recommended orders;

(iii) identify like or directly competitive articles that complainants, their licensees, or third parties make in the United States which could replace the subject articles if they were to be excluded;

(iv) indicate whether complainants, complainants' licensees, and/or third-party suppliers have the capacity to replace the volume of articles potentially subject to the recommended exclusion order and/or a cease and desist order within a commercially reasonable time; and

(v) explain how the GEO and/or CDOs would impact consumers in the United States.

Written submissions from the public must be filed no later than by close of business on June 15, 2020.

Persons filing written submissions must file the original document electronically on or before the deadlines stated above. The Commission's paper filing requirements in 19 CFR 210.4(f) are currently waived. 85 FR 15798 (March 19, 2020). Submissions should refer to the investigation number (''Inv. No. 337–TA–1155'') in a prominent place on the cover page and/or the first page. (See Handbook for Electronic Filing Procedures, *https://www.usitc.gov/documents/handbook_on_filing_procedures.pdf*). Persons with questions regarding filing should contact the Secretary (202–205–2000).

Any person desiring to submit a document to the Commission in confidence must request confidential treatment. All such requests should be directed to the Secretary to the Commission and must include a full statement of the reasons why the Commission should grant such treatment. *See* 19 CFR 201.6. Documents for which confidential treatment by the Commission is properly sought will be treated accordingly. All information, including confidential business information and documents for which confidential treatment is properly sought, submitted to the Commission for purposes of this Investigation may be disclosed to and used: (i) By the Commission, its employees and Offices, and contract personnel (a) for developing or maintaining the records of this or a related proceeding, or (b) in internal investigations, audits, reviews, and evaluations relating to the programs, personnel, and operations of the Commission including under 5 U.S.C. Appendix 3; or (ii) by U.S.

government employees and contract personnel, solely for cybersecurity purposes. All contract personnel will sign appropriate nondisclosure agreements. All nonconfidential written submissions will be available for public inspection at the Office of the Secretary and on EDIS.

This action is taken under the authority of section 337 of the Tariff Act of 1930, as amended (19 U.S.C. 1337), and in Part 210 of the Commission's Rules of Practice and Procedure (19 CFR part 210).

By order of the Commission.

Issued: May 27, 2020.

Lisa Barton,

Secretary to the Commission.

[FR Doc. 2020–11790 Filed 6–1–20; 8:45 am]

BILLING CODE 7020–02–P

INTERNATIONAL TRADE COMMISSION

[Investigation No. 332–575]

Seafood Obtained via Illegal, Unreported, and Unregulated Fishing: U.S. Imports and Economic Impact on U.S. Commercial Fisheries; Notice of New Dates for Public Hearing and Transmittal of the Commission's Report

AGENCY: United States International Trade Commission.

ACTION: Notice of new dates for public hearing and transmittal of the Commission's report.

SUMMARY: The Commission has changed the date of its public hearing for Investigation No. 332–575: *Seafood Obtained via Illegal, Unreported, and Unregulated Fishing: U.S. Imports and Economic Impact on U.S. Commercial Fisheries* from May 12, 2020 to September 3, 2020; and the date has changed for transmittal of its report to the U.S. House of Representatives Committee on Ways and Means (Committee) in this investigation from December 19, 2020 to February 18, 2021 due to COVID–19.

DATES:

August 12, 2020: Deadline for filing requests to appear at the public hearing.

August 21, 2020: Deadline for filing pre-hearing briefs and statements.

September 3, 2020: Public hearing.

September 17, 2020: Deadline for filing post-hearing briefs and statements.

October 9, 2020: Deadline for filing all other written submissions.

February 18, 2021: Transmittal of Commission report to the Committee.

ADDRESSES: All Commission offices, including the Commission's hearing rooms, are located in the United States International Trade Commission Building, 500 E Street SW, Washington, DC. All written submissions should be addressed to the Secretary, United States International Trade Commission, 500 E Street SW, Washington, DC 20436. The public record for this investigation may be viewed on the Commission's electronic docket (EDIS), *https://edis.usitc.gov*.

FOR FURTHER INFORMATION CONTACT: Project Leader Renee Berry (202–205–3498 or *renee.berry@usitc.gov*) or Deputy Project Leader Daniel Matthews (202–205–5991 or *daniel.matthews@usitc.gov*) for information specific to this investigation. For information on the legal aspects of these investigations, contact William Gearhart of the Commission's Office of the General Counsel (202–205–3091 or *william.gearhart@usitc.gov*). The media should contact Margaret O'Laughlin, Office of External Relations (202–205–1819 or *margaret.olaughlin@usitc.gov*). Hearing-impaired individuals may obtain information on this matter by contacting the Commission's TDD terminal at 202–205–1810. General information concerning the Commission may also be obtained by accessing its internet server (*https://www.usitc.gov*). Persons with mobility impairments who will need special assistance in gaining access to the Commission should contact the Office of the Secretary at 202–205–2000.

SUPPLEMENTARY INFORMATION: The Commission published notice of institution of the investigation in the **Federal Register** on January 31, 2020 (85 FR 5704, January 31, 2020). In that notice, the Commission announced it would hold a public hearing on May 12, 2020, and it also set dates by which requests to appear at the hearing, briefs, and other written submissions should be filed. However, due to COVID–19, the Commission postponed the hearing to a date to be determined (85 FR 21460, April 17, 2020). The Commission has rescheduled the public hearing as well as deadlines for requests to appear at the hearing, briefs, and other written submissions to the following dates. Please note the Secretary's Office will accept only electronic filings at this time. Filings must be made through the Commission's Electronic Document Information System (EDIS, *https://edis.usitc.gov*). No in-person paper-based filings or paper copies of any electronic filings will be accepted until further notice. The scope of the investigation remains the same as published in the **Federal Register** on January 31, 2020.

Public Hearing: A public hearing in connection with this investigation will be held beginning at 9:30 a.m. on September 3, 2020. This hearing may occur at the U.S. International Trade Commission Building, 500 E Street SW, Washington, DC, or via an online videoconferencing platform. Information about the place and form of the hearing, including about how to participate in or view the hearing, will be posted on the Commission's website at (*https://usitc.gov/research_and_analysis/what_we_are_working_on.htm*). Once on that web page, scroll down to the entry for investigation No. 332–575, *Seafood Obtained via Illegal, Unreported, and Unregulated Fishing: U.S. Imports and Economic Impact on U.S. Commercial Fisheries,* and click on the link to ''hearing instructions.''

Requests to appear at the public hearing should be filed with the Secretary, no later than 5:15 p.m., August 12, 2020 in accordance with the requirements in the ''Submissions'' section below. All pre-hearing briefs and statements should be filed no later than 5:15 p.m., August 21, 2020; and all post-hearing briefs and statements should be filed not later than 5:15 p.m., September 17, 2020. In the event that, as of the close of business on August 12, 2020, no witnesses are scheduled to appear at the hearing, the hearing will be canceled. Any person interested in attending the hearing as an observer or nonparticipant should contact the Office of the Secretary at 202–205–2000 after August 12, 2020, for information concerning whether the hearing will be held.

Written Submissions: In lieu of or in addition to participating in the hearing, interested parties are invited to file written submissions concerning this investigation. All written submissions should be addressed to the Secretary, and should be received not later than 5:15 p.m., October 9, 2020. All written submissions must conform to the provisions of section 201.8 of the Commission's Rules of Practice and Procedure (19 CFR 201.8), as temporarily amended by 85 FR 15798 (March 19, 2020). Under that rule waiver, the Office of the Secretary will accept only electronic filings at this time. Filings must be made through the Commission's Electronic Document Information System (EDIS, *https://edis.usitc.gov*). No in-person paper-based filings or paper copies of any electronic filings will be accepted until further notice. Persons with questions regarding electronic filing should contact the Office of the Secretary,

Docket Services Division (202–205–1802), or consult the Commission's Handbook on Filing Procedures.

Confidential Business Information. Any submissions that contain confidential business information must also conform to the requirements of section 201.6 of the Commission's Rules of Practice and Procedure (19 CFR 201.6). Section 201.6 of the rules requires that the cover of the document and the individual pages be clearly marked as to whether they are the ''confidential'' or ''non-confidential'' version, and that the confidential business information is clearly identified by means of brackets. All written submissions, except for confidential business information, will be made available for inspection by interested parties.

As requested by the Committee, the Commission will not include any confidential business information in the report that it sends to the Committee or makes available to the public. However, all information, including confidential business information, submitted in this investigation may be disclosed to and used: (i) By the Commission, its employees and Offices, and contract personnel (a) for developing or maintaining the records of this or a related proceeding, or (b) in internal investigations, audits, reviews, and evaluations relating to the programs, personnel, and operations of the Commission including under 5 U.S.C. Appendix 3; or (ii) by U.S. government employees and contract personnel for cybersecurity purposes. The Commission will not otherwise disclose any confidential business information in a manner that would reveal the operations of the firm supplying the information.

Summaries of Written Submissions: The Commission intends to publish summaries of the positions of interested persons in an appendix to the report. Persons wishing to have a summary of their position included in the report should include a summary with their written submission. The summary may not exceed 500 words, should be in a format that can be easily converted to MS Word, and should not include any confidential business information. The summary will be published as provided if it meets these requirements and is germane to the subject matter of the investigation. The Commission will identify the name of the organization furnishing the summary and will include a link to the Commission's Electronic Document Information System (EDIS) where the full written submission can be found.

By order of the Commission.

Issued: May 27, 2020.

Lisa Barton,

Secretary to the Commission.

[FR Doc. 2020–11760 Filed 6–1–20; 8:45 am]

BILLING CODE 7020–02–P

INTERNATIONAL TRADE COMMISSION

[Investigation Nos. 701–TA–648 and 731–TA–1521–1522 (Preliminary)]

Walk-Behind Lawn Mowers From China and Vietnam; Institution of Anti-Dumping and Countervailing Duty Investigations and Scheduling of Preliminary Phase Investigations

AGENCY: United States International Trade Commission.

ACTION: Notice.

SUMMARY: The Commission hereby gives notice of the institution of investigations and commencement of preliminary phase antidumping and countervailing duty investigation Nos. 701–TA–648 and 731–TA–1521–1522 (Preliminary) pursuant to the Tariff Act of 1930 (''the Act'') to determine whether there is a reasonable indication that an industry in the United States is materially injured or threatened with material injury, or the establishment of an industry in the United States is materially retarded, by reason of imports of walk-behind lawn mowers from China and Vietnam, provided for in subheading 8433.11.00 of the Harmonized Tariff Schedule of the United States, that are alleged to be sold in the United States at less than fair value and alleged to be subsidized by the Government of China. Unless the Department of Commerce (''Commerce'') extends the time for initiation, the Commission must reach a preliminary determination in antidumping and countervailing duty investigations in 45 days, or in this case by July 10, 2020. The Commission's views must be transmitted to Commerce within five business days thereafter, or by July 17, 2020.

DATES: May 26, 2020.

FOR FURTHER INFORMATION CONTACT: Nitin Joshi (202) 708–1669), Office of Investigations, U.S. International Trade Commission, 500 E Street SW, Washington, DC 20436. Hearing-impaired persons can obtain information on this matter by contacting the Commission's TDD terminal on 202–205–1810. Persons with mobility impairments who will need special assistance in gaining access to the Commission should contact the Office of the Secretary at 202–205–2000. General information concerning the Commission may also be obtained by accessing its internet server (*https://www.usitc.gov*). The public record for these investigations may be viewed on the Commission's electronic docket (EDIS) at *https://edis.usitc.gov.*

SUPPLEMENTARY INFORMATION:

Background.—These investigations are being instituted, pursuant to sections 703(a) and 733(a) of the Tariff Act of 1930 (19 U.S.C. 1671b(a) and 1673b(a)), in response to a petition filed on May 26, 2020, by MTD Products Inc., Valley City, Ohio.

For further information concerning the conduct of these investigations and rules of general application, consult the Commission's Rules of Practice and Procedure, part 201, subparts A and B (19 CFR part 201), and part 207, subparts A and B (19 CFR part 207).

Participation in the investigations and public service list.—Persons (other than petitioners) wishing to participate in the investigations as parties must file an entry of appearance with the Secretary to the Commission, as provided in sections 201.11 and 207.10 of the Commission's rules, not later than seven days after publication of this notice in the **Federal Register**. Industrial users and (if the merchandise under investigation is sold at the retail level) representative consumer organizations have the right to appear as parties in Commission antidumping duty and countervailing duty investigations. The Secretary will prepare a public service list containing the names and addresses of all persons, or their representatives, who are parties to these investigations upon the expiration of the period for filing entries of appearance.

Limited disclosure of business proprietary information (BPI) under an administrative protective order (APO) and BPI service list.—Pursuant to section 207.7(a) of the Commission's rules, the Secretary will make BPI gathered in these investigations available to authorized applicants representing interested parties (as defined in 19 U.S.C. 1677(9)) who are parties to the investigations under the APO issued in the investigations, provided that the application is made not later than seven days after the publication of this notice in the **Federal Register**. A separate service list will be maintained by the Secretary for those parties authorized to receive BPI under the APO.

Conference.—In light of the restrictions on access to the Commission building due to the COVID–19 pandemic, the Commission is

conducting its Title VII (antidumping and countervailing duty) preliminary phase staff conferences through submissions of written opening remarks and written testimony, staff questions and written responses to those questions, and postconference briefs. Requests to participate in these written proceedings should be emailed to *preliminaryconferences@usitc.gov* (DO NOT FILE ON EDIS) on or before June 12, 2020. A nonparty who has testimony that may aid the Commission's deliberations may request permission to participate by submitting a short statement. Please note the Secretary's Office will accept only electronic filings during this time. Filings must be made through the Commission's Electronic Document Information System (EDIS, *https://edis.usitc.gov*). No in-person paper-based filings or paper copies of any electronic filings will be accepted until further notice.

Written submissions.—As provided in sections 201.8 and 207.15 of the Commission's rules, any person may submit to the Commission on or before June 19, 2020, a written brief containing information and arguments pertinent to the subject matter of the investigations. Parties may file written opening remarks and testimony to the Commission on or before June 12, 2020. Staff questions will be provided to the parties on June 16, 2020, and written responses should be submitted to the Commission on or before June 19, 2020. All written submissions must conform with the provisions of section 201.8 of the Commission's rules; any submissions that contain BPI must also conform with the requirements of sections 201.6, 207.3, and 207.7 of the Commission's rules. The Commission's *Handbook on Filing Procedures,* available on the Commission's website at *https://www.usitc.gov/documents/handbook_on_filing_procedures.pdf,* elaborates upon the Commission's procedures with respect to filings.

In accordance with sections 201.16(c) and 207.3 of the rules, each document filed by a party to the investigations must be served on all other parties to the investigations (as identified by either the public or BPI service list), and a certificate of service must be timely filed. The Secretary will not accept a document for filing without a certificate of service.

Certification.—Pursuant to section 207.3 of the Commission's rules, any person submitting information to the Commission in connection with these investigations must certify that the information is accurate and complete to the best of the submitter's knowledge. In making the certification, the submitter will acknowledge that any information that it submits to the Commission during these investigations may be disclosed to and used: (i) By the Commission, its employees and Offices, and contract personnel (a) for developing or maintaining the records of these or related investigations or reviews, or (b) in internal investigations, audits, reviews, and evaluations relating to the programs, personnel, and operations of the Commission including under 5 U.S.C. Appendix 3; or (ii) by U.S. government employees and contract personnel, solely for cybersecurity purposes. All contract personnel will sign appropriate nondisclosure agreements.

Authority: These investigations are being conducted under authority of title VII of the Tariff Act of 1930; this notice is published pursuant to section 207.12 of the Commission's rules.

By order of the Commission.

Issued: May 27, 2020.

Lisa Barton,

Secretary to the Commission.

[FR Doc. 2020–11762 Filed 6–1–20; 8:45 am]

BILLING CODE 7020–02–P

INTERNATIONAL TRADE COMMISSION

[Investigation Nos. 701–TA–506 and 508 and 731–TA–1238–1243 (Review)]

Non-Oriented Electrical Steel From China, Germany, Japan, Korea, Sweden, and Taiwan; Scheduling of Full Five-Year Reviews

AGENCY: United States International Trade Commission.

ACTION: Notice.

SUMMARY: The Commission hereby gives notice of the scheduling of full reviews pursuant to the Tariff Act of 1930 (''the Act'') to determine whether revocation of the countervailing duty orders on non-oriented electrical steel from China and Taiwan and revocation of the antidumping duty orders on non-oriented electrical steel from China, Germany, Japan, Korea, Sweden, and Taiwan would be likely to lead to continuation or recurrence of material injury within a reasonably foreseeable time. The Commission has determined to exercise its authority to extend the review period by up to 90 days.

DATES: May 27, 2020.

FOR FURTHER INFORMATION CONTACT: Julie Duffy (202–708–2579), Office of Investigations, U.S. International Trade Commission, 500 E Street SW, Washington, DC 20436. Hearing-impaired persons can obtain information on this matter by contacting the Commission's TDD terminal on 202–205–1810. Persons with mobility impairments who will need special assistance in gaining access to the Commission should contact the Office of the Secretary at 202–205–2000. General information concerning the Commission may also be obtained by accessing its internet server (*https://www.usitc.gov*). The public record for these reviews may be viewed on the Commission's electronic docket (EDIS) at *https://edis.usitc.gov.*

SUPPLEMENTARY INFORMATION:

Background.—On February 4, 2020, the Commission determined that responses to its notice of institution of the subject five-year reviews were such that full reviews should proceed (85 FR 8325, February 13, 2020); accordingly, full reviews are being scheduled pursuant to section 751(c)(5) of the Tariff Act of 1930 (19 U.S.C. 1675(c)(5)). A record of the Commissioners' votes, the Commission's statement on adequacy, and any individual Commissioner's statements are available from the Office of the Secretary and at the Commission's website.

Participation in the reviews and public service list.—Persons, including industrial users of the subject merchandise and, if the merchandise is sold at the retail level, representative consumer organizations, wishing to participate in these reviews as parties must file an entry of appearance with the Secretary to the Commission, as provided in section 201.11 of the Commission's rules, by 45 days after publication of this notice. A party that filed a notice of appearance following publication of the Commission's notice of institution of the reviews need not file an additional notice of appearance. The Secretary will maintain a public service list containing the names and addresses of all persons, or their representatives, who are parties to the reviews.

For further information concerning the conduct of these reviews and rules of general application, consult the Commission's Rules of Practice and Procedure, part 201, subparts A and B (19 CFR part 201), and part 207, subparts A, D, E, and F (19 CFR part 207).

Please note the Secretary's Office will accept only electronic filings during this time. Filings must be made through the Commission's Electronic Document Information System (EDIS, *https://edis.usitc.gov.*) No in-person paper-based filings or paper copies of any electronic filings will be accepted until further notice.

Limited disclosure of business proprietary information (BPI) under an administrative protective order (APO) and BPI service list.—Pursuant to section 207.7(a) of the Commission's rules, the Secretary will make BPI gathered in these reviews available to authorized applicants under the APO issued in the reviews, provided that the application is made by 45 days after publication of this notice. Authorized applicants must represent interested parties, as defined by 19 U.S.C. 1677(9), who are parties to the reviews. A party granted access to BPI following publication of the Commission's notice of institution of the reviews need not reapply for such access. A separate service list will be maintained by the Secretary for those parties authorized to receive BPI under the APO.

Staff report.—The prehearing staff report in the reviews will be placed in the nonpublic record on September 22, 2020, and a public version will be issued thereafter, pursuant to section 207.64 of the Commission's rules.

Hearing.—The Commission will hold a hearing in connection with the reviews beginning at 9:30 a.m. on Thursday, October 8, 2020, at the U.S. International Trade Commission Building. Requests to appear at the hearing should be filed in writing with the Secretary to the Commission on or before September 23, 2020. A nonparty who has testimony that may aid the Commission's deliberations may request permission to present a short statement at the hearing. All parties and nonparties desiring to appear at the hearing and make oral presentations should participate in a prehearing conference to be held on October 7, 2020, at the U.S. International Trade Commission Building, if deemed necessary. Oral testimony and written materials to be submitted at the public hearing are governed by sections 201.6(b)(2), 201.13(f), 207.24, and 207.66 of the Commission's rules. Parties must submit any request to present a portion of their hearing testimony *in camera* no later than 7 business days prior to the date of the hearing.

Written submissions.—Each party to the reviews may submit a prehearing brief to the Commission. Prehearing briefs must conform with the provisions of section 207.65 of the Commission's rules; the deadline for filing is September 30, 2020. Parties may also file written testimony in connection with their presentation at the hearing, as provided in section 207.24 of the Commission's rules, and posthearing briefs, which must conform with the provisions of section 207.67 of the Commission's rules. The deadline for filing posthearing briefs is October 19, 2020. In addition, any person who has not entered an appearance as a party to the reviews may submit a written statement of information pertinent to the subject of the reviews on or before October 19, 2020. On November 10, 2020, the Commission will make available to parties all information on which they have not had an opportunity to comment. Parties may submit final comments on this information on or before November 13, 2020, but such final comments must not contain new factual information and must otherwise comply with section 207.68 of the Commission's rules. All written submissions must conform with the provisions of section 201.8 of the Commission's rules; any submissions that contain BPI must also conform with the requirements of sections 201.6, 207.3, and 207.7 of the Commission's rules. The Commission's *Handbook on Filing Procedures,* available on the Commission's website at *https://www.usitc.gov/documents/handbook_on_filing_procedures.pdf,* elaborates upon the Commission's procedures with respect to filings.

Additional written submissions to the Commission, including requests pursuant to section 201.12 of the Commission's rules, shall not be accepted unless good cause is shown for accepting such submissions, or unless the submission is pursuant to a specific request by a Commissioner or Commission staff.

In accordance with sections 201.16(c) and 207.3 of the Commission's rules, each document filed by a party to the reviews must be served on all other parties to the reviews (as identified by either the public or BPI service list), and a certificate of service must be timely filed. The Secretary will not accept a document for filing without a certificate of service.

The Commission has determined that these reviews are extraordinarily complicated and therefore has determined to exercise its authority to extend the review period by up to 90 days pursuant to 19 U.S.C. 1675(c)(5)(B).

Authority: These reviews are being conducted under authority of title VII of the Tariff Act of 1930; this notice is published pursuant to section 207.62 of the Commission's rules.

By order of the Commission.

Issued: May 27, 2020.

Lisa Barton,

Secretary to the Commission.

[FR Doc. 2020–11763 Filed 6–1–20; 8:45 am]

BILLING CODE 7020–02–P

DEPARTMENT OF JUSTICE

Antitrust Division

United States, et al. v. Dairy Farmers of America, Inc. and Dean Foods Company; Proposed Final Judgment and Competitive Impact Statement

Notice is hereby given pursuant to the Antitrust Procedures and Penalties Act, 15 U.S.C. 16(b)–(h), that a proposed Final Judgment, Stipulation, and Competitive Impact Statement have been filed with the United States District Court for the Northern District of Illinois in *United States of America, et al.* v. *Dairy Farmers of America, Inc., et al., Civil Action No. 1:20-cv-02658.* On May 1, 2020, the United States filed a Complaint alleging that Dairy Farmers of America, Inc.'s (''DFA'') proposed acquisition of certain assets from Dean Foods Company would violate Section 7 of the Clayton Act, 15 U.S.C. 18. The proposed Final Judgment, filed at the same time as the Complaint, requires DFA to divest three dairy processing plants and related tangible and intangible assets.

Copies of the Complaint, proposed Final Judgment, Competitive Impact Statement, and a letter the United States considered determinative in formulating the proposed Final Judgment are available for inspection on the Antitrust Division's website at *http://www.justice.gov/atr* and at the Office of the Clerk of the United States District Court for the Northern District of Illinois. Copies of these materials may be obtained from the Antitrust Division upon request and payment of the copying fee set by Department of Justice regulations.

Public comment is invited within 60 days of the date of this notice. Such comments, including the name of the submitter, and responses thereto, will be posted on the Antitrust Division's website, filed with the Court, and, under certain circumstances, published in the **Federal Register**. Comments should be directed to Eric D. Welsh, Acting Chief, Healthcare and Consumer Products Section, Antitrust Division, Department of Justice, 450 Fifth Street NW, Suite 4100, Washington, DC 20530 (telephone: 202–598–8681).

Suzanne Morris,

Chief, Premerger and Division Statistics.

UNITED STATES DISTRICT COURT FOR THE NORTHERN DISTRICT OF ILLINOIS EASTERN DIVISION

UNITED STATES OF AMERICA, COMMONWEALTH OF MASSACHUSETTS, and STATE OF WISCONSIN, Plaintiffs, v. *DAIRY*

FARMERS OF AMERICA, INC. and DEAN FOODS COMPANY, Defendants.

Case No. 1:20-cv-02658

Complaint

The United States of America, the Commonwealth of Massachusetts, and the State of Wisconsin (''Plaintiff States''), bring this civil antitrust action to prevent Dairy Farmers of America, Inc. (''DFA'') from acquiring certain fluid milk processing plants from Dean Foods Company (''Dean'').

I. Introduction

DFA's acquisition of most of Dean's fluid milk processing plants would further consolidate two highly concentrated fluid milk markets: (1) Northeastern Illinois and Wisconsin and (2) New England. The acquisition would make DFA the largest player in each market, with nearly 70% market share in northeastern Illinois and Wisconsin and over 50% in New England. DFA is the largest dairy cooperative in the United States, with nearly 14,000 farmer-members located in dozens of states. DFA also owns numerous fluid milk processing plants, including plants in Cedarburg, Wisconsin; New Britain, Connecticut; and Portland, Maine. Dean, the largest fluid milk processor in the nation, owns competing plants in Harvard, Illinois; De Pere, Wisconsin; and Franklin, Massachusetts.

DFA and Dean compete head-to-head to sell fluid milk to customers in the geographic areas served by these plants, including supermarkets, schools, convenience stores, and hospitals, among others. In these areas, DFA and Dean are two of only three significant competitive options for these customers. Competition between DFA and Dean has benefitted these customers by lowering fluid milk prices and improving service. The acquisition would eliminate competition between DFA and Dean in these geographic areas, threatening to increase prices for supermarkets, schools, and other fluid milk customers—price increases that would ultimately be passed on to millions of individual consumers.

For these reasons and those set forth below, DFA's proposed acquisition of assets from Dean threatens to lessen competition substantially in violation of Section 7 of the Clayton Act, 15 U.S.C. 18.

II. Background

A. Fluid Milk Processing

1. Approximately 10 million dairy cows produce over 200 billion pounds of raw milk in the United States each year. Dairy farmers sell the raw milk that their cows produce to processing plants that convert the raw milk into fluid milk, ice cream, cheese, and other dairy products. Fluid milk is raw milk that has been processed for human consumption. It is the ordinary fresh milk that can be found in supermarket and convenience store refrigerators.

2. Fluid milk processing plants purchase raw milk from dairy farmers, pasteurize and package the milk, and sell and distribute the processed product. Processors sell fluid milk to supermarkets, schools, convenience stores, hospitals, and others—sometimes through distributors and sometimes directly. The demand for fluid milk in the United States has declined, causing the closure of fluid milk processing plants around the country and, among other factors, leading to the pending bankruptcy of Dean and other fluid milk processors. Despite this reduction in demand, a significant group of consumers remains loyal to traditional fluid milk, and their demand for fluid milk continues to be largely unaffected by changes in price.

3. Fluid milk customers pay different prices based on a variety of factors, including the number of competitive alternatives available to the customer. Large customers and school districts typically request bids from fluid milk processors. The prices quoted by processors in these bids depend on the number and strength of competing processors, the processor's product, transportation and service costs, the processor's capacity utilization, and the ability of the processor to deliver directly to the customers' locations, among other factors. Distance between processors and purchasers also affects fluid milk pricing because fluid milk has a limited shelf life and is costly to transport. As a result, most customers purchase fluid milk from nearby processing plants.

B. The Defendants and the Merger

4. Dairy Farmers of America is the largest cooperative of dairy farmers in the country, with nearly 14,000 members. In 2018, DFA marketed 64.5 billion pounds of raw milk—approximately 30% of all raw milk produced in the United States. DFA had 2018 revenues of $13.6 billion.

5. DFA is also vertically integrated through its ownership interests in milk processing plants. DFA owns a number of dairy processing plants around the country, including eight fluid milk processing plants and a significant stake in a joint venture that owns twelve additional fluid milk plants. In the northeastern Illinois and Wisconsin area, DFA owns a fluid milk plant in Cedarburg, Wisconsin. In the New England area, DFA owns fluid milk plants in New Britain, Connecticut and Portland, Maine. These plants compete directly against certain processing plants that DFA proposes to acquire from Dean.

6. Dean Foods is the largest fluid milk processor in the country. It currently operates 57 fluid milk processing plants in 29 states. Dean's fluid milk processing network includes plants in the northeastern Illinois and Wisconsin area in Harvard, Illinois and De Pere, Wisconsin, and in the New England area in Franklin, Massachusetts. Dean had 2018 revenues of $7.75 billion.

7. Dean filed for Chapter 11 bankruptcy protection on November 12, 2019. Simultaneous with the bankruptcy filing, Dean announced that it was in discussions to sell some or all of its fluid milk plants to DFA. Dean's financial position continued to worsen in the months after its bankruptcy filing and was exacerbated by the coronavirus pandemic, which caused demand for milk by schools and restaurants to plummet. The growing financial crisis caused the bankruptcy process to be accelerated in order to find buyers for Dean's assets before the company ran out of money to continue operating. By order of the bankruptcy court, Dean accepted bids for its assets and selected winning bidders on March 30, 2020. Dean selected DFA as the winning bidder for the majority of Dean's assets.

8. On April 6, 2020, DFA and Dean entered into an asset purchase agreement whereby DFA agreed to purchase 44 of Dean's 57 fluid milk plants, along with various other assets, for a total value of $433 million. The purchase price consists of $325 million in cash and $108 million in forgiveness of debt owed by Dean to DFA.

III. Jurisdiction and Venue

9. The United States brings this action under Section 15 of the Clayton Act, 15 U.S.C. 25, as amended, to prevent and restrain Defendants from violating Section 7 of the Clayton Act, 15 U.S.C. 18.

10. The Plaintiff States bring this action under Section 16 of the Clayton Act, 15 U.S.C. 26, to prevent and restrain Defendants from violating Section 7 of the Clayton Act, 15 U.S.C. 18. The Plaintiff States, by and through their respective Attorneys General, bring this action as *parens patriae* on behalf of and to protect the health and welfare of their citizens and the general economy of each of their states.

11. DFA and Dean process, market, sell, and distribute fluid milk in the flow of interstate commerce, and their

sale of fluid milk substantially affects interstate commerce. This Court therefore has subject matter jurisdiction over this action pursuant to Section 15 of the Clayton Act, 15 U.S.C. 25, and 28 U.S.C. 1331, 1337(a), and 1345.

12. DFA and Dean both transact business in this district, including by selling fluid milk to customers in this district. Venue is therefore proper in this district under Section 12 of the Clayton Act, 15 U.S.C. 22 and under 28 U.S.C. 1391(c).

IV. The Merger Would Substantially Lessen Competition in the Sale of Fluid Milk

13. DFA's acquisition of Dean's plants in northeastern Illinois, Wisconsin, and New England is likely to lessen competition substantially for fluid milk customers. DFA and Dean are two of only three significant fluid milk processors that can serve customers in these areas. If the acquisition were permitted to proceed, DFA would control nearly 70% of the fluid milk market in northeastern Illinois and Wisconsin, and approximately 51% in New England. DFA and Dean compete head-to-head to supply fluid milk customers in these areas today, and those customers rely on competition between DFA and Dean to get lower prices and better terms. The acquisition would eliminate this competition and lead to higher prices and inferior service for supermarkets, schools, and other fluid milk customers and, ultimately, millions of individual consumers.

A. The processing and Sale of Fluid Milk Is a Relevant Product Market

14. The processing and sale of fluid milk is a relevant product market and line of commerce under Section 7 of the Clayton Act. Consumers have long-held cultural and taste preferences for fluid milk over other beverages, and fluid milk has particular nutritional benefits and qualities for use in cooking. Consequently, consumer demand for fluid milk is relatively inelastic; that is, fluid milk consumption does not decrease significantly in response to a price increase. Fluid milk is distinct from extended shelf-life milk, ultra-high temperature milk, and aseptic milk, which are produced by different processes, have numerous significant differences, and generally cost significantly more than fluid milk.

15. Retailers, supermarkets, distributors, and other fluid milk customers are unlikely to substitute other products for fluid milk because the individual consumers that they serve continue to demand fluid milk. Schools are similarly unlikely to substitute away from fluid milk in response to even a substantial price increase because they are required by federal regulations to offer fluid milk to students to receive federal reimbursements for meals served to lower-income students.

16. For these reasons, the processing and sale of fluid milk satisfies the well-accepted ''hypothetical monopolist'' test set forth in the U.S. Department of Justice and Federal Trade Commission *2010 Horizontal Merger Guidelines* (''*Horizontal Merger Guidelines*''). A hypothetical monopolist processing and selling fluid milk likely would impose a small but significant and non-transitory price increase (*e.g.,* five percent) because an insufficient number of customers would switch to alternatives to make that price increase unprofitable.

B. The Two Relevant Geographic Markets Are (1) Northeastern Illinois and Wisconsin and (2) New England

17. Fluid milk processors charge different prices to buyers in different areas. They negotiate prices individually, and fluid milk's high transportation costs and limited shelf life mean that customers cannot practically buy fluid milk from each other to avoid a higher price charged by processors. In other words, fluid milk processors can engage in ''price discrimination.'' When price discrimination is possible, relevant geographic markets may be defined by reference to the location of customers. In particular, a relevant geographic market for the processing and sale of fluid milk is a region within which customers can be targeted for a price increase. Most customers purchase fluid milk from suppliers and processing plants located near them because transportation costs and shelf life make sourcing from more distant suppliers prohibitive.

18. Northeastern Illinois, which includes Chicago and its suburbs, and the state of Wisconsin together comprise a relevant geographic market and section of the country within the meaning of Section 7 of the Clayton Act. Similarly, New England—including the states of Connecticut, Maine, Massachusetts, New Hampshire, Rhode Island, and Vermont—is a relevant geographic market and section of the country within the meaning of Section 7 of the Clayton Act. A hypothetical monopolist selling fluid milk in either of these two areas likely would find it profitable to impose a small but significant and non-transitory price increase (*e.g.,* five percent), because customers could not economically switch their source of supply to more distant sources.

C. The Merger Is Presumptively Unlawful in Both Geographic Markets

19. DFA's acquisition of Dean's fluid milk processing plants would result in a substantial increase in the concentration of processors that compete to supply fluid milk to customers in the northeastern Illinois and Wisconsin geographic market and the New England geographic market. DFA and Dean are two of only three significant fluid milk processors that sell into each of these geographic markets. In both geographic markets the acquisition would eliminate one competitor, leaving just two remaining competitive options for fluid milk customers, with DFA controlling a significant majority of fluid milk sales. Although there are small or fringe fluid milk processors in each market, these processors are not competitive options for most fluid milk customers because they are much smaller and lack the capabilities necessary to compete against processors like DFA and Dean.

20. The Supreme Court has held that mergers that significantly increase concentration in already concentrated markets are presumptively anticompetitive and therefore presumptively unlawful. To measure market concentration, courts often use the Herfindahl-Hirschman Index (''HHI'') as described in the *Horizontal Merger Guidelines.* HHIs range from 0 in markets with no concentration to 10,000 in markets where one firm has a 100% market share. According to the *Horizontal Merger Guidelines,* mergers that increase the HHI by more than 200 and result in an HHI above 2,500 in any market are presumed to be anticompetitive and, therefore, unlawful.

21. The acquisition of Dean's plants by DFA is presumptively unlawful in northeastern Illinois and Wisconsin. For fluid milk customers in this geographic market the combined market share of Dean's processing plants in Harvard, Illinois, and De Pere, Wisconsin, and DFA's processing plant in Cedarburg, Wisconsin is estimated to be approximately 70%. The result is a highly concentrated market with an HHI of nearly 5,200 and an increase in HHI of nearly 1,900.

22. The acquisition is also presumptively unlawful in the New England geographic market. For fluid milk customers in New England, the combined market share of Dean's processing plant in Franklin, Massachusetts, and DFA's processing plants in New Britain, Connecticut, and

Portland, Maine is estimated to be approximately 51%. The result is a highly concentrated market with an HHI of approximately 3,300 and an increase in HHI of over 1,000.

D. The Merger Would Reduce Competition That Benefits Fluid Milk Customers in Northeastern Illinois and Wisconsin and in New England

1. The Merger Would Eliminate Head-to-Head Competition Between DFA and Dean

23. DFA's acquisition of Dean's plants in northeastern Illinois and Wisconsin and in New England would eliminate head-to-head competition that has benefitted and would otherwise continue to benefit supermarkets, schools, and other fluid milk customers in the relevant geographic markets. Especially for large customers like supermarkets, DFA and Dean are two of only three competitive fluid milk processors, and they are often the two lowest-price options in these geographic markets. For reasons related to service and delivery capabilities, some fluid milk customers consider DFA and Dean to be their only practical options.

24. Many customers solicit bids from fluid milk processors and select the bidder that offers the lowest price. These customers often leverage a lower-priced bid from one supplier to obtain improved offers and lower prices from other bidders in individual negotiations. Even customers who use less formal procurement processes benefit from the presence of competitive alternatives, which constrain the prices that fluid milk processors can charge. Fluid milk customers in the relevant geographic markets have historically used competing bids from DFA and Dean to obtain lower prices.

25. As described above, customers typically purchase fluid milk from processing plants located near them because of shelf life and the costs associated with transportation. These costs comprise a significant portion of the prices that fluid milk processors offer to customers. Therefore, the lowest-price fluid milk processors available to customers typically are the processing plants located closest to them. For many fluid milk customers in the relevant geographic markets, DFA and Dean are two of the closest processing plants and, therefore, two of the most competitive options. The only other significant competitors selling fluid milk to customers in these markets are unlikely to substantially mitigate the loss of competition between DFA and Dean.

26. Many customers also have particular product and service requirements that not all fluid milk processors can meet. Many supermarkets, convenience stores, schools, and other customers require processors to arrange direct-store delivery, or ''DSD,'' where the processor delivers fluid milk to each of the customer's locations on a set schedule—sometimes as often as daily. Schools typically require milk to be packaged in small half-pint containers that require a separate bottling line and dedicated equipment. DFA and Dean, along with the third significant competitor in each of the relevant geographic markets, can satisfy these complex product and service requirements, while other smaller processors cannot.

2. The Merger Would Increase the Likelihood of Anticompetitive Coordination

27. The acquisition would result in easier and more stable coordinated interaction among DFA and the remaining fluid milk competitors in northeastern Illinois and Wisconsin and in New England. By reducing the number of significant fluid milk processors in these areas from three to two, the acquisition would make it easier for the remaining two processors to coordinate. Coordination is more likely to occur where it would be particularly effective and profitable, as in markets with few significant competitors, relatively homogenous products, and where demand for the product is not significantly affected by an increase in its price. Fluid milk markets exhibit each of these characteristics.

28. There is a history of anticompetitive coordination, including price-fixing, bid-rigging, and customer allocation in fluid milk markets in the United States and, in particular, in the sale of milk to schools. Numerous fluid milk processors, including Dean itself, have engaged in criminal collusive activities at various times over the last 40 years. Given this history of coordination among fluid milk processors and the reduction in the number of significant competitors, DFA's acquisition of Dean's assets makes coordination more likely to occur in these geographic markets.

E. Entry by Other Fluid Milk Processors Is Unlikely To Prevent an Anticompetitive Price Increase

29. Entry by fluid milk processors outside the relevant geographic markets is unlikely to be sufficient or timely enough to offset the anticompetitive effects of the acquisition. Processors who do not currently serve these markets are unlikely to begin shipping a significant quantity of fluid milk into the relevant geographic markets due to the same factors that make them uncompetitive in these markets today, including transportation costs and the lack of necessary capabilities or levels of service. Any milk that could be shipped into the relevant geographic markets likely could not be competitively priced because of high transportation costs, nor could it be economically delivered to customers like schools without local distribution networks.

30. The construction of a new fluid milk processing plant to serve customers in either of the relevant geographic markets is very unlikely because of the high costs of building a dairy processing plant—especially as fluid milk consumption has declined. Numerous fluid milk processing plants have closed in the last ten years across the United States, while only a few new plants have been built, largely for retailers to supply their own stores. The two largest fluid milk processors in the country, Dean and Borden, have filed for bankruptcy.

V. Countervailing Factors Do Not Offset the Anticompetitive Effects of the Merger

31. The proposed merger is unlikely to generate verifiable, merger-specific efficiencies sufficient to outweigh the anticompetitive effects that are likely to occur in the provision of fluid milk in the relevant geographic markets.

VI. Violations Alleged

32. The acquisition by DFA of certain Dean assets likely would lessen competition substantially for the processing and sale of fluid milk in the two relevant geographic markets alleged above in violation of Section 7 of the Clayton Act, 15 U.S.C. 18.

33. Unless enjoined, the acquisition likely would have the following anticompetitive effects, among others, in the relevant geographic markets:

(a) competition for the sale and processing of fluid milk between DFA and Dean would be eliminated;

(b) prices for fluid milk would increase; and

(c) quality and service levels would decrease.

VII. Request for Relief

34. Plaintiffs request that the Court:

(a) adjudge and decree that DFA's proposed acquisition of assets from Dean would be unlawful and violate Section 7 of the Clayton Act, 15 U.S.C. 18;

(b) preliminary and permanently enjoin and restrain Defendants and all persons acting on their behalf from consummating the planned acquisition or from entering into or carrying out any other contract, agreement, plan, or understanding, the effect of which would be to combine DFA and Dean in the relevant geographic markets alleged above;

(c) award Plaintiffs the costs of this action; and

(d) award Plaintiffs other relief that the Court deems just and proper.

Dated: May 1, 2020

Respectfully submitted,

FOR PLAINTIFF UNITED STATES OF AMERICA:

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UNITED STATES DISTRICT COURT FOR THE NORTHERN DISTRICT OF ILLINOIS EASTERN DIVISION

UNITED STATES OF AMERICA, COMMONWEALTH OF MASSACHUSETTS, and STATE OF WISCONSIN, Plaintiffs, v. *DAIRY FARMERS OF AMERICA, INC. and DEAN FOODS COMPANY, Defendants.*

Case No. 1:20–cv–02658

[Proposed] Final Judgment

Whereas, Plaintiffs, United States of America and the State of Wisconsin and the Commonwealth of Massachusetts (collectively, the ''Plaintiff States''), filed their Complaint on May 1, 2020, the United States and Defendants, Dairy Farmers of America, Inc. and Dean Foods Company, by their respective attorneys, have consented to entry of this Final Judgment without trial or adjudication of any issue of fact or law and without this Final Judgment constituting any evidence against or admission by a party regarding any issue of fact or law;

And whereas, Defendants agree to be bound by the provisions of this Final Judgment pending its approval by the Court;

And whereas, the essence of this Final Judgment is the prompt and certain divestiture of certain rights or assets by Defendants to assure that competition is not substantially lessened;

And whereas, Defendants agree to make certain divestitures for the purpose of remedying the loss of competition alleged in the Complaint;

And whereas, Defendants represent that the divestitures and other relief required by this Final Judgment can and will be made and that Defendants will not later raise a claim of hardship or difficulty as grounds for asking the Court to modify any provision of this Final Judgment;

Now therefore, before any testimony is taken, without trial or adjudication of any issue of fact or law, and upon consent of the parties, it is *ordered, adjudged, and decreed:*

I. Jurisdiction

The Court has jurisdiction over the subject matter of and each of the parties to this action. The Complaint states a claim upon which relief may be granted against Defendants under Section 7 of the Clayton Act, as amended (15 U.S.C. 18).

II. Definitions

As used in this Final Judgment:

A. ''Acquirer'' or ''Acquirers'' means the entity or entities to whom Defendants divest any of the Divestiture Assets.

B. ''DFA'' means Defendant Dairy Farmers of America, Inc., a Kansas cooperative marketing association with its headquarters in Kansas City, Kansas, its successors and assigns, and its subsidiaries, divisions, groups, affiliates, partnerships, and joint ventures, and their directors, officers, managers, agents, and employees.

C. ''Dean'' means Defendant Dean Foods Company, a Delaware corporation with its headquarters in Dallas, Texas, its successors and assigns, and its subsidiaries, divisions, groups, affiliates, partnerships, and joint ventures, and their directors, officers, managers, agents, and employees.

D. ''Fluid Milk'' means raw milk that has been processed for human consumption as a beverage, but does not include organic milk, soy milk, extended shelf life milk, ultra-high temperature milk, or aseptic milk.

E. ''De Pere Plant'' means Dean's dairy processing plant located at 3399 South Ridge Road, Ashwaubenon, Wisconsin 54115.

F. ''Franklin Plant'' means Dean's dairy processing plant located at 1199 West Central Street, Franklin, Massachusetts 02038.

G. ''Franklin Purchase Option'' means Dean's non-assignable option to purchase the real estate on which the Franklin Plant is located.

H. ''Harvard Plant'' means Dean's dairy processing plant located at 6303, 6306, and 6313 Maxon Road, Harvard, Illinois 60033.

I. ''Exclusive Territory'' means (1) the states of Illinois, Wisconsin, and Indiana; and (2) the Upper Peninsula of Michigan.

J. ''Non-Exclusive Territory'' means (1) the states of Minnesota and Iowa; and (2) the Lower Peninsula of Michigan.

K. ''Transitional Dean's Brand License'' means a non-exclusive, royalty-free, paid-up, irrevocable, nationwide license to use the ''Dean's'' brand name (and all associated trademarks, service marks, and service names) for all products for two (2) years from the date that the De Pere Divestiture Assets are divested to an Acquirer.

L. ''Dean's Brand Licenses'' means:

1. An exclusive (subject only to the rights of the Acquirer of the De Pere Divestiture Assets under the Transitional Dean's Brand License, if applicable), royalty-free, paid-up, irrevocable, perpetual license to use the ''Dean's'' brand name (and all associated trademarks, service marks, and service names) for all products in the Exclusive Territory; and

2. A non-exclusive, royalty-free, paid-up, irrevocable, perpetual license to use the ''Dean's'' brand name (and all associated trademarks, service marks, and service names) for all products in the Non-Exclusive Territory.

M. ''Transitional Dairy Pure Brand License'' means a non-exclusive, royalty-free, paid-up, irrevocable, nationwide license to use the ''Dairy Pure'' brand name (and all associated trademarks, service marks, and service names) for all products for two (2) years from the date that the relevant Divestiture Assets are divested to an Acquirer.

N. ''TruMoo Products'' means all products sold by Dean under the TruMoo brand name at any time from January 1, 2019 to the date that the relevant Divestiture Assets are divested to an Acquirer.

O. ''Transitional TruMoo Brand License'' means a non-exclusive, royalty-free, paid-up, irrevocable, nationwide license to use the ''TruMoo'' brand name (and all associated trademarks, service marks, and service names) for TruMoo Products for two (2) years from the date that the relevant Divestiture Assets are divested to an Acquirer.

P. ''TruMoo IP'' means all intellectual property, product formulas, technology, know-how, or other rights used in the manufacture or formulation of any TruMoo Products.

Q. ''TruMoo IP License'' means a non-exclusive, royalty-free, paid-up, irrevocable, perpetual, nationwide license to the TruMoo IP.

R. ''Divestiture Assets'' means the De Pere Divestiture Assets, the Franklin Divestiture Assets, and the Harvard Divestiture Assets.

S. ''De Pere Divestiture Assets'' means:

1. All of Defendants' rights, title, and interests in the De Pere Plant and the ancillary facilities listed in Appendix A;

2. All tangible assets related to or used in connection with the processing, marketing, sale, or distribution of Fluid Milk and all other products by the De Pere Plant or the ancillary facilities listed in Appendix A, including, but not limited to: research and development activities; all manufacturing and processing equipment, quality assurance equipment, research and development equipment, machine assembly equipment, tooling and fixed assets, personal property, inventory, office furniture, materials, supplies, and other tangible property; all licenses, permits, certifications, and authorizations issued by any governmental organization; all contracts, teaming arrangements, agreements, leases, commitments, certifications, and understandings, including supply agreements; all customer lists, contracts, accounts, and credit records; all repair and performance records; and all other records;

3. All intangible assets related to or used in connection with the processing, marketing, sale, or distribution of Fluid Milk and all other products by the De Pere Plant or the ancillary facilities listed in Appendix A, including, but not limited to: all patents; licenses and sublicenses; intellectual property (except the TruMoo IP); copyrights; trademarks, trade names, service marks, and service names (including the ''Morning Glory'' and ''Farm Fresh'' brand names and all associated trademarks, service marks, and service names), except the ''Dean's,'' ''Jilbert,'' ''Dairy Pure,'' and ''TruMoo'' brand names; technical information; computer software and related documentation; customer relationships, agreements, and contracts (or portions of such relationships, agreements, and contracts that relate to the De Pere Plant or the ancillary facilities listed in Appendix A); know-how; trade secrets; drawings; blueprints; designs; design protocols; specifications for materials; specifications for parts and devices; safety procedures for the handling of materials and substances; quality assurance and control procedures; design tools and simulation capability; all manuals and technical information Dean provides to its own employees, customers, suppliers, agents, or licensees; and all research data concerning historic and current research and development efforts, including but not limited to designs of experiments and the results of successful and unsuccessful designs and experiments;

4. A Transitional TruMoo Brand License;

5. The Transitional Dean's Brand License;

6. A TruMoo IP License; and

7. A Transitional Dairy Pure Brand License;

Provided, however, that the assets specified in Paragraphs II(S)(1)-(7) above do not include any rights, title, or interest in (i) Dean's corporate headquarters located at 2711 North Haskell Avenue, Dallas, Texas 75204 or (ii) Dean's dairy processing plant located at 1126 Kilburn Avenue, Rockford, Illinois 61101.

T. ''Franklin Divestiture Assets'' means:

1. All of Defendants' rights, title, and interests in the Franklin Plant and the ancillary facilities listed in Appendix B, except the Franklin Purchase Option;

2. All tangible assets related to or used in connection with the processing, marketing, sale, or distribution of Fluid Milk and all other products by the Franklin Plant or the ancillary facilities listed in Appendix B, including, but not limited to: Research and development activities; all manufacturing and processing equipment, quality assurance equipment, research and development equipment, machine assembly equipment, tooling and fixed assets, personal property, inventory, office furniture, materials, supplies, and other tangible property; all licenses, permits, certifications, and authorizations issued by any governmental organization; all contracts, teaming arrangements, agreements, leases, commitments, certifications, and understandings, including supply agreements; all customer lists, contracts, accounts, and credit records; all repair and performance records; and all other records;

3. All intangible assets related to or used in connection with the processing, marketing, sale, or distribution of Fluid Milk and all other products by the Franklin Plant or the ancillary facilities listed in Appendix B, including, but not limited to: all patents; licenses and sublicenses; intellectual property (except the TruMoo IP); copyrights; trademarks, trade names, service marks, and service names (including the ''Garelick Farms'' brand name and all associated trademarks, service marks, and service names), except the ''Dean's,'' ''Dairy Pure,'' and ''TruMoo'' brand names; technical information; computer software and related documentation; customer relationships, agreements, and contracts (or portions of such relationships, agreements, and contracts that relate to the Franklin Plant or the ancillary facilities listed in Appendix B); know-how; trade secrets; drawings; blueprints; designs; design protocols; specifications for materials; specifications for parts and devices; safety procedures for the handling of materials and substances; quality assurance and control procedures; design tools and simulation capability; all manuals and technical information Dean provides to its own employees, customers, suppliers, agents, or licensees; and all research data concerning historic and current research and development efforts, including but not limited to designs of experiments and the results of successful and unsuccessful designs and experiments;

4. A Transitional TruMoo Brand License;

5. A TruMoo IP License; and

6. A Transitional Dairy Pure Brand License;

Provided, however, that the assets specified in Paragraphs II(T)(1)-(6) above do not include any rights, title, or interest in Dean's corporate headquarters located at 2711 North Haskell Avenue, Dallas, Texas 75204.

U. ''Harvard Divestiture Assets'' means:

1. All of Defendants' rights, title, and interests in the Harvard Plant and the ancillary facilities listed in Appendix C;

2. All tangible assets related to or used in connection with the processing, marketing, sale, or distribution of Fluid Milk and all other products by the Harvard Plant or the ancillary facilities listed in Appendix C, including, but not limited to: research and development activities; all manufacturing and processing equipment, quality assurance equipment, research and development equipment, machine assembly equipment, tooling and fixed assets, personal property, inventory, office furniture, materials, supplies, and other tangible property; all licenses, permits, certifications, and authorizations issued by any governmental organization; all contracts, teaming arrangements, agreements, leases, commitments, certifications, and understandings, including supply agreements; all customer lists, contracts, accounts, and credit records; all repair and performance records; and all other records;

3. All intangible assets related to or used in connection with the processing, marketing, sale, or distribution of Fluid Milk and all other products by the Harvard Plant or the ancillary facilities listed in Appendix C, including, but not limited to: all patents; licenses and sublicenses; intellectual property (except the TruMoo IP); copyrights; trademarks, trade names, service marks, and service names, except the ''Dean's,'' ''Dairy Pure,'' and ''TruMoo'' brand names; technical information; computer software and related documentation; customer relationships, agreements, and contracts (or portions of such relationships, agreements, and contracts that relate to the Harvard plant or the ancillary facilities listed in Appendix C); know-how; trade secrets; drawings; blueprints; designs; design protocols; specifications for materials; specifications for parts and devices; safety procedures for the handling of materials and substances; quality assurance and control procedures; design tools and simulation capability; all manuals and technical information Dean provides to its own employees, customers, suppliers, agents, or licensees; and all research data concerning historic and current research and development efforts, including but not limited to designs of experiments and the results of successful and unsuccessful designs and experiments;

4. The Dean's Brand Licenses;

5. A Transitional TruMoo Brand License;

6. A TruMoo IP License; and

7. A Transitional Dairy Pure Brand License;

Provided, however, that the assets specified in Paragraphs II(U)(1)–(7) above do not include any rights, title, or interest in (i) Dean's corporate headquarters located at 2711 North Haskell Avenue, Dallas, Texas 75204 or (ii) Dean's dairy processing plant located at 1126 Kilburn Avenue, Rockford, Illinois 61101.

V. ''Relevant Personnel'' means all full-time, part-time, or contract personnel whose job responsibilities related in any way to the processing, marketing, sale, or distribution of Fluid Milk or any other products by the Divestiture Assets, at any time between July 1, 2019 and the date on which the Divestiture Assets are divested to Acquirer.

III. Applicability

A. This Final Judgment applies to DFA and Dean, as defined above, and all other persons, in active concert or participation with any Defendant, who receive actual notice of this Final Judgment.

B. If, prior to complying with Section IV and Section V of this Final Judgment, Defendants sell or otherwise dispose of all or substantially all of their assets or of lesser business units that include any of the Divestiture Assets, Defendants must require the purchaser to be bound by the provisions of this Final Judgment. Defendants need not obtain such an agreement from Acquirer(s).

IV. Divestitures

A. Defendants are ordered and directed, within 30 calendar days after the Court's entry of the Asset Preservation and Hold Separate Stipulation and Order in this matter, to divest the Divestiture Assets in a manner consistent with this Final Judgment to an Acquirer or Acquirers acceptable to the United States, in its sole discretion. The United States, in its sole discretion, may agree to one or more extensions of this time period not to exceed sixty (60) calendar days in total and will notify the Court of any extensions. Defendants agree to use their best efforts to divest the Divestiture Assets as expeditiously as possible.

B. Defendants promptly must make known, by usual and customary means, the availability of the Divestiture Assets. Defendants must inform any person making an inquiry regarding a possible purchase of some or all of the Divestiture Assets that the Divestiture Assets are being divested in accordance with this Final Judgment and must provide that person with a copy of this Final Judgment. Defendants must offer to furnish to all prospective Acquirers, subject to customary confidentiality assurances, all information and documents relating to the Divestiture Assets customarily provided in a due diligence process; provided, however, that Defendants need not provide information or documents subject to the attorney-client privilege or work-product doctrine. Defendants must make this information available to Plaintiffs at the same time that the information is made available to any other person.

C. Defendants must cooperate with and assist each Acquirer in identifying and hiring all Relevant Personnel associated with the particular Divestiture Assets that each Acquirer is acquiring, including:

1. Within ten (10) business days following receipt of a request by Acquirer or the United States, Defendants must identify all Relevant Personnel to Acquirer and Plaintiffs, including by providing organization charts covering all Relevant Personnel.

2. Within ten (10) business days following receipt of a request by Acquirer or the United States, Defendants must provide to Acquirer and Plaintiffs the following additional information related to Relevant Personnel: name; job title; current salary and benefits, including most recent bonus paid, aggregate annual compensation, current target or guaranteed bonus, if any, and any other payments due to or promises made to the individual; descriptions of reporting relationships, past experience, responsibilities, and training and educational histories; lists of all certifications; and all job performance evaluations. If Defendants are barred by any applicable laws from providing any of this information, within ten (10) business days following receipt of the request, Defendants must provide the requested information to the full extent permitted by law and also must provide a written explanation of Defendants' inability to provide the remaining information.

3. At the request of Acquirer, Defendants must promptly make Relevant Personnel available for private interviews with Acquirer during normal business hours at a mutually agreeable location.

4. Defendants must not interfere with any efforts by Acquirer to employ any Relevant Personnel. Interference includes but is not limited to offering to increase the salary or improve the benefits of Relevant Personnel unless the offer is part of a company-wide increase in salary or benefits that was announced prior to November 12, 2019 or has been approved by the United States, in its sole discretion, after consultation with the Plaintiff States. Defendants' obligations under this paragraph will expire six (6) months after the divestiture of the Divestiture Assets pursuant to this Final Judgment.

5. For Relevant Personnel who elect employment with Acquirer within six (6) months of the date on which the Divestiture Assets are divested to Acquirer, Defendants must waive all non-compete and non-disclosure agreements, vest all unvested pension and other equity rights, and provide all benefits that those Relevant Personnel otherwise would have been provided had the Relevant Personnel continued employment with Defendants, including but not limited to any retention bonuses or payments. Defendants may maintain reasonable restrictions on disclosure by Relevant Personnel of Defendants' proprietary non-public information that is unrelated to the Divestiture Assets and not otherwise required to be disclosed by this Final Judgment.

D. Defendants must permit prospective Acquirers of some or all of the Divestiture Assets to have reasonable access to make inspections of the Divestiture Assets for which they are prospective Acquirers and access to all environmental, zoning, and other permit documents and information, and all financial, operational, or other documents and information customarily provided as part of a due diligence process.

E. Defendants must warrant to Acquirer(s) that each asset to be divested will be fully operational and without material defect on the date of sale.

F. Defendants must not take any action that will impede in any way the permitting, operation, or divestiture of the Divestiture Assets.

G. Defendants must assign, subcontract, or otherwise transfer all contracts, agreements, and customer relationships (or portions of such contracts, agreements and customer relationships, including but not limited to relevant portions of national contracts) related to the Divestiture Assets, including all supply and sales contracts, to Acquirer(s); *provided however,* that for any contracts or agreements (including but not limited to customer contracts and supply contracts) that require the consent of another party to assign, subcontract or otherwise transfer, Defendants must use best efforts to accomplish the assignment, subcontracting, or other transfer.

1. For any customer of the Divestiture Assets with which Dean does not have a written contract, within five (5) business days of the closing of the divestiture of each set of Divestiture Assets, Defendants must send a letter, in a form approved by the United States in its sole discretion and signed by representatives of Dean and of the relevant Acquirer, to that customer, notifying the customer that the Acquirer will be the customer's new supplier pursuant to this Final Judgment.

2. Defendants must not interfere with any negotiations between Acquirer(s) and a customer or other contracting party, and Defendants must not encourage any customer of the Divestiture Assets to terminate a contract that has been assigned or otherwise transferred to Acquirer.

3. Notwithstanding any other provision in this Paragraph IV(G), Defendants must release each Acquirer from any of Dean's obligations to purchase raw milk from DFA that would otherwise be assigned to that Acquirer as part of the divestiture required by this Final Judgment.

H. For any governmental license, permit, registration, authorization, approval, or the discontinuation of any obligation thereunder that cannot be transferred to the relevant Acquirer (collectively, the ''Non-Transferred Licenses''), Defendants must use best efforts to assist Acquirer(s) in applying for and securing all necessary government approvals for the issuance of the Non-Transferred License(s) to Acquirer(s).

I. At the option of each Acquirer, and subject to approval by the United States in its sole discretion, on or before the date on which some or all of the Divestiture Assets are divested to that Acquirer, DFA must enter into a supply contract or contracts for raw milk sufficient to meet that Acquirer's needs, as determined by that Acquirer, for a period of up to three (3) months, on terms and conditions reasonably related to market conditions for the supply of raw milk. The United States, in its sole discretion, may approve one or more extensions of any supply contract, for a total of up to an additional three (3) months. If Acquirer seeks an extension of the term of a supply contract, Defendants must notify the United States in writing at least one (1) month prior to the date the supply contract expires. Acquirer may terminate a supply contract without cost or penalty at any time upon commercially reasonable notice.

J. At the option of each Acquirer, and subject to approval by the United States in its sole discretion, on or before the date on which some or all of the Divestiture Assets are divested to that Acquirer, Defendants must enter into a contract or contracts, on terms and conditions reasonably related to market conditions, to provide transition services (including but not limited to back office, human resource, accounting, employee health and safety, and information technology services and support) for a period of up to six (6) months to facilitate the transfer of the relevant Divestiture Assets to that Acquirer or to allow that Acquirer to operate the relevant Divestiture Assets. The United States, in its sole discretion, after consultation with the Plaintiff States, may approve one or more extensions of a contract for transition services, for a total of up to an additional six (6) months. If Acquirer seeks an extension of the term of a contract for transition services, Defendants must notify the United States in writing at least one (1) month prior to the date the contract expires. Acquirer may terminate a contract for transition services without cost or penalty at any time upon commercially reasonable notice. The employee(s), contractors, or other personnel of Defendants tasked with providing these transition services must not share any competitively sensitive information of Acquirer with any other employee of Defendants.

K. Defendants must warrant to Acquirer(s) that there are no material defects in the environmental, zoning, or other permits pertaining to the operation of the Divestiture Assets. Following the sale of any of the Divestiture Assets, Defendants must not undertake, directly or indirectly, any challenges to the environmental, zoning, or other permits relating to the operation of the Divestiture Assets.

L. For a period of one (1) year following the divestiture of each set of Divestiture Assets to the relevant Acquirer, Defendants must not initiate customer-specific communications to solicit any customer for the portion of that customer's business covered by the contract, agreement or relationship (or portion thereof) that is included in the Divestiture Assets; *provided, however,* that:

1. Defendants may respond to inquiries initiated by customers and enter into negotiations at the request of customers (including responding to

requests for quotation or proposal) to supply any business, whether or not such business was included in the Divestiture Assets; and

2. Defendants must maintain a log of telephonic, electronic, in-person, and other communications that constitute inquiries or requests from customers within the meaning of Paragraph IV(L)(1) above and make it available to the United States for inspection upon request.

M. DFA will not exercise the Franklin Purchase Option except that, upon Acquirer's request, DFA will (1) exercise the Franklin Purchase Option and (2) sell to Acquirer all of DFA's resulting rights, title, and interest in the property covered by the Franklin Purchase Option at the same price that DFA pays for that property under the Franklin Purchase Option.

N. Unless the United States otherwise consents in writing, the divestitures pursuant to Section IV or by a Divestiture Trustee appointed pursuant to Section V of this Final Judgment must include (1) the entirety of the De Pere Divestiture Assets and the entirety of the Harvard Divestiture Assets to a single Acquirer and (2) the entirety of the Franklin Divestiture Assets to a single Acquirer, and must be accomplished in such a way as to satisfy the United States, in its sole discretion, after consultation with the Plaintiff States, that the Divestiture Assets can and will be used by the relevant Acquirer as part of a viable, ongoing business of processing and selling Fluid Milk and will remedy the competitive harm alleged in the Complaint. Divestiture of the Divestiture Assets may be made to one or more Acquirers, provided that in each instance it is demonstrated to the sole satisfaction of the United States, after consultation with the Plaintiff States, that the Divestiture Assets will remain viable and that the divestiture will remedy the competitive harm alleged in the Complaint. The divestiture(s), whether pursuant to Section IV or Section V of this Final Judgment,

(1) must be made to Acquirer(s) that, in the United States' sole judgment, after consultation with the Plaintiff States, has the intent and capability (including the necessary managerial, operational, technical, and financial capability) of competing effectively in the business of processing and selling Fluid Milk; and

(2) must be accomplished so as to satisfy the United States, in its sole discretion, after consultation with the Plaintiff States, that none of the terms of any agreement between Acquirer(s) and Defendants give Defendants the ability unreasonably to raise the costs of Acquirer(s), to lower the efficiency of Acquirer(s), or otherwise to interfere in the ability of Acquirer(s) to compete effectively.

O. If any of the terms of an agreement between Defendants and Acquirer(s) to effectuate the divestiture required by this Final Judgment varies from a term of this Final Judgment then, to the extent that Defendants cannot fully comply with both, this Final Judgment determines Defendants' obligations.

V. Appointment of Divestiture Trustee

A. If Defendants have not divested the Divestiture Assets within the period specified in Paragraph IV(A), or if Defendants waive their right to first attempt such divestiture of (1) the De Pere Divestiture Assets and the Harvard Divestiture Assets or (2) the Franklin Divestiture Assets, Defendants must immediately notify Plaintiffs of that fact in writing. Upon application of the United States, the Court will appoint a Divestiture Trustee selected by the United States and approved by the Court to effect the divestiture(s) of any of the Divestiture Assets that have not been sold during the period specified in Paragraph IV(A).

B. After the appointment of a Divestiture Trustee by the Court, only the Divestiture Trustee will have the right to sell the Divestiture Assets that the Divestiture Trustee has been appointed to sell. The Divestiture Trustee will have the power and authority to accomplish the divestiture(s) to Acquirer(s) acceptable to the United States, in its sole discretion, at a price and on terms that are then obtainable upon reasonable effort by the Divestiture Trustee, subject to the provisions of Sections IV, V, and VI of this Final Judgment, and will have other powers as the Court deems appropriate. Subject to Paragraph V(D) of this Final Judgment, the Divestiture Trustee may hire at the cost and expense of Defendants any agents or consultants, including, but not limited to, investment bankers, attorneys, and accountants, who will be solely accountable to the Divestiture Trustee, reasonably necessary in the Divestiture Trustee's judgment to assist in the divestiture(s). Any such agents or consultants will serve on such terms and conditions as the United States approves, including confidentiality requirements and conflict of interest certifications.

C. Defendants may not object to a sale by the Divestiture Trustee on any ground other than malfeasance by the Divestiture Trustee. Objections by Defendants must be conveyed in writing to Plaintiffs and the Divestiture Trustee within ten (10) calendar days after the Divestiture Trustee has provided the notice required under Section VI.

D. The Divestiture Trustee will serve at the cost and expense of Defendants pursuant to a written agreement, on such terms and conditions as the United States approves, including confidentiality requirements and conflict of interest certifications. The Divestiture Trustee will account for all monies derived from the sale of the assets sold by the Divestiture Trustee and all costs and expenses so incurred. After approval by the Court of the Divestiture Trustee's accounting, including fees for any of its services yet unpaid and those of agents and consultants retained by the Divestiture Trustee, all remaining money will be paid to Defendants and the trust will then be terminated. The compensation of the Divestiture Trustee and any agents or consultants retained by the Divestiture Trustee must be reasonable in light of the value of the Divestiture Assets and based on a fee arrangement that provides the Divestiture Trustee with incentives based on the price and terms of the divestiture(s) and the speed with which it is accomplished, but the timeliness of the divestiture(s) is paramount. If the Divestiture Trustee and Defendants are unable to reach agreement on the Divestiture Trustee's or any agents' or consultants' compensation or other terms and conditions of engagement within fourteen (14) calendar days of the appointment of the Divestiture Trustee, the United States may, in its sole discretion, take appropriate action, including making a recommendation to the Court. Within three (3) business days of hiring any agent or consultant, the Divestiture Trustee must provide written notice of the hiring and rate of compensation to Defendants and the United States.

E. Defendants must use their best efforts to assist the Divestiture Trustee in accomplishing the required divestiture(s). The Divestiture Trustee and any agents or consultants retained by the Divestiture Trustee must have full and complete access to the personnel, books, records, and facilities of the Divestiture Assets the Divestiture Trustee is responsible for selling, and Defendants must provide or develop financial and other information relevant to the Divestiture Assets as the Divestiture Trustee may reasonably request, subject to reasonable protection for trade secrets; other confidential research, development, or commercial information; or any applicable privileges. Defendants may not take any action to interfere with or to impede the

Divestiture Trustee's accomplishment of the divestiture(s).

F. After appointment, the Divestiture Trustee will file monthly reports with Plaintiffs, setting forth the Divestiture Trustee's efforts to accomplish the divestiture(s) ordered by this Final Judgment. Reports must include the name, address, and telephone number of each person who, during the preceding month, made an offer to acquire, expressed an interest in acquiring, entered into negotiations to acquire, or was contacted or made an inquiry about acquiring, any interest in any of the Divestiture Assets and will describe in detail each contact with any such person. The Divestiture Trustee will maintain full records of all efforts made to divest the Divestiture Assets.

G. If the Divestiture Trustee has not accomplished the divestiture(s) ordered by this Final Judgment within sixty (60) days of appointment, the Divestiture Trustee must promptly file with the Court a report setting forth (1) the Divestiture Trustee's efforts to accomplish the required divestiture; (2) the reasons, in the Divestiture Trustee's judgment, why the required divestiture has not been accomplished; and (3) the Divestiture Trustee's recommendations. To the extent such report contains information that the Divestiture Trustee deems confidential, such report will not be filed in the public docket of the Court. The Divestiture Trustee will at the same time furnish such report to Plaintiffs. Within five (5) days of receiving the Divestiture Trustee's report, the United States, in its sole discretion, may extend the period of the trust for no more than sixty (60) additional days by written notice to the Divestiture Trustee and the Court. If, at the expiration of the initial time period and any extension thereof, the Divestiture Trustee has not secured a definitive agreement for the sale of the Divestiture Assets consistent with this Final Judgment and acceptable to the United States, in its sole discretion, DFA may file a motion with the Court, which the United States will not unreasonably oppose, requesting that, solely with respect to any Divestiture Assets for which the Divestiture Trustee was unable to secure a definitive divestiture agreement, (i) the Asset Preservation and Hold Separate Stipulation and Order be terminated and (ii) this Final Judgment be modified to permit DFA to retain those assets.

H. If the United States determines that the Divestiture Trustee is not acting diligently or in a reasonably cost-effective manner, the United States may recommend that the Court appoint a substitute Divestiture Trustee.

VI. Notice of Proposed Divestiture

A. Within two (2) business days following execution of a definitive divestiture agreement, Defendants or the Divestiture Trustee, whichever is then responsible for effecting any divestiture required herein, must notify Plaintiffs of a proposed divestiture required by this Final Judgment. If the Divestiture Trustee is responsible for effecting the divestiture, the Divestiture Trustee also must notify Defendants. The notice must set forth the details of the proposed divestiture and list the name, address, and telephone number of each person not previously identified who offered or expressed an interest in or desire to acquire any ownership interest in the Divestiture Assets, together with full details of the same.

B. Within fifteen (15) calendar days of receipt by the United States of this notice, the United States may request from Defendants, the proposed Acquirer(s), other third parties, or the Divestiture Trustee, if applicable, additional information concerning the proposed divestiture, the proposed Acquirer(s), and other prospective Acquirer(s). Defendants and the Divestiture Trustee must furnish the additional information requested to Plaintiffs within fifteen (15) calendar days of the receipt of the request, unless the United States provides written agreement to a different period.

C. Within forty-five (45) calendar days after receipt of the notice or within twenty (20) calendar days after the United States has been provided the additional information requested from Defendants, the proposed Acquirer(s), other third parties, and the Divestiture Trustee, whichever is later, the United States will provide written notice to Defendants and the Divestiture Trustee, if there is one, stating whether or not the United States, in its sole discretion, after consultation with the Plaintiff States, objects to the proposed Acquirer(s) or any other aspect of the proposed divestiture. If the United States provides written notice that it does not object, the divestiture may be consummated, subject only to Defendants' limited right to object to the sale under Paragraph V(C) of this Final Judgment. Absent written notice that the United States does not object or upon objection by the United States, a divestiture may not be consummated. Upon objection by Defendants pursuant to Paragraph V(C), a divestiture by the Divestiture Trustee may not be consummated unless approved by the Court.

D. No information or documents obtained pursuant to Section VI may be divulged by Plaintiffs to any person other than an authorized representative of the executive branch of the United States or the Plaintiff States, except in the course of legal proceedings to which the United States is a party (including grand-jury proceedings), for the purpose of evaluating a proposed Acquirer or securing compliance with this Final Judgment, or as otherwise required by law.

E. In the event of a request by a third party for disclosure of information under the Freedom of Information Act, 5 U.S.C. 552, the Antitrust Division will act in accordance with that statute, and the Department of Justice regulations at 28 CFR part 16, including the provision on confidential commercial information, at 28 CFR 16.7. Persons submitting information to the Antitrust Division should designate the confidential commercial information portions of all applicable documents and information under 28 CFR 16.7. Designations of confidentiality expire ten years after submission, ''unless the submitter requests and provides justification for a longer designation period.'' *See* 28 CFR 16.7(b).

F. If at the time a person furnishes information or documents to the United States pursuant to Section VI, that person represents and identifies in writing information or documents for which a claim of protection may be asserted under Rule 26(c)(1)(G) of the Federal Rules of Civil Procedure, and marks each pertinent page of such material, ''Subject to claim of protection under Rule 26(c)(1)(G) of the Federal Rules of Civil Procedure,'' the United States must give that person ten calendar days' notice before divulging the material in any legal proceeding (other than a grand-jury proceeding).

VII. Financing

Defendants may not finance all or any part of Acquirers' purchase of all or part of the Divestiture Assets made pursuant to this Final Judgment.

VIII. Asset Preservation and Hold Separate

Until the divestiture(s) required by this Final Judgment have been accomplished, Defendants must take all steps necessary to comply with the Asset Preservation and Hold Separate Stipulation and Order entered by the Court. Defendants will take no action that would jeopardize the divestiture(s) ordered by the Court.

IX. Affidavits

A. Within twenty (20) calendar days of the filing of the Complaint in this matter, and every thirty (30) calendar days thereafter until the divestiture

required by this Final Judgment has been completed, Defendants must deliver to Plaintiffs an affidavit, signed by each Defendant's Chief Financial Officer, Dean's General Counsel, and DFA's Chief Legal Officer, describing the fact and manner of Defendants' compliance with this Final Judgment. Each affidavit must include the name, address, and telephone number of each person who, during the preceding thirty (30) calendar days, made an offer to acquire, expressed an interest in acquiring, entered into negotiations to acquire, or was contacted or made an inquiry about acquiring, an interest in some or all of the Divestiture Assets, and must describe in detail each contact with such persons during that period. Each affidavit also must include a description of the efforts Defendants have taken to solicit buyers for and complete the sale of the Divestiture Assets, and to provide required information to prospective Acquirers. Each affidavit also must include a description of any limitations placed by Defendants on information provided to prospective Acquirers. If the information set forth in the affidavit is true and complete, objection by the United States to information provided by Defendants to prospective Acquirers must be made within fourteen (14) calendar days of receipt of the affidavit.

B. Within twenty (20) calendar days of the filing of the Complaint in this matter, Defendants must deliver to Plaintiffs an affidavit that describes in reasonable detail all actions Defendants have taken and all steps Defendants have implemented on an ongoing basis to comply with Section VIII of this Final Judgment. Defendants must deliver to the United States an affidavit describing any changes to the efforts and actions outlined in Defendants' earlier affidavits filed pursuant to Section IX within fifteen (15) calendar days after the change is implemented.

C. Defendants must keep all records of all efforts made to preserve and divest the Divestiture Assets until one year after the divestiture has been completed.

X. Compliance Inspection

A. For the purposes of determining or securing compliance with this Final Judgment, or of related orders such as an Asset Preservation and Hold Separate Stipulation and Order, or of determining whether this Final Judgment should be modified or vacated, and subject to any legally-recognized privilege, from time to time authorized representatives of the United States, including agents retained by the United States, must, upon written request of an authorized representative of the Assistant Attorney General in charge of the Antitrust Division, and reasonable notice to Defendants, be permitted:

(1) access during Defendants' office hours to inspect and copy or, at the option of the United States, to require Defendants to provide electronic copies of all books, ledgers, accounts, records, data, and documents in the possession, custody, or control of Defendants relating to any matters contained in this Final Judgment; and

(2) to interview, either informally or on the record, Defendants' officers, employees, or agents, who may have their individual counsel present, regarding such matters. The interviews must be subject to the reasonable convenience of the interviewee and without restraint or interference by Defendants.

B. Upon the written request of an authorized representative of the Assistant Attorney General in charge of the Antitrust Division, Defendants must submit written reports or respond to written interrogatories, under oath if requested, relating to any of the matters contained in this Final Judgment.

C. No information or documents obtained pursuant to Section X may be divulged by the United States to any person other than an authorized representative of the executive branch of the United States or the Plaintiff States, except in the course of legal proceedings to which the United States is a party (including grand jury proceedings), for the purpose of securing compliance with this Final Judgment, or as otherwise required by law.

D. In the event of a request by a third party for disclosure of information under the Freedom of Information Act, 5 U.S.C. 552, the Antitrust Division will act in accordance with that statute, and the Department of Justice regulations at 28 CFR part 16, including the provision on confidential commercial information, at 28 CFR 16.7. Defendants submitting information to the Antitrust Division should designate the confidential commercial information portions of all applicable documents and information under 28 CFR 16.7. Designations of confidentiality expire ten years after submission, ''unless the submitter requests and provides justification for a longer designation period.'' *See* 28 CFR 16.7(b).

E. If at the time that Defendants furnish information or documents to the United States pursuant to Section X, Defendants represent and identify in writing information or documents for which a claim of protection may be asserted under Rule 26(c)(1)(G) of the Federal Rules of Civil Procedure, and Defendants mark each pertinent page of such material, ''Subject to claim of protection under Rule 26(c)(1)(G) of the Federal Rules of Civil Procedure,'' the United States must give Defendants ten (10) calendar days' notice before divulging the material in any legal proceeding (other than a grand jury proceeding).

XI. Notification

A. Unless a transaction is otherwise subject to the reporting and waiting period requirements of the Hart-Scott-Rodino Antitrust Improvements Act of 1976, as amended, 15 U.S.C. 18a (the ''HSR Act''), Defendants may not, during the term of this Final Judgment, directly or indirectly acquire any assets of or any interest, including any financial, security, loan, equity, or management interest, in an entity involved in Fluid Milk processing in the United States without providing advance notification to the United States and to any Plaintiff State in which any of the assets or interests are located or whose border is less than 150 miles from any such assets or interests; provided that notification will not be required pursuant to this Section where the assets or interest being acquired generated less than $1 million in revenue from the processing, marketing, sale, and distribution of Fluid Milk in the most recent completed calendar year.

B. Defendants must provide the notification required by Section XI in the same format as, and in accordance with the instructions relating to, the Notification and Report Form set forth in the Appendix to Part 803 of Title 16 of the Code of Federal Regulations as amended, except that the information requested in Items 5 through 8 of the instructions must be provided only about Fluid Milk processing. Notification must be provided at least thirty (30) calendar days before acquiring any such interest, and must include, beyond the information required by the instructions, the names of the principal representatives who negotiated the agreement on behalf of each party, and all management or strategic plans discussing the proposed transaction. If, within the 30-day period following notification, representatives of the United States make a written request for additional information, Defendants may not consummate the proposed transaction or agreement until thirty (30) calendar days after submitting all requested information. Early termination of the waiting periods in this Paragraph may be requested and, where appropriate, granted in the same manner as is applicable under the requirements and provisions of the HSR Act and rules promulgated thereunder. Section XI will be broadly construed and any ambiguity or uncertainty

regarding the filing of notice under Section XI will be resolved in favor of filing notice.

XII. No Reacquisition, Limitations on Collaborations

Defendants may not reacquire any part of or any interest in the Divestiture Assets during the term of this Final Judgment without the prior written consent of the United States in its sole discretion, after consultation with the Plaintiff States. In addition, Defendants and Acquirer(s) may not, without the prior written consent of the United States, enter into a new collaboration or expand the scope of an existing collaboration involving any of the Divestiture Assets during the term of this Final Judgment. The decision whether to consent to a collaboration is within the sole discretion of the United States.

XIII. Retention of Jurisdiction

The Court retains jurisdiction to enable any party to this Final Judgment to apply to the Court at any time for further orders and directions as may be necessary or appropriate to carry out or construe this Final Judgment, to modify any of its provisions, to enforce compliance, and to punish violations of its provisions.

XIV. Enforcement of Final Judgment

A. The United States retains and reserves all rights to enforce the provisions of this Final Judgment, including the right to seek an order of contempt from the Court. Defendants agree that in a civil contempt action, a motion to show cause, or a similar action brought by the United States regarding an alleged violation of this Final Judgment, the United States may establish a violation of this Final Judgment and the appropriateness of a remedy therefor by a preponderance of the evidence, and Defendants waive any argument that a different standard of proof should apply.

B. This Final Judgment should be interpreted to give full effect to the procompetitive purposes of the antitrust laws and to restore the competition the United States alleged was harmed by the challenged conduct. Defendants agree that they may be held in contempt of, and that the Court may enforce, any provision of this Final Judgment that, as interpreted by the Court in light of these procompetitive principles and applying ordinary tools of interpretation, is stated specifically and in reasonable detail, whether or not it is clear and unambiguous on its face. In any such interpretation, the terms of this Final Judgment should not be construed against either party as the drafter.

C. In an enforcement proceeding in which the Court finds that Defendants have violated this Final Judgment, the United States may apply to the Court for a one-time extension of this Final Judgment, together with other relief that may be appropriate. In connection with a successful effort by the United States to enforce this Final Judgment against a Defendant, whether litigated or resolved before litigation, that Defendant agrees to reimburse the United States for the fees and expenses of its attorneys, as well as all other costs, including experts' fees, incurred in connection with that enforcement effort, including in the investigation of the potential violation.

D. For a period of four (4) years following the expiration of this Final Judgment, if the United States has evidence that a Defendant violated this Final Judgment before it expired, the United States may file an action against that Defendant in this Court requesting that the Court order: (1) Defendant to comply with the terms of this Final Judgment for an additional term of at least four years following the filing of the enforcement action; (2) all appropriate contempt remedies; (3) additional relief needed to ensure the Defendant complies with the terms of this Final Judgment; and (4) fees or expenses as called for by this Section XIV.

XV. Expiration of Final Judgment

Unless the Court grants an extension, this Final Judgment will expire ten (10) years from the date of its entry, except that after five (5) years from the date of its entry, this Final Judgment may be terminated upon notice by the United States to the Court and Defendants that the divestitures have been completed and the continuation of this Final Judgment no longer is necessary or in the public interest.

XVI. Public Interest Determination

Entry of this Final Judgment is in the public interest. The parties have complied with the requirements of the Antitrust Procedures and Penalties Act, 15 U.S.C. 16, including by making available to the public copies of this Final Judgment, the Competitive Impact Statement, comments thereon, and the United States' responses to comments. Based upon the record before the Court, which includes the Competitive Impact Statement and any comments and responses to comments filed with the Court, entry of this Final Judgment is in the public interest.

Date: _____

[Court approval subject to procedures of Antitrust Procedures and Penalties Act, 15 U.S.C. 16]

_____

United States District Judge

Appendix A—DePere Ancillary Facilities

1. 1118 N. 17th Street, Sheboygan, Wisconsin 54115 (Garage/Parking)
2. 1233 Contract Drive, Ashwaubenon, Wisconsin 54304 (Warehouse)

Appendix B—Franklin Ancillary Facilities

1. 10 DiNunzio Road, Watertown, Connecticut 06795 (Cross-Dock/Warehouse)
2. 1376 West Central Street, Franklin, Massachusetts 02038 (Warehouse/Sales Office)
3. 1701 Hammond Street, Hermon, Maine 04401 (Distribution Depot)
4. 131 Rand Road, Portland, Maine 04102 (Parking)
5. 10 Creek Brook Drive, Haverhill, Massachusetts 01832 (Warehouse)

Appendix C—Harvard Ancillary Facilities

1. 3600 River Road, Franklin Park, Illinois 60131 (Depot)
2. 23914 and 23916 Center Street, Harvard, Illinois 60033 (Parking/Part of Plant)
3. 24114 Route 173, Harvard, Illinois 60033 (Part of Plant)
4. 965 S. Wyckles Road, Decatur, Illinois 62521 (Depot/Office)
5. 450 Comanche Circle, Harvard, Illinois 60033 (Warehouse)
6. Dry Storage, 6303 Maxon Road, Harvard, Illinois 60033
7. Sludge Site, 6303 Maxon Road, Harvard, Illinois 60033
8. Alco (Alders) Storage Area, 6303 Maxon Road, Harvard, Illinois 60033
9. Railroad Encroachment Area, 6303 Maxon Road, Harvard, Illinois 60033

UNITED STATES DISTRICT COURT FOR NORTHERN DISTRICT OF ILLINOIS EASTERN DIVISION

UNITED STATES OF AMERICA, COMMONWEALTH OF MASSACHUSETTS, and STATE OF WISCONSIN, Plaintiffs, v. *DAIRY FARMERS OF AMERICA, INC. and DEAN FOODS COMPANY, Defendants.*

Case No. 1:20–cv–02658

Competitive Impact Statement

The United States of America, under Section 2(b) of the Antitrust Procedures and Penalties Act, 15 U.S.C. 16(b)–(h) (the ''APPA'' or ''Tunney Act''), files this Competitive Impact Statement relating to the proposed Final Judgment submitted for entry in this civil antitrust proceeding.

I. Nature And Purpose of the Proceeding

Dean Foods Company (''Dean'') filed for bankruptcy on November 12, 2019, in the United States Bankruptcy Court for the Southern District of Texas. The

bankruptcy court ordered an auction and then accelerated the auction process because of Dean's liquidity condition. On March 30, 2020, Dairy Farmers of America, Inc. (''DFA'') bid for 44 of Dean's plants for a total value of $433 million. No other bidder submitted a bid for the 44 Dean plants, or anything even close to that number of plants, under the bankruptcy court's schedule. The bid was accepted by Dean and was the only transaction for those 44 plants approved by the bankruptcy court.

The United States, along with the state of Wisconsin and the Commonwealth of Massachusetts (collectively, the ''Plaintiff States''), filed a civil antitrust complaint on May 1, 2020, seeking to enjoin the proposed transaction. Based on a comprehensive investigation, the Complaint alleges that the likely effect of this transaction would be to substantially lessen competition for the processing and sale of Fluid Milk in areas encompassing (1) northeastern Illinois and Wisconsin and (2) New England in violation of Section 7 of the Clayton Act, 15 U.S.C. 18. ''Fluid Milk'' is raw milk that has been processed for human consumption as a beverage, but does not include organic milk, soy milk, extended shelf life milk, ultra-high temperature milk, or aseptic milk.

At the same time the Complaint was filed, the United States filed an Asset Preservation and Hold Separate Stipulation and Order (''Stipulation and Order'') and proposed Final Judgment, which are designed to address the anticompetitive effects of the acquisition. Under the proposed Final Judgment, which is explained more fully below, DFA is required to divest Dean's Fluid Milk processing plants, ancillary facilities, and related tangible and intangible assets located in Franklin, Massachusetts (''Franklin Plant''); De Pere, Wisconsin (''De Pere Plant''); and Harvard, Illinois (''Harvard Plant'') (collectively the ''Divestiture Plants''). Under the terms of the Stipulation and Order, Defendants will take certain steps to ensure that, during the pendency of the required divestitures, the Divestiture Plants will remain independent and ongoing business concerns that will remain uninfluenced by Defendants and the level of competition for the processing and sale of Fluid Milk that existed between Defendants prior to the transaction will be maintained.

The United States and Defendants have stipulated that the proposed Final Judgment may be entered after compliance with the APPA. Entry of the proposed Final Judgment will terminate this action, except that the Court will retain jurisdiction to construe, modify, or enforce the provisions of the Final Judgment and to punish violations thereof.

II. Description of Events Giving Rise to the Alleged Violation

(A) The Defendants and the Proposed Transaction

35. Dean is a Delaware corporation with its headquarters in Dallas, Texas. Until its recent bankruptcy filing, Dean was the largest Fluid Milk processor in the country, operating at that time 57 Fluid Milk processing plants in 29 states. Dean had 2018 revenues of $7.75 billion.

36. DFA is organized under the laws of the State of Kansas and is the largest cooperative of dairy farmers in the country, with nearly 14,000 members. In 2018, DFA marketed 64.5 billion pounds of raw milk—an amount that accounted for approximately 30% of all raw milk produced in the United States. DFA had 2018 revenues of $13.6 billion.

37. DFA is vertically integrated through its ownership interests in milk processing plants. DFA owns eight Fluid Milk processing plants around the country and has a significant stake in a joint venture that owns twelve additional Fluid Milk processing plants. In the northeastern Illinois and Wisconsin area, DFA owns a Fluid Milk processing plant in Cedarburg, Wisconsin. In the New England area, DFA owns Fluid Milk processing plants in New Britain, Connecticut and Portland, Maine. These plants compete directly against the Harvard Plant, De Pere Plant, and/or Franklin Plant that DFA proposes to acquire from Dean.

38. Dean filed for Chapter 11 bankruptcy protection on November 12, 2019. Simultaneous with the bankruptcy filing, Dean announced that it was in discussions to sell some or all of its Fluid Milk processing plants to DFA. Dean's financial position continued to worsen in the months after its bankruptcy filing and then was exacerbated by shrinking school and restaurant demand for milk caused by the coronavirus pandemic. Dean informed the bankruptcy court of its worsening financial condition and that it would not be able to pay farmers for raw milk or be certain that it could continue to process Fluid Milk beyond May 2020. Dean's worsening financial condition caused the bankruptcy court to accelerate the bankruptcy auction process to allow Dean to find buyers for its assets before the company would have to cease operations due to a lack of funds. By order of the bankruptcy court, Dean accepted bids for its assets and selected winning bidders on March 30, 2020. Dean selected DFA as the winning bidder for most of Dean's assets and began the process of closing down some plants that no one had sought to acquire during the bankruptcy process.

On March 31, 2020, DFA and Dean entered into an asset purchase agreement whereby DFA agreed to purchase 44 of Dean's 57 Fluid Milk processing plants, along with related assets, for $433 million. The purchase price includes $325 million in cash and $108 million in forgiveness of debt Dean owed DFA.

(B) The Competitive Effects of the Proposed Transaction

DFA's existing Fluid Milk processing plants overlap with two Dean plants that it proposes to acquire in northeastern Illinois and Wisconsin—the Harvard Plant and the De Pere Plant—and with Dean's Franklin Plant in New England. The Complaint alleges that DFA and Dean are two of only three significant Fluid Milk processors that can serve customers, including supermarkets and schools, in each of these geographic areas. If the acquisition were permitted to proceed, DFA would control nearly 70% of the Fluid Milk market in northeastern Illinois and Wisconsin and approximately 51% of the Fluid Milk market in New England. DFA and Dean compete head-to-head to supply Fluid Milk customers in these areas today, and those customers rely on competition between DFA and Dean to get lower prices and better terms. If DFA's and Dean's plants in these areas were owned by a single entity, this competitive dynamic would no longer exist, leading to higher prices and inferior service for supermarkets, schools, and other Fluid Milk customers and ultimately, millions of individual consumers.

1. The Processing and Sale of Fluid Milk Is a Relevant Product Market

39. The Complaint alleges that the processing and sale of Fluid Milk is a relevant product market and line of commerce under Section 7 of the Clayton Act. Consumers have long-held cultural and taste preferences for Fluid Milk over other beverages, and Fluid Milk has particular nutritional benefits and qualities for use in cooking. Consequently, consumer demand for Fluid Milk is relatively inelastic, which simply means that Fluid Milk consumption does not decrease significantly in response to a price increase. Fluid Milk is distinct from organic milk, soy milk, extended shelf-life milk, ultra-high temperature milk, and aseptic milk, which are produced

by different processes, have numerous significant differences, and generally cost much more than Fluid Milk.

40. The Complaint alleges that retailers, supermarkets, distributors, and other Fluid Milk customers are unlikely to substitute other products for Fluid Milk because the individual consumers that they serve continue to demand Fluid Milk. This means, for example, that a grocery store would not substitute to other beverages because its customers will not buy other beverages as an alternative to Fluid Milk. Schools are similarly unlikely to substitute away from Fluid Milk in response to even a substantial price increase because they are required by federal regulations to offer Fluid Milk to students in order to qualify to receive federal reimbursements for meals served to lower-income students.

41. For these reasons, the Complaint alleges that the processing and sale of Fluid Milk satisfies the well-accepted ''hypothetical monopolist'' test set forth in the U.S. Department of Justice and Federal Trade Commission *2010 Horizontal Merger Guidelines* (''*Horizontal Merger Guidelines*''). This test asks whether a hypothetical monopolist processing and selling Fluid Milk likely would impose a small but significant and non-transitory price increase (*e.g.,* five percent) because an insufficient number of customers would switch to alternatives to make that price increase unprofitable. The Complaint alleges that this test is satisfied.

2. The Two Relevant Geographic Markets Are Northeastern Illinois and Wisconsin and New England

42. The Complaint also alleges two relevant geographic markets: (1) northeastern Illinois and Wisconsin and (2) New England. Fluid Milk processors charge different prices to buyers in different areas. Prices are negotiated individually, and Fluid Milk's high transportation costs and limited shelf life mean that customers cannot practically buy Fluid Milk from each other to avoid a higher price charged by processors. In other words, Fluid Milk processors can engage in ''price discrimination,'' meaning that they can charge different prices to different customers. When price discrimination is possible, relevant geographic markets may be defined by reference to the location of the customer. In particular, a relevant geographic market for the processing and sale of Fluid Milk, as alleged in the Complaint, is a region within which customers can be targeted for a price increase. Most customers purchase Fluid Milk from suppliers and processing plants located near them because transportation costs and shelf life make sourcing from more distant suppliers prohibitive.

43. The Complaint alleges that northeastern Illinois, which includes Chicago and its suburbs, and the state of Wisconsin together comprise a relevant geographic market and section of the country within the meaning of Section 7 of the Clayton Act. Similarly, New England—including the states of Connecticut, Maine, Massachusetts, New Hampshire, Rhode Island, and Vermont—is a relevant geographic market and section of the country within the meaning of Section 7 of the Clayton Act. A hypothetical monopolist processing and selling Fluid Milk in either of these two areas likely would find it profitable to impose a small but significant and non-transitory price increase (*e.g.,* five percent) because customers could not economically switch their source of supply to more distant sources.

3. The Acquisition Results in Large Combined Market Shares

44. DFA's acquisition of Dean's Fluid Milk processing plants would result in a substantial increase in the concentration of processors that compete to supply Fluid Milk to customers in the northeastern Illinois and Wisconsin geographic market and the New England geographic market. The Complaint alleges that DFA and Dean are two of only three significant Fluid Milk processors that sell into each of these geographic markets. In both geographic markets, the acquisition would eliminate one competitor, leaving only two remaining competitive options for Fluid Milk customers, with DFA controlling a significant majority of the Fluid Milk sales. Although there are also small or fringe Fluid Milk processors in each market, these processors are not competitive options for most Fluid Milk customers because they are much smaller and lack the capabilities necessary to compete against processors like DFA and Dean.

45. The Supreme Court has held that mergers that significantly increase concentration in already concentrated markets are presumptively anticompetitive and therefore presumptively unlawful. To measure market concentration, courts often use the Herfindahl-Hirschman Index (''HHI'') as described in the *Horizontal Merger Guidelines.* HHIs range from 0 in markets with no concentration to 10,000 in markets where one firm has a 100% market share. According to the *Horizontal Merger Guidelines,* mergers that increase the HHI by more than 200 and result in an HHI above 2,500 in any market are presumed to be anticompetitive and, therefore, unlawful.

46. The Complaint alleges that the acquisition of Dean's plants by DFA is presumptively unlawful in northeastern Illinois and Wisconsin. For Fluid Milk customers in this geographic market, a conservative estimate of the combined market share of Dean's Harvard Plant and De Pere Plant and DFA's processing plant in Cedarburg, Wisconsin is 70%. The result is a highly concentrated market with an HHI of nearly 5,200 and an increase in HHI of almost 1,900.

47. As alleged in the Complaint, the acquisition is also presumptively unlawful in the New England geographic market. For Fluid Milk customers in the New England geographic market, a conservative estimate of the combined market share of Dean's Franklin Plant and DFA's processing plants in New Britain, Connecticut, and Portland, Maine is 51%. The result is a highly concentrated market with an HHI of approximately 3,300 and an increase in HHI of over 1,000.

4. The Merger Would Eliminate Head-to-Head Competition Between DFA and Dean

48. The Complaint alleges that DFA's acquisition of Dean's plants in northeastern Illinois and Wisconsin and in New England would eliminate head-to-head competition that has benefitted and would otherwise continue to benefit supermarkets, schools, and other Fluid Milk customers in the relevant geographic markets. For reasons related to service and delivery capabilities, some Fluid Milk customers consider DFA and Dean to be their only practical options. Especially for customers like large supermarket chains, DFA and Dean are two of only three competitive Fluid Milk processors in these geographic markets, and they are often the two lowest-price options in these geographic markets.

49. Customers often solicit bids from Fluid Milk processors and select the bidder that offers the lowest price. These customers often leverage a lower-priced bid from one supplier to obtain improved offers and lower prices from other bidders during individual negotiations. Even customers who use less formal procurement processes benefit from the presence of competitive alternatives, which constrain the prices that all Fluid Milk processors can charge. The Complaint alleges that Fluid Milk customers in the relevant geographic markets have historically used competing bids from DFA and Dean to obtain lower prices.

50. As described above, the Complaint alleges that customers typically purchase Fluid Milk from processing plants located close to them because of shelf-life restrictions and the costs associated with transportation of the product. These transportation costs comprise a significant portion of the prices that Fluid Milk processors charge customers. Therefore, the lowest-price Fluid Milk processors available to customers typically are the ones located closest to them. For many Fluid Milk customers in the relevant geographic markets, DFA and Dean are two of the closest processing plants and, as the Complaint alleges, two of the most competitive or lowest-price options. The only other significant competitors selling Fluid Milk to customers in these markets are unlikely to substantially mitigate the loss of competition between DFA and Dean that would result from the acquisition.

51. Many customers also have particular product and service requirements that not all Fluid Milk processors can meet. Supermarkets, convenience stores, schools, and other customers often require processors to arrange direct-store delivery, or ''DSD,'' where the processor delivers Fluid Milk to each of the customer's locations on a set schedule—sometimes as often as daily. Schools typically require milk to be packaged in small half-pint containers that require a separate bottling line and dedicated equipment. Only DFA and Dean, along with the third significant competitor in each of the relevant geographic markets, can satisfy these complex product and service requirements, while other smaller processors cannot.

5. The Acquisition Would Make It Easier for Competitors To Coordinate

52. The Complaint alleges that by reducing the number of significant Fluid Milk processors in northeastern Illinois and Wisconsin and in New England from three to two, the acquisition would make it easier for the remaining two significant processors to coordinate. Markets, such as Fluid Milk markets, with few significant competitors, relatively homogenous products, and where demand for the product is not significantly affected by an increase in its price are susceptible to coordination because these features are among those that make coordination more likely to be effective and profitable.

53. In addition, there is a history of anticompetitive coordination, including price fixing, bid rigging, and customer allocation in Fluid Milk markets in the United States and, in particular, in the sale of milk to schools. Numerous Fluid Milk processors, including Dean itself, have engaged in criminal collusive activities at various times over the last 40 years. Given this history of coordination among Fluid Milk processors and the reduction in the number of significant competitors in each of the relevant geographic markets, the acquisition makes coordination more likely to occur in these markets.

6. Potential Entrants and Merger Efficiencies Do Not Offset Competitive Harm From the Merger

54. As alleged in the Complaint, entry by Fluid Milk processors outside the relevant geographic markets is unlikely to be sufficient or timely enough to offset the anticompetitive effects of the acquisition. Processors who do not currently serve these markets are unlikely to begin shipping a significant quantity of Fluid Milk into the relevant geographic markets due to the same factors that make them uncompetitive in these markets today, including transportation costs and the lack of necessary capabilities or levels of service. Any milk that could be shipped into the relevant geographic markets likely could not be competitively priced because of the high transportation costs. Nor could these processors economically deliver Fluid Milk to customers like schools because they lack local distribution networks.

55. The construction of a new Fluid Milk processing plant to serve customers in either of the relevant geographic markets is very unlikely because of the high costs of building a Fluid Milk processing plant—especially as Fluid Milk consumption continues to decline. Numerous Fluid Milk processing plants have closed in the last ten years across the United States, while only a few new plants have been built, and these newly-built plants were largely for retailers to supply their own stores. Finally, the two largest Fluid Milk processors in the country, Dean and Borden Dairy Company, have filed for bankruptcy.

The Complaint also alleges that potential harm from the proposed merger is unlikely to generate verifiable, merger-specific efficiencies sufficient to outweigh the anticompetitive effects that are likely to occur in the provision of Fluid Milk in the relevant geographic markets.

III. Explanation of the Proposed Final Judgment

The divestitures required by the proposed Final Judgment will remedy the loss of competition alleged in the Complaint by establishing independent Fluid Milk processing competitors in northeastern Illinois and Wisconsin and in New England. The proposed Final Judgment requires DFA to divest Dean's De Pere Plant, Franklin Plant, and Harvard Plant, related ancillary facilities (such as warehouses and sales offices), and tangible and intangible assets related to or used in connection with the processing, marketing, sale, or distribution of Fluid Milk and all other products by each of the Divestiture Plants. The divestitures are to occur within 30 days (with extensions that may be granted in the sole discretion of the United States not to exceed 60 days) after the entry of the Stipulation and Order by the Court.

(A) The Divestiture Plants

The proposed Final Judgment defines three sets of divestiture assets, one for each Divestiture Plant. Each set of assets must be divested in such a way as to satisfy the United States in its sole discretion, after consultation with the Plaintiff States, that they can and will be operated by the purchaser as a viable, ongoing business that can compete effectively in the market for the processing and sale of Fluid Milk in the relevant geographic market. Defendants must use their best efforts to accomplish the divestitures as expeditiously as possible and must cooperate with potential divestiture buyers.

The proposed Final Judgment requires that a single divestiture buyer acquire both the De Pere Plant and the Harvard Plant, unless the United States exercises its discretion to permit separate purchasers. The United States prefers that the Harvard Plant and De Pere Plant be sold together because the plants will likely be able to more successfully compete if operated jointly. Though the Harvard Plant and De Pere Plant could each operate independently, divesting them to the same buyer would more closely replicate for the buyer the advantages that Dean held before the transaction, including, among others, the ability for the plants to (1) assist each other with operations and distribution, including the capability to serve as backup for each other, (2) serve a contiguous set of customers, and (3) share the regional ''Dean's'' brand. The United States maintains the sole discretion to approve separate buyers for the Harvard Plant and De Pere Plant under the proposed Final Judgment if it can be demonstrated to the United States that separate buyers can restore the competition that the Complaint alleges would have been lost by the transaction. The Franklin Plant, which is in a different geographic market than the Harvard and De Pere Plants, may be divested to a different purchaser.

(B) Brands and Licenses

Branded milk represents a distinct minority of total Fluid Milk sales at the Divestiture Plants. The majority of Fluid Milk sales are for private-label products—that is, products labeled with the brand of the retailer rather than the manufacturer. Nevertheless, in order to protect the viability of the Divestiture Plants and related businesses that will be divested, the proposed Final Judgment requires a combination of brand divestitures and brand licenses that are based upon a fact-specific analysis of the historic sales by each individual Divestiture Plant.

The brands used at each of the Divestiture Plants varies among a combination of local or sub-regional, regional, and national brands. The local or sub-regional brands include Garelick Farms, which is used at the Franklin Plant, and Morning Glory and Farm Fresh, which are both used at the De Pere Plant. The regional ''Dean's'' brand is used at the De Pere Plant and the Harvard Plant. Dean's national brands—used at all three Divestiture Plants—are Dairy Pure and Dean's chocolate milk brand, TruMoo. Dean typically uses Dairy Pure as a cobrand with local or sub-regional brands and regional brands, including the Garelick Farms, Morning Glory, and Farm Fresh brands used at the Divestiture Plants.

The local or sub-regional brands—Garelick Farms, Morning Glory, and Farm Fresh—will transfer to the divestiture buyers of the plants where the local or sub-regional branded products are sold. Garelick Farms will transfer to the buyer of the Franklin Plant. Morning Glory and Farm Fresh will transfer to the buyer of the De Pere Plant. Transferring ownership of these brands will place the divestiture buyers in the same position as Dean was before the transaction with respect to these local or sub-regional brands.

The buyer(s) of the Divestiture Plants will receive licenses—rather than ownership—to use the national and regional brands (*i.e.,* Dairy Pure, TruMoo, and ''Dean's'') in geographic areas that cover nearly all of each of the Divestiture Plants' existing sales footprints. The proposed Final Judgment provides licenses rather than ownership for these brands because the brands are used across the United States. Most Dean plants sell at least some TruMoo, ''Dean's,'' and Dairy Pure brand products, and an overwhelming majority of the sales for these brands come from Dean plants that DFA has acquired and is retaining. In contrast, the local or sub-regional brands that are being divested are used at a smaller number of Dean plants in smaller areas surrounding the Divestiture Plants.

The divestiture buyer of each Divestiture Plant will receive transitional licenses to the national brands, TruMoo and Dairy Pure. Because Dairy Pure frequently is cobranded, the divestiture buyer will be able to use the transitional license to continue to cobrand products while it changes its packaging and rebrands its products. The TruMoo brand makes up a small percentage of the sales at the Divestiture Plants and is not necessary for the future viability of the Divestiture Plants and related business. Therefore, the divestiture buyers will each receive a transitional license for the TruMoo brand. They will also receive a perpetual license to the intellectual property, product formulas, technology, and know-how for TruMoo because consumers value the taste of the TruMoo milk and the divestiture buyers will benefit from the ability to perpetually offer chocolate milk with the same taste. These TruMoo licenses will permit each buyer to transition chocolate milk sales to its local or sub-regional brand, the ''Dean's'' brand, or another brand of its choice while continuing to use the same chocolate milk formula perpetually.

If the buyer of the Harvard Plant and the De Pere Plant are the same, as the proposed Final Judgment anticipates, the buyer will receive a perpetual license to the ''Dean's'' brand that it could use for sales within a multistate area set forth in the proposed Final Judgment from either or both plants. If the buyers of the two plants are different, the buyer of the Harvard Plant, and not the buyer of the De Pere Plant, will receive a perpetual license to the ''Dean's'' brand. This accounts for the fact that the Harvard Plant sells more than two times the amount of ''Dean's'' brand Fluid Milk as compared to the De Pere Plant and the buyer of the Harvard Plant will not receive a perpetual license or ownership of any other brand. If a separate buyer acquires the De Pere Plant, it will receive a transitional license to the ''Dean's'' brand. This transitional license will give the buyer the opportunity to move sales to its local or sub-regional brands or another brand.

The proposed Final Judgment requires these transfers and licenses so that the divestiture buyers will be placed, to the greatest extent possible, in the same position as Dean prior to the transaction and will have the ability to operate the Divestiture Plants as independent and ongoing business concerns.

1. Franklin Plant

Under the proposed Final Judgment, the divestiture buyer of the Franklin Plant will own the local and sub-regional brands used at the Franklin Plant and receive transitional licenses for the national brands. The Franklin Plant currently uses the Garelick Farms brand and the national brands Dairy Pure and TruMoo. Garelick Farms branded products are sold throughout New England. Ownership of the Garelick Farms brand will transfer to the buyer of the Franklin Plant. The buyer of the Franklin Plant will also receive a non-exclusive, royalty-free, paid-up, irrevocable, nationwide two-year transitional license for both the Dairy Pure and TruMoo national brands. The Dairy Pure license ensures that the buyer will have sufficient time to transition away from the cobranding of Dairy Pure with Garelick Farms. Similarly, the TruMoo license will permit the buyer time to transition its chocolate milk to the Garelick Farms brand or develop its own chocolate milk brand. In order to ensure consistency in the quality of the TruMoo branded products and to allow the divestiture buyer to offer its own chocolate milk brand without altering the taste that consumers may prefer, the divestiture assets also include a non-exclusive, royalty-free, paid-up, irrevocable, perpetual, nationwide license to the intellectual property, including the formula and know-how, for the TruMoo products.

2. Harvard Plant

Under the proposed Final Judgment, the divestiture buyer of the Harvard Plant will receive perpetual licenses to the regional ''Dean's'' brand and transitional licenses for the national brands. The Harvard Plant currently uses the regional ''Dean's'' brand and the national brands Dairy Pure and TruMoo. Because the Harvard Plant relies on the ''Dean's'' brand for its branded sales, the buyer will receive an exclusive, royalty-free, paid-up, irrevocable, perpetual license to use the ''Dean's'' brand in Illinois, Wisconsin, Indiana, and the Upper Peninsula of Michigan. Further, the buyer will receive a non-exclusive, royalty-free, paid-up, irrevocable, perpetual license to use the ''Dean's'' brand in Minnesota, Iowa, and the Lower Peninsula of Michigan. The geographies where the buyer's license is exclusive represents the primary area where the Harvard Plant sells its products. The addition of the non-exclusive geographies ensures that the buyer will be able to offer the same brand to more distant customers

and will not be hampered in its ability to compete in those more distant geographies. The divestiture assets for the Harvard Plant also include the same transitional licenses to Dairy Pure and TruMoo, as well as the same perpetual license for the TruMoo intellectual property, as the divestiture assets for the Franklin Plant.

3. De Pere Plant

Under the proposed Final Judgment, the divestiture buyer of the De Pere Plant will own the local brands that are primarily used by the De Pere plant and will receive transitional licenses for the national brands and regional ''Dean's'' brand. The De Pere Plant currently uses the local Morning Glory, Farm Fresh, and Jilbert brands, the national brands Dairy Pure and TruMoo, and the regional ''Dean's'' brand. Ownership of the Morning Glory and Farm Fresh brands, both of which are strong local brands, will transfer to the buyer of the De Pere Plant. The buyer of the De Pere Plant also will receive the same transitional licenses to Dairy Pure and TruMoo, as well as the same perpetual license for the TruMoo intellectual property, as the buyers of the Franklin Plant and the Harvard Plant. In addition to ownership of the local brands and licenses to the national brands, the De Pere Plant buyer will receive a two-year non-exclusive, royalty-free, paid-up, irrevocable, nationwide license to use the ''Dean's'' brand. This transitional license will ensure that, in the event that the buyer of the De Pere Plant is not the same as the buyer of the Harvard Plant, the De Pere Plant buyer will have sufficient time to transition away from cobranding. If, as expected, the buyer of the De Pere Plant is also the buyer of the Harvard Plant, the buyer will also be able to use the perpetual ''Dean's'' license from the Harvard Plant divestiture to cover sales from the De Pere Plant within the applicable geography. Though the De Pere Plant also sells some products under the local Jilbert brand, those sales are *de minimis.* Because of the very limited use of that brand, which is used primarily by a plant that is not subject to divestiture, the Jilbert brand is not a part of the De Pere divestiture assets.

(C) Other Provisions

In order to preserve competition and facilitate the success of the potential divestiture buyers, the proposed Final Judgment contains additional obligations for Defendants. Paragraph IV(C) of the proposed Final Judgment requires Defendants to facilitate each buyer's hiring of employees whose jobs relate to the processing, marketing, sale, or distribution of Fluid Milk or any other products by the Divestiture Plants. In particular, the proposed Final Judgment requires that Defendants provide each buyer, the United States, and the Plaintiff States, with organization charts and information relating to the employees and make employees available for interviews. It also provides that Defendants must not interfere with any negotiations to hire these employees by a buyer of these assets. In addition, for employees who elect employment with a buyer, Defendants must waive all non-compete and non-disclosure agreements, vest all unvested pension and other equity rights, and provide all benefits that the employees would generally have been provided if the employees had continued employment with Defendants. This provision will help to ensure that the buyers will be able to hire qualified employees for the Divestiture Plants and related businesses.

Paragraph IV(G) of the proposed Final Judgment facilitates the transfer of customers and other contractual relationships from Defendants to each buyer. Defendants must transfer all contracts, agreements, and customer relationships. For those contracts, agreements, or customer relationships that extend beyond the Divestiture Plants, Defendants must transfer the relevant portions of those contracts, agreements, or customer relationships. For contracts or agreements that require another party's consent to transfer, Defendants must use their best efforts to accomplish the transfer. The paragraph also requires Defendants to send a letter to any customer of a Divestiture Plant that does not have a written contract within five business days of the closing of the divestiture of the relevant Divestiture Plant. The letter, which is subject to the prior approval of the United States, must notify each such customer that the buyer of the Divestiture Plant will be the customer's new supplier. This provision will help initiate contact between the buyer and the customer so that a relationship can be immediately established. Defendants may not interfere with any negotiations between a buyer and a customer or another contracting party. Finally, Defendants must release each buyer from any of Dean's obligations to purchase raw milk from DFA, allowing the buyer to seek its own suppliers for raw milk and not be beholden to DFA. Defendants are, however, required to enter into a supply contract for raw milk for a transitional period at the option of each buyer, as described below, to ensure that the buyer has an adequate supply as it takes over operations.

Paragraph IV(H) of the proposed Final Judgment requires Defendants to use best efforts to help each buyer apply for and secure any necessary governmental approval for any governmental license or authorization that cannot be transferred to the buyer. This provision will help to facilitate the transition of the business to the buyer without disruption due to any issues involving governmental licensures or authorizations.

Paragraph IV(I) of the proposed Final Judgment requires Defendants, at the option of each buyer, to enter raw milk supply agreements sufficient to meet each buyer's needs for up to three months. The United States, in its sole discretion, and upon the buyer's request, may approve an extension for up to an additional three months. This provision will help to ensure that the buyers will not face disruption to their supply of raw milk during this important transitional period.

Paragraph IV(J) of the proposed Final Judgment requires Defendants, at the option of each buyer, to enter agreements to provide transition services for a period of up to six months (with an option for the United States, after consultation with the Plaintiff States, to extend the period for an additional six months, in its sole discretion) to facilitate the transfer and operation of the relevant divestiture assets. This paragraph further provides that employees of Defendants tasked with supporting these agreements must not share any competitively sensitive information of the buyers with any other employees of Defendants.

Paragraph IV(L) of the proposed Final Judgment prohibits, for a period of one year, Defendants from soliciting business from customers supplied from a Divestiture Plant by initiating customer-specific communications for the portion of that customer's business that is covered by a contract, agreement, or relationship that is included in the divestiture assets. This prohibition will help each buyer establish and maintain important customer relationships.

Paragraph IV(M) addresses the fact that the Franklin Plant is located on leased property. Dean had an unassignable option to acquire the land, which it had not exercised. Through the bankruptcy process, the otherwise unassignable option was assigned to DFA but cannot be further assigned to the divestiture buyer of the Franklin Plant. Paragraph IV(M) requires DFA, at the Franklin Plant buyer's request, to (1) exercise DFA's non-assignable option to purchase the real estate on which the

Franklin Plant is located, and (2) sell to the buyer of the Franklin Plant the real estate at the same price that DFA pays for the property under DFA's non-assignable option to purchase. This provision puts the buyer of the Franklin Plant in the same position as Dean before DFA acquired the Dean assets by providing the buyer with the same option to acquire the real estate that Dean had, even though the option is non-assignable and therefore cannot be included in the Franklin Plant divestiture assets.

If Defendants do not accomplish the divestitures within the period prescribed in the proposed Final Judgment, or if Defendants waive their right to first attempt to divest the Franklin Plant and related assets, or the Harvard Plant and De Pere Plant and their related assets, as permitted by Paragraph V(A) of the proposed Final Judgment, the proposed Final Judgment provides that the Court will appoint a divestiture trustee selected by the United States to effect the divestitures, or a portion thereof. If a divestiture trustee is appointed, the proposed Final Judgment provides that Defendants will pay all costs and expenses of the trustee. The divestiture trustee's commission will be structured so as to provide an incentive for the trustee based on the price obtained and the speed with which the divestiture is accomplished. After the divestiture trustee's appointment becomes effective, the trustee will provide monthly reports to the United States and Plaintiff States setting forth his or her efforts to accomplish the divestiture.

At the end of an initial term of 60 days (with extensions that may be granted in the sole discretion of the United States not to exceed an additional 60 days), if the divestiture of the Divestiture Plants and other divestiture assets has not been accomplished, DFA can file a motion with the Court requesting that the Stipulation and Order be terminated and the Final Judgment be modified to allow DFA to retain those divestiture assets. This option for the divestiture assets to potentially revert back to DFA is included because of Dean's dire financial circumstance, the distressed condition of the Fluid Milk industry, the likelihood of additional Fluid Milk processing plant closures, and the desire to keep the plants operating, rather than shutting them down if buyers cannot be found. This will allow customers to continue having an adequate supply of Fluid Milk.

The proposed Final Judgment contains a notification provision in Section XI designed to give the United States the opportunity to review all of Defendants' future acquisitions, including acquisitions of partial or indirect interests, that involve entities that have generated more than $1 million in revenue from the processing, marketing, sale, and distribution of Fluid Milk in the prior completed calendar year. Section XI requires DFA to notify the United States, and any Plaintiff State in which any of the assets or interests are located or whose border is less than 150 miles from any such assets or interests, in the same form, with some modifications, as it would for a Hart-Scott-Rodino Antitrust Improvements Act (the ''HSR Act'') filing, as specified in the Appendix to Part 803 of Title 16 of the Code of Federal Regulations. Notice must be made 30 calendar days before the acquisition. Section XI further provides for waiting periods and opportunities for the United States to obtain additional information similar to the provisions of the HSR Act before such acquisitions can be consummated. This provision ensures that the United States and relevant Plaintiff States will have the opportunity to review, for example, any future acquisitions of additional Dean assets by DFA. In particular, this provision would require advance notice of any attempt by DFA to acquire the Land O'Lakes plants in Woodbury, Minnesota; Sioux Falls, South Dakota; and Bismarck, North Dakota, which DFA did not include in its present acquisition due to the competitive concerns expressed to DFA by the United States.

Section XII of the proposed Final Judgment prevents Defendants from reacquiring any part of or interest in the divestiture assets without prior consent from the United States, after consultation with the Plaintiff States. It also prevents Defendants from entering new collaborations or expanding existing collaborations involving the divestiture assets without prior consent.

The proposed Final Judgment also contains provisions designed to promote compliance and make the enforcement of the Final Judgment as effective as possible. Paragraph XIV(A) provides that the United States retains and reserves all rights to enforce the provisions of the Final Judgment, including its rights to seek an order of contempt from the Court. Under the terms of this paragraph, Defendants have agreed that in any civil contempt action, any motion to show cause, or any similar action brought by the United States regarding an alleged violation of the Final Judgment, the United States may establish the violation and the appropriateness of any remedy by a preponderance of the evidence and that Defendants have waived any argument that a different standard of proof should apply. This provision aligns the standard for compliance obligations with the standard of proof that applies to the underlying offense that the compliance commitments address.

Paragraph XIV(B) provides additional clarification regarding the interpretation of the provisions of the proposed Final Judgment. The proposed Final Judgment is intended to restore competition that the United States alleged would otherwise be harmed by the transaction. Defendants agree that they will abide by the proposed Final Judgment, and that they may be held in contempt of this Court for failing to comply with any provision of the proposed Final Judgment that is stated specifically and in reasonable detail, as interpreted in light of this procompetitive purpose.

Paragraph XIV(C) of the proposed Final Judgment provides that if the Court finds in an enforcement proceeding that Defendants have violated the Final Judgment, the United States may apply to the Court for a one-time extension of the Final Judgment, together with such other relief as may be appropriate. In addition, to compensate American taxpayers for any costs associated with investigating and enforcing violations of the Final Judgment, Paragraph XIV(C) provides that in any successful effort by the United States to enforce the Final Judgment against a Defendant, whether litigated or resolved before litigation, that Defendant will reimburse the United States for attorneys' fees, experts' fees, and other costs incurred in connection with any enforcement effort, including the investigation of the potential violation.

Paragraph XIV(D) states that the United States may file an action against a Defendant for violating the Final Judgment for up to four years after the Final Judgment has expired or been terminated. This provision is meant to address circumstances such as when evidence that a violation of the Final Judgment occurred during the term of the Final Judgment is not discovered until after the Final Judgment has expired or been terminated or when there is not sufficient time for the United States to complete an investigation of an alleged violation until after the Final Judgment has expired or been terminated. This provision, therefore, makes clear that, for four years after the Final Judgment has expired or been terminated, the United States may still challenge a violation that occurred during the term of the Final Judgment.

Finally, Section XV of the proposed Final Judgment provides that the Final Judgment will expire ten years from the date of its entry, except that after five years from the date of its entry, the Final Judgment may be terminated upon notice by the United States to the Court and Defendants that the divestiture has been completed and that the continuation of the Final Judgment is no longer necessary or in the public interest.

IV. Remedies Available to Potential Private Litigants

Section 4 of the Clayton Act, 15 U.S.C. 15, provides that any person who has been injured as a result of conduct prohibited by the antitrust laws may bring suit in federal court to recover three times the damages the person has suffered, as well as costs and reasonable attorneys' fees. Entry of the proposed Final Judgment neither impairs nor assists the bringing of any private antitrust damage action. Under the provisions of Section 5(a) of the Clayton Act, 15 U.S.C. 16(a), the proposed Final Judgment has no prima facie effect in any subsequent private lawsuit that may be brought against Defendants.

V. Procedures Available for Modification of the Proposed Final Judgment

The United States and Defendants have stipulated that the proposed Final Judgment may be entered by the Court after compliance with the provisions of the APPA, provided that the United States has not withdrawn its consent. The APPA conditions entry upon the Court's determination that the proposed Final Judgment is in the public interest.

The APPA provides a period of at least 60 days preceding the effective date of the proposed Final Judgment within which any person may submit to the United States written comments regarding the proposed Final Judgment. Any person who wishes to comment should do so within 60 days of the date of publication of this Competitive Impact Statement in the **Federal Register**, or the last date of publication in a newspaper of the summary of this Competitive Impact Statement, whichever is later. All comments received during this period will be considered by the U.S. Department of Justice, which remains free to withdraw its consent to the proposed Final Judgment at any time before the Court's entry of the Final Judgment. The comments and the response of the United States will be filed with the Court. In addition, comments will be posted on the U.S. Department of Justice, Antitrust Division's internet website and, under certain circumstances, published in the **Federal Register**.

Written comments should be submitted to: Eric D. Welsh, Acting Chief, Healthcare and Consumer Products Section, Antitrust Division, U.S. Department of Justice, 450 Fifth Street, NW, Suite 4100, Washington, DC 20530.

The proposed Final Judgment provides that the Court retains jurisdiction over this action, and the parties may apply to the Court for any order necessary or appropriate for the modification, interpretation, or enforcement of the Final Judgment.

VI. Alternatives to the Proposed Final Judgment

As an alternative to the proposed Final Judgment, the United States considered a full trial on the merits against Defendants. The United States could have continued the litigation and sought preliminary and permanent injunctions against DFA's acquisition of certain assets from Dean. The United States is satisfied, however, that the divestiture of assets described in the proposed Final Judgment will remedy the anticompetitive effects alleged in the Complaint, preserving competition for the processing and sale of Fluid Milk in northeastern Illinois and Wisconsin and in New England. Thus, the proposed Final Judgment achieves all or substantially all of the relief the United States would have obtained through litigation, but avoids the time, expense, and uncertainty of a full trial on the merits of the Complaint.

VII. Standard of Review Under The APPA for the Proposed Final Judgment

The Clayton Act, as amended by the APPA, requires that proposed consent judgments in antitrust cases brought by the United States be subject to a 60-day comment period, after which the Court shall determine whether entry of the proposed Final Judgment ''is in the public interest.'' 15 U.S.C. 16(e)(1). In making that determination, the Court, in accordance with the statute as amended in 2004, is required to consider:

(B) the impact of entry of such judgment upon competition in the relevant market or markets, upon the public generally and individuals alleging specific injury from the violations set forth in the complaint including consideration of the public benefit, if any, to be derived from a determination of the issues at trial.

15 U.S.C. 16(e)(1)(A) & (B). In considering these statutory factors, the Court's inquiry is necessarily a limited one as the government is entitled to ''broad discretion to settle with the defendant within the reaches of the public interest.'' *United States* v. *Microsoft Corp.,* 56 F.3d 1448, 1461 (DC Cir. 1995); *United States* v. *U.S. Airways Grp., Inc.,* 38 F. Supp. 3d 69, 75 (D.D.C. 2014) (explaining that the ''court's inquiry is limited'' in Tunney Act settlements); *United States* v. *InBev N.V./S.A.,* No. 08–1965 (JR), 2009 U.S. Dist. LEXIS 84787, at *3 (D.D.C. Aug. 11, 2009) (noting that a court's review of a consent judgment is limited and only inquires ''into whether the government's determination that the proposed remedies will cure the antitrust violations alleged in the complaint was reasonable, and whether the mechanism to enforce the final judgment are clear and manageable'').

As the U.S. Court of Appeals for the District of Columbia Circuit has held, under the APPA a court considers, among other things, the relationship between the remedy secured and the specific allegations in the government's complaint, whether the proposed Final Judgment is sufficiently clear, whether its enforcement mechanisms are sufficient, and whether it may positively harm third parties. *See Microsoft,* 56 F.3d at 1458–62. With respect to the adequacy of the relief secured by the proposed Final Judgment, a court may not ''make de novo determination of facts and issues.'' *United States* v. *W. Elec. Co.,* 993 F.2d 1572, 1577 (D.C. Cir. 1993) (quotation marks omitted); *see also Microsoft,* 56 F.3d at 1460–62; *United States* v. *Alcoa, Inc.,* 152 F. Supp. 2d 37, 40 (D.D.C. 2001); *United States* v. *Enova Corp.,* 107 F. Supp. 2d 10, 16 (D.D.C. 2000); *InBev,* 2009 U.S. Dist. LEXIS 84787, at *3. Instead, ''[t]he balancing of competing social and political interests affected by a proposed antitrust consent decree must be left, in the first instance, to the discretion of the Attorney General.'' *W. Elec. Co.,* 993 F.2d at 1577 (quotation marks omitted). ''The court should bear in mind the *flexibility* of the public interest inquiry: the court's function is not to determine whether the resulting array of rights and liabilities is one that will *best* serve society, but only to confirm that the resulting settlement is within the

reaches of the public interest.'' *Microsoft,* 56 F.3d at 1460 (quotation marks omitted); *see also United States* v. *Deutsche Telekom AG,* No. 19–2232 (TJK), 2020 WL 1873555, at *7 (D.D.C. Apr. 14, 2020). More demanding requirements would ''have enormous practical consequences for the government's ability to negotiate future settlements,'' contrary to congressional intent. *Id.* at 1456. ''The Tunney Act was not intended to create a disincentive to the use of the consent decree.'' *Id.*

The United States' predictions about the efficacy of the remedy are to be afforded deference by the Court. *See, e.g., Microsoft,* 56 F.3d at 1461 (recognizing courts should give ''due respect to the Justice Department's . . . view of the nature of its case''); *United States* v. *Iron Mountain, Inc.,* 217 F. Supp. 3d 146, 152–53 (D.D.C. 2016) (''In evaluating objections to settlement agreements under the Tunney Act, a court must be mindful that [t]he government need not prove that the settlements will perfectly remedy the alleged antitrust harms[;] it need only provide a factual basis for concluding that the settlements are reasonably adequate remedies for the alleged harms.'') (internal citations omitted); *United States* v. *Republic Servs., Inc.,* 723 F. Supp. 2d 157, 160 (D.D.C. 2010) (noting ''the deferential review to which the government's proposed remedy is accorded''); *United States* v. *Archer-Daniels-Midland Co.,* 272 F. Supp. 2d 1, 6 (D.D.C. 2003) (''A district court must accord due respect to the government's prediction as to the effect of proposed remedies, its perception of the market structure, and its view of the nature of the case.''). The ultimate question is whether ''the remedies [obtained by the Final Judgment are] so inconsonant with the allegations charged as to fall outside of the 'reaches of the public interest.''' *Microsoft,* 56 F.3d at 1461 (*quoting W. Elec. Co.,* 900 F.2d at 309).

Moreover, the Court's role under the APPA is limited to reviewing the remedy in relationship to the violations that the United States has alleged in its complaint, and does not authorize the Court to ''construct [its] own hypothetical case and then evaluate the decree against that case.'' *Microsoft,* 56 F.3d at 1459; *see also U.S. Airways,* 38 F. Supp. 3d at 75 (noting that the court must simply determine whether there is a factual foundation for the government's decisions such that its conclusions regarding the proposed settlements are reasonable); *InBev,* 2009 U.S. Dist. LEXIS 84787, at *20 (''[T]he 'public interest' is not to be measured by comparing the violations alleged in the complaint against those the court believes could have, or even should have, been alleged.''). Because the ''court's authority to review the decree depends entirely on the government's exercising its prosecutorial discretion by bringing a case in the first place,'' it follows that ''the court is only authorized to review the decree itself,'' and not to ''effectively redraft the complaint'' to inquire into other matters that the United States did not pursue. *Microsoft,* 56 F.3d at 1459–60.

In its 2004 amendments to the APPA, Congress made clear its intent to preserve the practical benefits of using consent judgments proposed by the United States in antitrust enforcement, Public Law 108–237 § 221, and added the unambiguous instruction that ''[n]othing in this section shall be construed to require the court to conduct an evidentiary hearing or to require the court to permit anyone to intervene.'' 15 U.S.C. 16(e)(2); *see also U.S. Airways,* 38 F. Supp. 3d at 76 (indicating that a court is not required to hold an evidentiary hearing or to permit intervenors as part of its review under the Tunney Act). This language explicitly wrote into the statute what Congress intended when it first enacted the Tunney Act in 1974. As Senator Tunney explained: ''[t]he court is nowhere compelled to go to trial or to engage in extended proceedings which might have the effect of vitiating the benefits of prompt and less costly settlement through the consent decree process.'' 119 Cong. Rec. 24,598 (1973) (statement of Sen. Tunney). ''A court can make its public interest determination based on the competitive impact statement and response to public comments alone.'' *U.S. Airways,* 38 F. Supp. 3d at 76 (citing *Enova Corp.,* 107 F. Supp. 2d at 17).

VIII. Determinative Documents

In formulating the proposed Final Judgment, the United States has considered one determinative document within the meaning of the APPA, a May 1, 2020 letter from Richard P. Smith, President and Chief Executive Officer of DFA, to the United States Department of Justice, Antitrust Division and to the Capper-Volstead Act Committee, United States Department of Agriculture (''Letter''). The Letter is included as Attachment 1 to this Competitive Impact Statement.

DFA has previously asserted that the Capper-Volstead Act, 7 U.S.C. 291–292, permits farmers and cooperatives collectively to market not only raw milk, but also processed Fluid Milk. The United States, however, does not agree with DFA's categorical assertion, which raises questions of fact and of unsettled law.

Through the Letter, DFA has committed not to jointly process, market, or sell Fluid Milk with agricultural cooperatives or producers (other than its own farmer members) and has waived any right to assert in any legal, regulatory, administrative, or adjudicative proceeding that such conduct is exempt from the antitrust laws or otherwise permissible under Section 6 of the Clayton Act or the Capper-Volstead Act. The Letter, which provides additional detail, decreases the likelihood that DFA would harm competition through coordination on output and prices of Fluid Milk.

Dated: May 26, 2020

Respectfully submitted,

Karl D. Knutsen
Nathaniel J. Harris
U.S. Department of Justice, Antitrust Division, Healthcare and Consumer Products Section, 450 Fifth Street NW, Suite 4100, Washington, DC 20530, 202–514–0976, karl.knutsen@usdoj

Attachment 1

BILLING CODE 4410–11–P

THIS MARK MATTERS. DFA Dairy Farmers of America

May 1, 2020

Antitrust Division
U.S. Department of Justice
950 Pennsylvania Avenue, NW
Washington, DC 20530-0001

Capper-Volstead Act Committee
U.S. Department of Agriculture 1400 Independence Avenue, SW Washington, DC 20250

To the Capper-Volstead Committee and the Antitrust Division of the U.S. Department of Justice:

Dairy Farmers of America, Inc. ("DFA"), which is organized as an Agricultural Cooperative within the meaning of Section 6 of the Clayton Act, 15 U.S.C. § 17, and the Capper-Volstead Act, 7 U.S.C. §§ 291-292, hereby irrevocably commits that it will not, other than through its participation in a joint venture or other joint ownership entity:

1. Jointly process, market, or sell in the United States any Class I or Class II product with any Agricultural Cooperative or agricultural producer other than its own farmer members; or

2. Agree or otherwise coordinate with any other Agricultural Cooperative or agricultural producer other than its own farmer members with respect to the processing, marketing, or sale in the United States for any Class I or Class II product, including, but not limited to prices, output levels, or other terms of sale.

For the avoidance of doubt, DFA will not coordinate, in the manner described in Paragraphs (1) and (2) above, the activities of its independently owned operations with those of any joint venture or other joint ownership entity in which DFA holds a non-controlling ownership interest. Nothing in this letter prevents DFA from (a) purchasing milk from other cooperatives or agricultural producers for processing into Class I and Class II products, (b) selling milk to other cooperatives for their use in Class I and Class II processing, (c) directly and periodically selling or buying Class I and Class II products in the ordinary course of business from other cooperatives or agricultural producers, or (d) entering into marketing agencies in common with regard to raw milk or raw milk components.

Furthermore, with respect to any litigation or other action brought against DFA by the United States Department of Justice or Department of Agriculture or the Attorney General of any State, DFA, as to those parties, agrees not to contest a finding that the conduct described in Paragraph (1) and (2) above would be likely to unduly enhance the price of the relevant Class I and Class II products. In addition, as to those governmental parties, DFA irrevocably waives

any right to assert in any legal, regulatory, administrative, or adjudicative proceeding, including a proceeding instituted by the Secretary of Agriculture pursuant to 7 U.S.C. § 292, that the conduct described in Paragraph (1) or (2) above is exempt from the antitrust laws or is otherwise permissible under Section 6 of the Clayton Act, 15 U.S.C. § 17, or the Capper-Volstead Act, 7 U.S.C. §§ 291-292.

For the avoidance of doubt, DFA's intention is to waive, in the circumstances described above, Section 6 of the Clayton Act and the Capper-Volstead Act as exemptions from the antitrust laws. Nothing in this letter prohibits DFA from defending its conduct in any legal, regulatory, administrative, or adjudicative proceeding on the basis that its conduct does not violate the antitrust laws in the first instance.

Sincerely,

Richard P. Smith

Richard P. Smith
President and Chief Executive Officer

[FR Doc. 2020–11857 Filed 6–1–20; 8:45 am]
BILLING CODE 4410–11–C

DEPARTMENT OF JUSTICE

Antitrust Division

Notice Pursuant to the National Cooperative Research and Production Act of 1993—Open Source Imaging Consortium, Inc.

Notice is hereby given that, on May 19, 2020, pursuant to Section 6(a) of the National Cooperative Research and Production Act of 1993, 15 U.S.C. 4301 *et seq.* (''the Act''), Open Source Imaging Consortium, Inc. (''Open Source Imaging Consortium'') filed written notifications simultaneously with the Attorney General and the Federal Trade Commission disclosing changes in its membership. The notifications were filed for the purpose of extending the Act's provisions limiting the recovery of antitrust plaintiffs to actual damages under specified circumstances. Specifically, Lyon Hospital, Lyon, FRANCE has been added as a party to this venture.

No other changes have been made in either the membership or planned activity of the group research project. Membership in this group research project remains open, and Open Source Imaging Consortium intends to file additional written notifications disclosing all changes in membership.

On March 20, 2019, Open Source Imaging Consortium filed its original notification pursuant to Section 6(a) of the Act. The Department of Justice published a notice in the **Federal Register** pursuant to Section 6(b) of the Act on April 12, 2019 (84 FR 14973).

The last notification was filed with the Department on March 3, 2020. A notice was published in the **Federal Register** pursuant to Section 6(b) of the Act on March 20, 2020 (85 FR 16131).

Suzanne Morris,

Chief, Premerger and Division Statistics, Antitrust Division.

[FR Doc. 2020–11852 Filed 6–1–20; 8:45 am]
BILLING CODE 4410–11–P

DEPARTMENT OF LABOR

Employment and Training Administration

Notice of a Change in Status of the Extended Benefit (EB) Program for New Hampshire, California, Georgia, Louisiana, Maine, Ohio, and Oregon

AGENCY: Employment and Training Administration, Labor.

ACTION: Notice.

SUMMARY: This notice announces a change in benefit payment status under the EB program for New Hampshire, California, Georgia, Louisiana, Maine, Ohio, and Oregon.

FOR FURTHER INFORMATION CONTACT: U.S. Department of Labor, Employment and Training Administration, Office of Unemployment Insurance Room S–4524, Attn: Kevin Stapleton, 200 Constitution Avenue NW, Washington, DC 20210, telephone number: (202)–693–3009 (this is not a toll-free number) or by email: *Stapleton.Kevin@dol.gov.*

SUPPLEMENTARY INFORMATION: The following change has occurred since the publication of the last notice regarding each State's EB status:

- The 13-week insured unemployment rates (IUR) for New Hampshire, California, Georgia, Louisiana, Maine, Ohio, and Oregon, for the week ending April 25, 2020, rose above 5.0 percent and exceeded 120 percent of the corresponding average rates in the two prior years. Therefore, beginning the week of May 10, 2020, eligible unemployed workers will be able to collect up to an additional 13 weeks of UI benefits.

The trigger notice covering state eligibility for the EB program can be found at: *http://oui.doleta.gov/unemploy/claims_arch.asp.*

Information for Claimants

The duration of benefits payable in the EB program and the terms and conditions on which they are payable are governed by the Federal-State Extended Unemployment Compensation Act of 1970, as amended, and the operating instructions issued to the states by the U.S. Department of Labor. In the case of a state beginning an EB period, the State Workforce Agency will furnish a written notice of potential entitlement to each individual who has exhausted all rights to regular benefits and is potentially eligible for EB (20 CFR 615.13 (c)(1)).

Persons who believe they may be entitled to EB, or who wish to inquire about their rights under the program, should contact their State Workforce Agency.

Signed in Washington, DC.

John Pallasch,

Assistant Secretary for Employment and Training.

[FR Doc. 2020–11807 Filed 6–1–20; 8:45 am]

BILLING CODE 4510–FW–P

DEPARTMENT OF LABOR

Employment and Training Administration

Notice of a Change in Status of the Extended Benefit (EB) Program for Hawaii, Iowa, Illinois, Kentucky, Mississippi, North Carolina, New Mexico, and Wisconsin

AGENCY: Employment and Training Administration, Labor.

ACTION: Notice.

This notice announces a change in benefit payment status under the EB program for Hawaii, Iowa, Illinois, Kentucky, Mississippi, North Carolina, New Mexico, and Wisconsin.

The following change has occurred since the publication of the last notice regarding each States' EB status:

The 13-week insured unemployment rates (IUR) for Hawaii, Iowa, Illinois, Kentucky, Mississippi, North Carolina, New Mexico, and Wisconsin, for the week ending May 2, 2020, rose above 5.0 percent and exceeded 120 percent of the corresponding average rates in the two prior years. Therefore, beginning the week of May 17, 2020, eligible unemployed workers will be able to collect up to an additional 13 weeks of UI benefits.

The trigger notice covering state eligibility for the EB program can be found at: *http://oui.doleta.gov/unemploy/claims_arch.asp.*

Information for Claimants

The duration of benefits payable in the EB program and the terms and conditions on which they are payable are governed by the Federal-State Extended Unemployment Compensation Act of 1970, as amended, and the operating instructions issued to the States by the U.S. Department of Labor. In the case of a state beginning an EB period, the State Workforce Agency will furnish a written notice of potential entitlement to each individual who has exhausted all rights to regular benefits and is potentially eligible for EB (20 CFR 615.13(c)(1)).

Persons who believe they may be entitled to EB, or who wish to inquire about their rights under the program, should contact their State Workforce Agency.

FOR FURTHER INFORMATION CONTACT: U.S. Department of Labor, Employment and Training Administration, Office of Unemployment Insurance Room S–4524, Attn: Kevin Stapleton, 200 Constitution Avenue NW, Washington, DC 20210, telephone number: (202)-693–3009 (this is not a toll-free number) or by email: *Stapleton.Kevin@dol.gov.*

Signed in Washington, DC.

John Pallasch,

Assistant Secretary for Employment and Training.

[FR Doc. 2020–11806 Filed 6–1–20; 8:45 am]

BILLING CODE 4510–FW–P

DEPARTMENT OF LABOR

Occupational Safety and Health Administration

[Docket No. OSHA–2010–0051]

Manlifts; Extension of the Office of Management and Budget's (OMB) Approval of the Information Collection (Paperwork) Requirements

AGENCY: Occupational Safety and Health Administration (OSHA), Labor.

ACTION: Request for public comments.

SUMMARY: OSHA solicits public comments concerning the proposal to extend the Office of Management and Budget's (OMB) approval of the collection of information contained in the Standard on Manlifts.

DATES: Comments must be submitted (postmarked, sent, or received) by August 3, 2020.

ADDRESSES:

Electronically: You may submit comments and attachments electronically at *http://www.regulations.gov,* which is the Federal eRulemaking Portal. Follow the instructions online for submitting comments.

Facsimile: If your comments, including attachments, are not longer than 10 pages you may fax them to the OSHA Docket Office at (202) 693–1648.

Mail, hand delivery, express mail, messenger, or courier service: When using this method, you must submit a copy of your comments and attachments to the OSHA Docket Office, Docket No. OSHA–2010–0051, Occupational Safety and Health Administration, U.S. Department of Labor, Room N–3653, 200 Constitution Avenue NW, Washington, DC 20210. Deliveries (hand, express mail, messenger, and courier service) are accepted during the OSHA Docket Office's normal business hours, 10:00 a.m. to 3:00 p.m., ET.

Instructions: All submissions must include the agency name and the OSHA docket number (OSHA–2010–0051) for the Information Collection Request (ICR). All comments, including any personal information you provide, such as social security number and date of birth, are placed in the public docket without change, and may be made available online at *http://www.regulations.gov.* For further information on submitting comments see the ''Public Participation'' heading in the section of this notice titled **SUPPLEMENTARY INFORMATION**.

Docket: To read or download comments or other material in the docket, go to *http://www.regulations.gov* or the OSHA Docket Office at the above address. All documents in the docket (including this **Federal Register** notice) are listed in the *http://www.regulations.gov* index; however, some information (*e.g.,* copyrighted material) is not publicly available to read or download from the website. All submissions, including copyrighted material, are available for inspection and copying at the OSHA Docket Office. You may also contact Theda Kenney or Seleda Perryman at (202) 693–2222 to obtain a copy of the ICR.

FOR FURTHER INFORMATION CONTACT: Theda Kenney or Seleda Perryman, Directorate of Standards and Guidance, OSHA, U.S. Department of Labor, telephone (202) 693–2222.

SUPPLEMENTARY INFORMATION:

I. Background

The Department of Labor, as part of the continuing effort to reduce paperwork and respondent (*i.e.,* employer) burden, conducts a preclearance consultation program to provide the public with an opportunity to comment on proposed and continuing collection of information in accordance with the Paperwork Reduction Act (PRA) (44 U.S.C. 3506(c)(2)(A)). This program ensures that information is in the desired format, reporting burden (time and costs) is minimal, collection instruments are clearly understood, and OSHA's estimate of the information collection burden is accurate. The Occupational Safety and Health Act of 1970 (OSH Act) (29 U.S.C. 651 *et seq.*) authorizes information collection by employers as necessary or appropriate for enforcement of the OSH Act or for developing information regarding the causes and prevention of occupational injuries, illnesses, and accidents (29 U.S.C. 657). The OSH Act also requires OSHA to obtain such information with minimum burden upon employers, especially those operating small businesses, and to reduce to the maximum extent feasible unnecessary

duplication of efforts in obtaining information (29 U.S.C. 657).

The Standard specifies two paperwork requirements. The following sections describe who uses the information collected under each requirement, as well as how they use it. The purpose of the requirements is to reduce workers' risk of death or serious injury by ensuring that manlifts are in safe operating condition.

Periodic Inspections and Records (paragraph (e)). This provision requires that each manlift be inspected at least once every 30 days and it also requires that limit switches shall be checked weekly. The manlift inspection is to cover at least the following items: Steps; step fastenings; rails; rail supports and fastenings; rollers and slides; belt and belt tension; handholds and fastenings; floor landings; guardrails; lubrication; limit switches; warning signs and lights; illumination; drive pulley; bottom (boot) pulley and clearance; pulley supports; motor; driving mechanism; brake; electrical switches; vibration and misalignment; and any ''skip'' on the up or down run when mounting a step (indicating worn gears). A certification record of the inspection must be prepared upon completion of the inspection. The record must contain the date of the inspection, the signature of the person who performed the inspection, and the serial number or other identifier of the inspected manlift.

Disclosure of Inspection Certification Records. The agency has no annualized cost associated with enforcing the Standard. OSHA would only review records in the context of an investigation of a particular employer to determine compliance with the Standard. These activities are outside the scope of the PRA. See 5 CFR 1320.4(a)(2).

II. Special Issues for Comment

OSHA has a particular interest in comments on the following issues:

- Whether the proposed information collection requirements are necessary for the proper performance of the agency's functions, including whether the information is useful;
- The accuracy of OSHA's estimate of the burden (time and costs) of the information collection requirements, including the validity of the methodology and assumptions used;
- The quality, utility, and clarity of the information collected; and
- Ways to minimize the burden on employers who must comply; for example, by using automated or other technological information collection and transmission techniques.

III. Proposed Actions

The agency is requesting no change to the burden hours associated with this Information Collection Request. Therefore, the agency would like to retain the previous estimate of 37,800 hours.

Type of Review: Extension of a currently approved collection.

Title: Manlifts (29 CFR 1910.68).

OMB Control Number: 1218–0226.

Affected Public: Business or other for-profits.

Number of Respondents: 3,000.

Number of Responses: 36,000.

Frequency of Responses: On Occasion.

Average Time per Response: Varies.

Estimated Total Burden Hours: 37,800.

Estimated Cost (Operation and Maintenance): $0.

IV. Public Participation—Submission of Comments on This Notice and Internet Access to Comments and Submissions

You may submit comments in response to this document as follows: (1) Electronically at *http://www.regulations.gov,* which is the Federal eRulemaking Portal; (2) by facsimile (fax); or (3) by hard copy. All comments, attachments, and other material must identify the agency name and the OSHA docket number for the ICR (Docket No. OSHA–2010–0051). You may supplement electronic submissions by uploading document files electronically. If you wish to mail additional materials in reference to an electronic or facsimile submission, you must submit them to the OSHA Docket Office (see the section of this notice titled **ADDRESSES**). The additional materials must clearly identify your electronic comments by your name, date, and the docket number so the agency can attach them to your comments.

Due to security procedures, the use of regular mail may cause a significant delay in the receipt of comments. For information about security procedures concerning the delivery of materials by hand, express delivery, messenger, or courier service, please contact the OSHA Docket Office at (202) 693–2350, (TTY (877) 889–5627).

Comments and submissions are posted without change at *http://www.regulations.gov.* Therefore, OSHA cautions commenters about submitting personal information such as social security numbers and dates of birth. Although all submissions are listed in the *http://www.regulations.gov* index, some information (*e.g.,* copyrighted material) is not publicly available to read or download through this website.

All submissions, including copyrighted material, are available for inspection and copying at the OSHA Docket Office. Information on using the *http://www.regulations.gov* website to submit comments and access the docket is available at the website's ''User Tips'' link. Contact the OSHA Docket Office for information about materials not available through the website, and for assistance in using the internet to locate docket submissions.

V. Authority and Signature

Loren Sweatt, Principal Deputy Assistant Secretary of Labor for Occupational Safety and Health, directed the preparation of this notice. The authority for this notice is the Paperwork Reduction Act of 1995 (44 U.S.C. 3506 *et seq.*) and Secretary of Labor's Order No. 1–2012 (77 FR 3912).

Signed at Washington, DC.

Loren Sweatt,

Principal Deputy Assistant Secretary of Labor for Occupational Safety and Health.

[FR Doc. 2020–11805 Filed 6–1–20; 8:45 am]

BILLING CODE 4510–26–P

LIBRARY OF CONGRESS

U.S. Copyright Office

[Docket No. 2019–6]

Unclaimed Royalties Study: Notice of Inquiry

AGENCY: U.S. Copyright Office, Library of Congress.

ACTION: Notice of inquiry.

SUMMARY: The U.S. Copyright Office is undertaking a study as directed by the Music Modernization Act to evaluate best practices that the newly-established mechanical licensing collective (''MLC'') may implement to: Identify and locate musical work copyright owners and unclaimed accrued royalties held by the collective; encourage musical work copyright owners to claim their royalties; and reduce the incidence of unclaimed royalties. The MLC is expected to carefully consider, and give substantial weight to, the Office's recommendations when establishing procedures for the identification and location of musical work copyright owners and the distribution of unclaimed royalties. The Office is soliciting input from music industry participants and other interested members of the public on these issues to aid its study.

DATES: Written comments must be received no later than August 3, 2020 at 11:59 p.m. Eastern Time. Written reply

comments must be received no later than August 31, 2020 at 11:59 p.m. Eastern Time. The Office will be announcing one or more public meetings, potentially virtually, by separate notice in the future.

ADDRESSES: For reasons of government efficiency, the Copyright Office is using the *regulations.gov* system for the submission and posting of public comments in this proceeding. All comments are therefore to be submitted electronically through *regulations.gov.* Specific instructions for submitting comments are available on the Copyright Office website at *http://copyright.gov/policy/unclaimed-royalties.* If electronic submission of comments is not feasible due to lack of access to a computer and/or the internet, please contact the Office using the contact information below for special instructions.

FOR FURTHER INFORMATION CONTACT: Regan A. Smith, General Counsel and Associate Register of Copyrights, by email at *regans@copyright.gov* or John R. Riley, Assistant General Counsel, by email at *jril@copyright.gov.* They can be reached by telephone at 202–707–8350.

SUPPLEMENTARY INFORMATION:

I. Background

The Orrin G. Hatch–Bob Goodlatte Music Modernization Act [1] significantly changed the section 115 compulsory license to make and distribute phonorecords of nondramatic musical works (the ''mechanical license''). Prior to the MMA, those who wished to obtain a section 115 compulsory license were able to do so by serving a notice of intention to obtain a compulsory license (''NOI'') on the copyright owner and then paying applicable royalties accompanied by accounting statements or, if the Copyright Office's records did not identify the copyright owner, by filing the notice with the Office.[2] Where the musical work copyright owner was not identified in the Office's records, royalties were not due.[3]

Frustrations with the former song-by-song licensing system's inefficiencies are well-documented, both in the legislative history and the Copyright Office's 2015 comprehensive study on the music licensing marketplace.[4] Digital services ''complain[ed] about the lack of readily available data concerning musical work ownership'' and ''asserted that the inaccessibility of ownership information leads to costly and burdensome efforts to identify the rightsholders and potentially incomplete or incorrect licenses, exposing them to the risk of statutory infringement damages despite diligent efforts.'' [5] Publishers, songwriters, and licensing administrators were also frustrated with noncompliant statutory licensees, noting that NOIs were ''frequently deficient, and licensees regularly fail[ed] to timely and accurately pay and report usage.'' [6] Some copyright owners sued digital music services for missing mechanical licenses,[7] in some instances resulting in settlements whose terms included the establishment of online portals allowing copyright owners to claim their settlement shares.[8]

A. Identifying and Paying Copyright Owners Under the New Blanket License

The MMA largely eliminated the song-by-song mechanical compulsory licensing regime by establishing a new blanket compulsory license that digital music providers may obtain to make digital phonorecord deliveries (''DPDs'') of musical works, including in the form of permanent downloads, limited downloads, or interactive streams.[9] Instead of licensing one song at a time by serving NOIs on individual copyright owners, the blanket license will cover all musical works available for compulsory licensing and will be centrally administered by a new entity called the mechanical licensing collective (''MLC''), which was designated last summer by the Copyright Office.[10] Following a present transition period, the MLC will begin administering the blanket license on what the statute terms the ''license availability date,'' or January 1, 2021.[11] The MMA's legislative history explains that the blanket licensing structure is designed to improve efficiency by allowing digital music services to offer ''as much music as possible,'' while ''ensuring fair and timely payment to all creators'' of the musical works used on these digital services.[12]

By consolidating musical work usage and ownership data and royalty distributions with the MLC, the MMA aims to improve the preexisting problems of missing data and incomplete royalty payments. Digital music providers using the blanket license are required to pay royalties and provide reports of usage for all covered activities to the MLC on a monthly basis.[13] The MLC will collect those royalties and distribute them to musical work copyright owners in accordance with the digital service providers' usage reports and the ownership and other information contained in the MLC's records, including its public database.[14]

1. The MLC's Public Musical Works Database

The MLC's musical works database will contain information relating to musical works (and shares of such works), including, to the extent known, the identity and location of the copyright owners of such works and the sound recordings in which the musical works are embodied.[15] Accurately identifying musical works and their associated sound recordings and owners requires reliable data throughout the statutory licensing ecosystem. To this end, as explained in more detail in separate notices published by the Office,[16] the MMA outlines roles for digital music providers, musical work owners, and the MLC in providing, reporting, and curating accurate music data.

Digital music providers operating under the blanket license will ''engage in good-faith, commercially reasonable efforts to obtain'' various sound recording and musical work information from sound recording copyright owners and other licensors of sound recordings made available through the digital music providers' services.[17] These digital music providers will deliver

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[1] Public Law 115–264, 132 Stat. 3676 (2018) (''MMA'').

[2] 17 U.S.C. 115(b)(1) (2017).

[3] *Id.* at 115(c)(1) (2017).

[4] Report and Section-by-Section Analysis of H.R. 1551 by the Chairmen and Ranking Members of Senate and House Judiciary Committees, at 3 (2018), *https://www.copyright.gov/legislation/mma_conference_report.pdf* (''Conf. Rep.'') (''Song-by-song licensing negotiations increase the transaction costs to the extent that only a limited amount of music would be worth engaging in such licensing discussions, depriving artists of revenue for less popular works and encouraging piracy of such works by customers looking for such music''); U.S. Copyright Office, *Copyright and the Music Marketplace* 107 (2015), *https://www.copyright.gov/docs/musiclicensingstudy/copyright-and-the-music-marketplace.pdf.*

[5] U.S. Copyright Office, *Copyright and the Music Marketplace* 107 (2015).

[6] *Id.* at 110.

[7] *See, e.g.,* Dan Rys, *Tidal Hit With Lawsuit Over Royalty Payments* (Feb. 29, 2016), *https://www.billboard.com/articles/business/6890854/tidal-lawsuit-royalty-payments* (noting lawsuits against Spotify, Tidal, Slacker, Deezer, Rdio, Rhapsody, and Beats Music).

[8] *See, e.g., Ferrick* v. *Spotify USA Inc.* (last updated Mar. 30, 2020), *https://spotifypublishingsettlement.com.*

[9] The mechanical compulsory license for non-DPDs (*e.g.,* CDs, vinyl) continues to follow the preexisting song-by-song NOI system.

[10] 17 U.S.C. 115(b)(1), (c)(5) (2017); 84 FR 32274 (July 8, 2019).

[11] 17 U.S.C. 115(d)(2)(B), (e)(15).

[12] S. Rep. No. 115–339, at 4, 8 (2018).

[13] 17 U.S.C. 115(e)(7), (d)(4).

[14] *Id.* at 115(d)(3)(G)(i)(II).

[15] *Id.* at 115(d)(3)(E)(i).

[16] 85 FR 22549 (Apr. 22, 2020); 85 FR 22518 (Apr. 22, 2020).

[17] 17 U.S.C. 115(d)(4)(B); *see also* 85 FR at 22521–25.

reports of usage to the MLC containing usage data for musical works used in covered activities under the blanket license, voluntary licenses, and individual download licenses.[18] Certain entities engaging in covered activities pursuant to voluntary licenses or individual download licenses, but that do not operate under a blanket license (called significant nonblanket licensees), will also submit reports of usage to the MLC.[19] And musical work copyright owners with works listed in the MLC's database will ''engage in commercially reasonable efforts to deliver'' to the MLC if not already listed in the database, ''information regarding the names of the sound recordings in which that copyright owner's musical works (or shares thereof) are embodied, to the extent practicable.'' [20] On April 22, 2020, the Office issued a notice of proposed rulemaking discussing these matters in more detail and seeking public comment on proposed regulatory language to govern these obligations.[21]

Once these inputs are provided to the MLC, it will engage in efforts ''to identify the musical works embodied in particular sound recordings, as well as to identify and locate the copyright owners of such works (and shares thereof), and update such data as appropriate.'' [22] The MMA's legislative history describes this duty to locate and identify musical work owners as the MLC's ''highest responsibility,'' next to the MLC's ''efficient and accurate collection and distribution of royalties.'' [23] The Senate Judiciary Chairman subsequently reaffirmed this sentiment, writing to the Office that ''[a]ll artists deserve to be fully paid for the uses of their works [and] . . . [r]educing unmatched funds is the measure by which the success of this important legislation should be measured.'' [24]

Information for both matched and unmatched works will be provided in the MLC's public musical works database, and the statute lists a number of fields that must be included with respect to matched and unmatched works.[25] In addition, the Office may promulgate regulations to require additional information to be included in the MLC's database,[26] and must also ''establish requirements by regulations to ensure the usability, interoperability, and usage restrictions of the musical works database.'' [27] The Office has recently published a notification of inquiry soliciting information on these topics.[28]

For those musical works (or shares thereof) that are unmatched, copyright owners will be able to come forward and assert ownership claims by viewing the MLC's public database, including through a public online portal.[29] The MLC has announced intentions that its claiming portal, expected to premiere in the third quarter of this year, will be ''user-friendly, ADA-compliant, and can be used by stakeholders of any sophistication.'' [30] For technologically sophisticated entities, the MLC will also use ''APIs and data transfer processes and formats to allow for bulk submission and updating of rights data.'' [31]

2. Education and Outreach

Congress has directed the MLC to ''engage in diligent, good-faith efforts to publicize, throughout the music industry . . . the procedures by which copyright owners may identify themselves and provide contact, ownership, and other relevant information to the collective in order to receive payments of accrued royalties.'' [32] The digital licensee coordinator (''DLC'') (an entity that was designated by the Copyright Office to represent the interests of digital services pursuant to the statute), and Copyright Office also have roles in educating copyright owners and songwriters about the existence of the MLC and its role in the new blanket license system.[33] For the DLC, this includes encouraging digital music providers to post the MLC's contact information on services' websites and applications and conduct in-person songwriter outreach.[34] The Copyright Office has engaged in several activities to fulfill its educational duties thus far, including by establishing a MMA-related web page with FAQs, informational handouts, seven MMA-related videos, three new circulars, and information related to the statute's legislative history, as well as hosting an all-day symposium and speaking at approximately 40 in-person or virtual events.[35]

3. Unclaimed, Accrued Royalties

For those works for which royalties have accrued but the copyright owner is unknown or not located, the MLC will hold such royalties for a designated minimum time period. This holding period will provide the MLC with an additional period of time [36] (compared to the pre-MMA system) to engage in efforts to identify the musical works embodied in particular sound recordings, and locate their associated copyright owners, and for copyright owners and other songwriters to identify their works in the MLC database and come forward to claim their ownership interests.[37] In general, the MLC must hold accrued royalties for ''a period of not less than 3 years after the date on which the funds were received by the [MLC], or not less than 3 years after the date on which the funds were accrued by a digital music provider that subsequently transferred such funds to the [MLC] . . . whichever period expires sooner.'' [38] The MMA also states that the first such distribution ''shall occur on or after January 1 of the second full calendar year to commence after the license availability date, with not less than 1 such distribution to take place

[18] 17 U.S.C. 115(d)(4)(A); *see also* 85 FR at 22526–35. The statute prescribes categories of information that must be included in reports of usage, including a provision for the Copyright Office to prescribe additional categories by regulation. 17 U.S.C. 115(d)(4)(A)(ii)(I).

[19] 17 U.S.C. 115(d)(6)(A)(ii), (e)(31); *see also* 85 FR at 22535–36.

[20] 17 U.S.C. 115(d)(3)(E)(iv); *see also* 85 FR at 22525–26.

[21] 85 FR 22518.

[22] 17 U.S.C. 115(d)(3)(E)(i).

[23] Conf. Rep. at 7.

[24] Letter from Lindsey Graham, Chairman, Senate Judiciary Committee, to Karyn Temple, Register of Copyrights 1 (Nov. 1, 2019) (on file with Copyright Office).

[25] 17 U.S.C. 115(d)(3)(E)(ii), *id.* at 115(d)(3)(E)(iii)(I).

[26] *Id.* at 115(d)(3)(E)(ii)(V), (iii)(II).

[27] *Id.* at 115(d)(3)(E)(vi).

[28] 85 FR 22568 (Apr. 22, 2020).

[29] 17 U.S.C. 115(d)(3)(J)(iii)(I).

[30] Mechanical Licensing Collective, Designation Proposal at 37, U.S. Copyright Office Dkt. No. 2018–11 (Mar. 22, 2019), *https://www.regulations.gov/document?D=COLC-2018-0011-0012* (''MLC Designation Proposal'').

[31] *Id.*

[32] 17 U.S.C. 115(d)(3)(J)(iii)(II)(bb).

[33] *Id.* at 115(d)(5)(C)(i)(VII); MMA at sec. 102(e), 132 Stat. at 3722.

[34] 117 U.S.C. 115(d)(5)(C)(iii).

[35] *See* U.S. Copyright Office, *MMA Educational Materials, https://www.copyright.gov/music-modernization/educational-materials/* (last visited, May 19, 2020).

[36] For works that were initially accrued by a digital music provider prior to the license availability date and then transferred to the MLC, the MLC may have as few as two years to locate the copyright owner, but the minimum total holding period for these funds will be three years. *See* 17 U.S.C. 115(d)(3)(H)(i), (3)(J)(i)(I), (10)(B)(iv)(III)(aa).

[37] Conf. Rep. at 11 (''For unmatched works, the collective must wait for the prescribed holding period of three years before making such distribution. This is intended to give the collective time to actively search for the copyright owner.''); *see also* U.S. Copyright Office, *Unclaimed Royalties Study: Kickoff Symposium,* Tr. at 194:18–195:01, 213:03–05 (Dec. 6, 2019) (Sarah Rosenbaum, Google) (noting that the MMA allows the music industry to address data issues in a ''less time-pressured environment''). Transcripts of the Office's symposium are cited with the abbreviation ''Tr.'' along with the page and line numbers, and date, of the cited material. These citations also include the name of the speaker and organization (if any) with which the speaker is affiliated. Transcripts of the symposium is available at *https://www.copyright.gov/policy/royalties/transcript.pdf.*

[38] 17 U.S.C. 115(d)(3)(H)(i).

during each calendar year thereafter.'' [39] Reading these provisions together, in no case can these unclaimed royalties be distributed before 2023.[40]

After the holding period, the MLC ''shall distribute [unmatched works'] accrued royalties, along with a proportionate share of accrued interest, to copyright owners identified in the records of the collective.'' [41] It must also ''engag[e] in diligent, good-faith efforts to publicize . . . any pending distribution of unclaimed accrued royalties and accrued interest, not less than 90 days before the date on which the distribution is made.'' [42] Once the MLC makes an initial distribution of unclaimed, accrued royalties, ''not less than 1 such distribution [shall] take place during each calendar year thereafter.'' [43] Copyright owners' shares of distributions of unclaimed accrued royalties will be determined by the MLC in accordance with unclaimed accrued royalties for particular payment periods, and ''determined in a transparent and equitable manner based on data indicating the relative market shares of such copyright owners as reflected in reports of usage provided by digital music providers for covered activities for the periods in question'' as well as available ''usage data provided to copyright owners under voluntary licenses and individual download licenses for covered activities.'' [44]

By statute, the MLC has established an Unclaimed Royalties Oversight Committee, which will establish policies and procedures ''for the distribution of unclaimed accrued royalties and accrued interest . . . including the provision of usage data to copyright owners to allocate payments and credits to songwriters,'' subject to the MLC board's approval.[45] During the public process of designating the collective, the MLC noted that it ''does not intend to ever distribute the entirety of unclaimed royalties simultaneously,'' and that it interprets section 115(d)(3)(J) ''to grant discretion to MLC to retain unclaimed accrued royalties beyond the year that they become eligible for distribution, to allow diligent attempts to match all uses and works, no matter the vintage, to continue. MLC intends to implement policies allowing use of that discretion to retain unclaimed accrued royalties and continue matching efforts in situations where there is reasonable evidence that this will result in material increases in matching success.'' [46] In designating the MLC, the Office noted its agreement with this interpretation.[47]

B. Copyright Office Study on Best Practices Study, and Related Foundational Work

To further Congress's intent to reduce the instance of unmatched works and unclaimed royalties, the MMA directs the Copyright Office to conduct a policy study, in consultation with the Government Accountability Office, recommending best practices that the MLC may implement to:

(A) Identify and locate musical work copyright owners with unclaimed accrued royalties held by the collective;

(B) encourage musical work copyright owners to claim the royalties of those owners; and

(C) reduce the incidence of unclaimed royalties.[48]

The MLC must carefully consider and give substantial weight to the Office's recommendations when establishing procedures to identify and locate musical work copyright owners and to distribute unclaimed royalties.[49]

1. Educational Symposium

To initiate the study, the Office held an all-day educational symposium to facilitate public understanding and discussion on issues relevant to the study. The Office invited industry participants, including songwriters and other interested members of the public, to discuss topics including: (i) Past and current initiatives to facilitate authoritative and comprehensive music ownership databases; (ii) challenges of matching musical works to sound recordings, including current matching methods and challenges, the role of technology, and how success can be measured; and (iii) the most effective ways to educate creators on the changes effected by the MMA. The symposium featured an update from the MLC and DLC, and a discussion among creators concerning the challenges and benefits associated with accurately capturing metadata during the creative process as well as the role of creators in taking ownership of their song data. The event concluded with an opportunity for audience participation. The Office has posted videos and a transcript of the symposium on its website, as well as a glossary of acronyms and other frequently used terms that arose during discussions.[50]

While observing that the MLC's mission shares some similarities with past music ownership database development efforts, panelists noted that the MLC lacks the funding challenges of earlier European efforts, and that it may benefit from being narrower in scope.[51] There was discussion on the role of standards setting, including the common works registration (''CWR'') standard format used by publishers and DDEX messaging standards; the MLC has confirmed it intends to ingest data through multiple formats, including CWR as well as through its claiming portal.[52] The symposium addressed other industry efforts to facilitate improved data quality, including a best practices working group established between record labels and music publishers that generated a platform called the Music Data Exchange and the Open Music Initiative, an effort to build consensus towards establishing open data protocols and promote increased education and monetization opportunities for artists.[53] Other panelists discussed ways to determine whether the ownership data for a work is authoritative, which may involve algorithmic matching, different levels of manual review, inspecting the

[39] *Id.* at 115(d)(3)(J)(i)(I).

[40] *Id.; see also* 84 FR at 32291 (July 8, 2019) (noting ''the statute does not permit the first such distribution to occur before January 1, 2023''); MLC Designation Proposal at 52 (same).

[41] 17 U.S.C. 115(d)(3)(J)(i).

[42] *Id.* at 115(d)(3)(J)(iii)(II)(dd).

[43] *Id.* at 115(d)(3)(J)(i)(I).

[44] *Id.* at 115 (d)(3)(J)(i)(II). Songwriters' unclaimed accrued royalty shares will be paid ''in accordance with applicable contractual terms,'' but ''in no case shall the payment or credit to an individual songwriter be less than 50 percent of the payment received by the copyright owner.'' *Id.* at 115(d)(3)(J)(iv)(II).

[45] *Id.* at 115(d)(3)(J)(ii).

[46] MLCI Designation Proposal at 52–53.

[47] 84 FR at 32291.

[48] MMA at sec. 102(f)(1), 132 Stat. at 3722.

[49] *Id.* at sec. 102(f)(2), 132 Stat. at 3722–23.

[50] U.S. Copyright Office, *Unclaimed Royalties Study, https://www.copyright.gov/policy/unclaimed-royalties/* (last visited May 19, 2020).

[51] Tr. at 79:04–07 (Dec. 6, 2019) (Michel Allain, WIPO); Tr. at 83:15–85:11 (Dec. 6, 2019) (David Hughes, Recording Industry Association of America (''RIAA'')).

[52] Tr. at 76:10–20 (Dec. 6, 2019) (Michel Allain, WIPO) (discussing utility of CWR format as used by ''main publishers'' while noting that its complexity is not always accessible for smaller publishers); Tr. at 61:12–62:08, 62:16–63:14, 130:13–131:10 (Dec. 6, 2019) (Mark Isherwood, DDEX) (noting that DDEX ''standardiz[es] . . . the communication of data between all the different business partners that exist within the music industry value chain'' and ''create[s] standard choreographies around those messages,'' but ''to implement DDEX standards, you've got to have a half-decent IT facility . . . [a]nd that immediately cuts lots of people out''); Mechanical Licensing Collective Initial Comments at 25–26, U.S. Copyright Office Dkt. No. 2019–5 (Nov. 9, 2019), *https://www.regulations.gov/document?D=COLC-2019-0002-0011* (''the MLC has joined and is working with DDEX, and continues to explore the proper formats and standards for efficient and accurate data sharing''); MLCI Designation Proposal at 37–38 (discussing the CWR format's utility).

[53] Tr. at 111:15–112:05 (Dec. 6, 2019) (Nicole d'Avis, Open Music Initiative) (discussing the Open Music Initiative's efforts); Tr. at 90:10–91:07 (Dec. 6, 2019) (David Hughes, RIAA) (discussing creation of the MDX best practice working group).

Copyright Office's records, or reaching directly out to rightsholders to address ownership conflicts.[54] Specific practices that frustrate accurate royalty payments were addressed, including instances where digital music providers may alter song titles or artist names supplied by a record label.[55]

Artists and others who work with creators noted the lack of a one-size-fits-all solution to educating self-administered songwriters about how the MMA may affect their interests. Singer-songwriter Rosanne Cash emphasized that increased transparency ''would take so much pressure off of musicians and songwriters'' and help ensure they are paid fairly.[56] There was agreement that talking to creators ''in ways that really resonate . . . looks different in LA than it does in Miami.'' [57] In some cases, reaching creators may involve making free educational information available in the form of blog posts, webinars, e-books, or podcasts [58] or it may require ''peers talking to peers from their local community that have credibility.'' [59] It was suggested that ''the more information that songwriters have and the easier we make it for them to act on that information, the more successful [educating them] is going to be.'' [60]

2. Practices of Other Collective Management Organizations

The Copyright Office also commissioned a report by Susan Butler, publisher of Music Confidential, to provide a factual report detailing matching and royalty distribution practices of global collective management organizations (''CMOs''). In preparing her report, Ms. Butler surveyed CMOs around the world that represent musical works (whether performing rights, mechanical rights, or both) or public performance rights in recordings (neighboring rights).[61] Along with the Office's symposium, Ms. Butler's report is designed to give commenting parties an understanding of some of the activities and practical solutions that the MLC may potentially consider, based on experiences of CMOs around the world. It also highlights some of the structural distinctions between the MLC on the one hand and the many membership-based collectives throughout the world. Ms. Butler's report outlines several reasons why CMOs may encounter difficulty linking a recording title reported by a digital music provider to a specific musical work or specific rights holders to be able to distribute money to those rights holders, and methods that CMOs may employ in an attempt to identify and match works to recordings and rights holders, even after automated and manual methods have been employed.[62] The Butler report is available on the Copyright Office's website at *https://www.copyright.gov/policy/unclaimed-royalties/CMO-report.*

II. Subjects of Inquiry

The Office is seeking public comment on the following topics. While the focus of the study remains on best practices that may be recommended to the MLC, the Office has previously noted that ''the problems in the music marketplace need to be evaluated as a whole, rather than as isolated or individual concerns of particular stakeholders.'' [63] Therefore, the Office is also soliciting limited input related to policies or actions that digital music providers and others may implement to reduce the instance of unclaimed royalties as well as ways to empower and educate songwriters and copyright owners to address ownership data issues themselves.

In responding to the questions below, the Office encourages commenters to provide evidentiary support for their views, including by providing empirical data if possible. A party choosing to respond to this notice of inquiry need not address every topic, but the Office requests that responding parties clearly identify and separately address each topic for which a response is submitted.

A. Identifying and Locating Musical Work Copyright Owners

1. Please describe best practices that the MLC may employ in matching musical works to sound recordings and otherwise identifying and locating musical work copyright owners associated with works embodied in sound recordings pursuant to administering the blanket license. As applicable, please identify specific technological or manual approaches, as well as considerations relevant to the MLC's prioritization of resources.

2. Please identify any special issues with respect to the MLC's matching and distribution policies for musical works with identified, but unlocated copyright owners, or works for which only a partial amount of ownership information is available.

3. If you believe that practices of similar CMOs, here or abroad, are relevant or helpful, please identify those practices.

4. If you believe that past practices of individual digital music providers or vendors facilitating voluntary or statutory licensing are relevant or helpful, including any under the prior song-by-song licensing system, please identify those practices.

5. Are past efforts to build music ownership databases, such as the Global Repertoire Database, International Music Rights Registry, and International Music Joint Venture, helpful to consider in identifying best practices for the MLC? If so, how?

B. Encouraging Musical Work Copyright Owners To Claim Royalties

6. How can the MLC facilitate claiming of accrued royalties through its public database? If there are specific fields, search capabilities, or tools that would be beneficial, or not, to the MLC's core project, please identify them.

7. Please identify particular data formats or file types that would be helpful for the MLC to use in connection with encouraging copyright owners to have their works identified in the MLC's database.

8. What lessons can be learned from prior music dispute settlements and claiming systems, including the *Ferrick* v. *Spotify, Football Association Premier League v. YouTube,* and National Music Publishers' Association/Spotify settlements? What about the claiming portals or opt-in procedures for these agreements were beneficial or

[54] Tr. at 198:16–21, 247:01–08 (Dec. 6, 2019) (Bill Colitre, Music Reports) (noting that Music Reports uses syntax matching and unique identifiers to match works, but also ''50 copyright professionals'' to check the Copyright Office's records ''on a regular basis'' and contact rightsowners); Tr. at 222:22–224:21 (Dec. 6, 2019) (John Raso, Harry Fox Agency) (discussing how the Harry Fox Agency approaches automated matching and the ''push and pull of which way that algorithm should move'' to pay royalties and avoid ''bad matches''); Tr. at 231:12–232:07 (Dec. 6, 2019) (Sarah Rosenbaum, Google) (discussing using Google's ''proposer tool,'' used to reach out to rightsholders when there conflicting ownership assertions).

[55] Tr. at 119:03–120:06 (Dec. 6, 2019) (David Hughes, RIAA); *see also* 85 FR at 22522–23.

[56] Tr. at 163:09–11 (Dec. 6, 2019) (Rosanne Cash).

[57] Tr. at 346:01– 22 (Dec. 6, 2019) (Kimberly Tignor, Institute for Intellectual Property & Social Justice); *see also* Tr. at 296:13–20, 297:02–12 (Dec. 6, 2019) (Jennifer Turnbow, Nashville Songwriters Association International) (noting that ''Nashville is kind of a unicorn in the music industry because really, most of the commerce of music . . . happens on about three streets'' and there is opportunity and encouragement for songwriters to talk about issues like the MMA).

[58] Tr. at 311:05–09 (Dec. 6, 2019) (Dae Bogan, TuneRegistry) (discussing these engagement methods).

[59] Tr. at 318:13–16 (Dec. 6, 2019) (Todd Dupler, Recording Academy).

[60] Tr. at 291:05–08 (Dec. 6, 2019) (Todd Dupler, Recording Academy).

[61] Susan Butler, *Collective Rights Management Practices Around the World: A Survey of CMO Practices to Reduce the Occurrence of Unclaimed Royalties in Musical Works* 3 (2020), *https://www.copyright.gov/policy/unclaimed-royalties/CMO-full-report.pdf.*

[62] *Id.* at 11–13.

[63] U.S. Copyright Office, *Copyright and the Music Marketplace* at Preface (2015).

detrimental in encouraging copyright owners to claim accrued royalties?

9. Please identify education and outreach practices that the MLC should consider adopting in encouraging copyright owners to claim royalties.

10. Please identify activities or policies that the MLC may take or adopt to encourage groups of musical work copyright owners who may be underrepresented in the MLC's database to come forward and claim accrued royalties. Your response may consider, for example, the unique experiences of self-administered songwriters; genres expected to generate a more diffuse record of musical work ownership; [64] non-English language works or genres; non-U.S. based musical work copyright owners, including the role of international collection societies; and particular challenges associated with classical music metadata.

C. Reducing Incidence of Unclaimed, Accrued Royalties and Distribution of Royalties

11. Please identify issues for the MLC to consider in establishing policies related to its duty to distribute unclaimed accrued royalties after a prescribed holding period in a manner that incentivizes reduction in the overall incidence of unclaimed accrued royalties. In particular, identify considerations related to the timing of the initial distribution of unclaimed, accrued royalties, as well as the retention of a portion of accrued royalties in the hope that they may later be matched.

12. Please identify preferred methods for the MLC to publicize the existence of unclaimed accrued royalties before they are distributed, in light of the minimum 90-day period required by the statute.

13. Please describe how success in lowering the incidence of unclaimed royalties may best be measured.

D. Others in the Music Marketplace

14. What actions can others, including those engaged in digital platform, sound recording, music publishing, and music creation activities, voluntarily take to contribute to a more accurate musical work data supply chain?

15. What actions can better ensure the accurate assignment of unique identifiers like the International Standard Recording Code (''ISRC'') and International Standard Musical Work Code (''ISWC'') identifiers early in the digital supply chain?

16. Please identify education and outreach practices that digital music providers and others may consider adopting in encouraging copyright owners to claim royalties.

17. Please recommend existing guides or other resources regarding music data that can be used by copyright owners and songwriters, and/or information to be included in such educational materials.

E. Other Issues

18. Please identify any pertinent issues not referenced above that the Copyright Office should consider in conducting its study, including any further legislative changes that you believe are needed to reduce the instance of unclaimed royalties.

Dated: May 28, 2020.

Regan A. Smith,

General Counsel and Associate Register of Copyrights.

[FR Doc. 2020–11893 Filed 6–1–20; 8:45 am]

BILLING CODE 1410–30–P

[64] *See* Tr. at 263:17–22 (Dec. 6, 2019) (Ed Arrow, Universal Music Publishing Group) (noting collaborative nature of rap, hip-hop, and pop music); Tr. at 264:09–11 (Dec. 6, 2019) (Bill Colitre, Music Reports) (noting that the rap song ''Grillz'' by Nelly has ''17 writers and 23 music publishers'').

NATIONAL ARCHIVES AND RECORDS ADMINISTRATION

[NARA–2020–043]

Agency Information Collection Activities: Proposed Collection; Comment Request

AGENCY: National Archives and Records Administration (NARA).

ACTION: Notice of proposed extension request.

SUMMARY: We are planning to request that the Office of Management and Budget (OMB) renew its approval for us to engage in the following information collection and invite you to comment on it. We use this collection to obtain information from private foundations or other entities involved in designing, constructing, and equipping Presidential libraries.

DATES: We must receive in writing on or before August 3, 2020.

ADDRESSES: Send comments by email to *tamee.fechhelm@nara.gov.* Because our buildings are temporarily closed during the COVID–19 restrictions, we are not able to receive comments by mail during this time.

FOR FURTHER INFORMATION CONTACT: Contact Tamee Fechhelm, Paperwork Reduction Act Officer, by email at *tamee.fechhelm@nara.gov* or by telephone at 301.837.1694 with requests for additional information or copies of the proposed information collection and supporting statement.

SUPPLEMENTARY INFORMATION: Pursuant to the Paperwork Reduction Act of 1995 (Pub. L. 104–13), we invite the public and other Federal agencies to comment on proposed information collections. The comments and suggestions should address one or more of the following points: (a) Whether the proposed information collections are necessary for NARA to properly perform its functions; (b) our estimates of the burden of the proposed information collections and their accuracy; (c) ways we could enhance the quality, utility, and clarity of the information we collect; (d) ways we could minimize the burden on respondents of collecting the information, including through information technology; and (e) whether these collections affect small businesses. We will summarize any comments you submit and include the summary in our request for OMB approval. All comments will become a matter of public record. In this notice, we solicit comments concerning the following information collection:

Title: Presidential Library Facilities.

OMB number: 3095–0036.

Agency form number: None.

Type of review: Regular.

Affected public: Presidential library foundations or other entities proposing to transfer a Presidential library facility to NARA.

Estimated number of respondents: 1.

Estimated time per response: 40 hours.

Frequency of response: On occasion.

Estimated total annual burden hours: 40 hours.

Abstract: The information collection is required for NARA to meet its obligations under 44 U.S.C. 2112(a)(3) to submit a report to Congress before accepting a new Presidential library facility. The report contains information that can be furnished only by the foundation or other entity responsible for building the facility and establishing the library endowment.

Swarnali Haldar,

Executive for Information Services/CIO.

[FR Doc. 2020–11829 Filed 6–1–20; 8:45 am]

BILLING CODE 7515–01–P

NATIONAL ARCHIVES AND RECORDS ADMINISTRATION

[NARA–2020–042]

Agency Information Collection Activities: Submission for OMB Review; Comment Request

AGENCY: National Archives and Records Administration (NARA).

ACTION: Notice.

SUMMARY: We have submitted to OMB for approval our request to continue to use the information collection described in this notice, consisting of National Archives Trust Fund (NATF) order forms for genealogical research in the National Archives. The NATF forms included in this information collection are: NATF 84, National Archives Order for Copies of Land Entry Files; NATF 85, National Archives Order for Copies of Pension or Bounty Land Warrant Applications; and NATF 86, National Archives Order for Copies of Military Service Records. We invite you to comment on the proposed extension.

DATES: OMB must receive written comments on or before July 2, 2020.

ADDRESSES: Send comments and recommendations for the proposed information collection to *www.reginfo.gov/public/do/PRAMain* by July 2, 2020. Find this particular information collection by selecting ''Currently under 30-day Review—Open for Public Comments'' or by using the search function.

FOR FURTHER INFORMATION CONTACT: Contact Tamee Fechhelm, Paperwork Reduction Act Officer, by email at *tamee.fechhelm@nara.gov* or by telephone at 301.837.1694 with requests for additional information or copies of the proposed information collection and supporting statement.

SUPPLEMENTARY INFORMATION: Pursuant to the Paperwork Reduction Act of 1995 (Pub. L. 104–13), we invite the general public and other Federal agencies to comment on proposed information collections. We published a notice of proposed collection for this information collection on March 20, 2020 (85 FR 16135) and we received no comments. We have therefore submitted the described information collection to OMB for approval.

You should address one or more of the following points in any comments or suggestions you submit: (a) whether the proposed information collections are necessary for NARA to properly perform its functions; (b) our estimates of the burden of the proposed information collections and their accuracy; (c) ways we could enhance the quality, utility, and clarity of the information we collect; (d) ways we could minimize the burden on respondents of collecting the information, including through information technology; and (e) whether these collections affect small businesses. All comments will become a matter of public record. In this notice, we solicit comments concerning the following information collection:

Title: Order Forms for Genealogical Research in the National Archives.

OMB number: 3095–0027.

Agency form numbers: NATF Forms 84, 85, and 86.

Type of review: Regular.

Affected public: Individuals or households.

Estimated number of respondents: 7,139.

Estimated time per response: 10 minutes.

Frequency of response: On occasion.

Estimated total annual burden hours: 1,190.

Abstract: We need to obtain specific information from researchers who wish to request copies of these records, in order to search for the specific records they seek and to handle their order and payment for copies of the records. We use these standardized forms as the means of collecting the needed information so that we can handle the volume of requests we receive for these records in a timely fashion. Researchers provide credit card information to authorize billing or request expedited mailing of the copies. They may use paper or electronic versions of the forms or may fill them out and order online through our Order Online! service at *http://www.archives.gov/research_room/obtain_copies/military_and_genealogy_order_forms.html.*

Swarnali Haldar,

Executive for Information Services/CIO.

[FR Doc. 2020–11826 Filed 6–1–20; 8:45 am]

BILLING CODE 7515–01–P

NUCLEAR REGULATORY COMMISSION

[NRC–2019–0061]

Seismic Qualification of Electrical and Active Mechanical Equipment and Functional Qualification of Active Mechanical Equipment for Nuclear Power Plants

AGENCY: Nuclear Regulatory Commission.

ACTION: Regulatory guide; issuance.

SUMMARY: The U.S. Nuclear Regulatory Commission (NRC) is issuing Revision 4 to Regulatory Guide (RG) 1.100, ''Seismic Qualification of Electrical and Active Mechanical Equipment and Functional Qualification of Active Mechanical Equipment for Nuclear Power Plants.'' RG 1.100 was revised to endorse industry consensus standards with certain exceptions and clarifications. The guide describes methods that the staff of the NRC considers acceptable for use in the seismic qualification of electrical and active mechanical equipment and the functional qualification of active mechanical equipment for nuclear power plants.

DATES: Revision 4 to RG 1.100 is available on June 2, 2020.

ADDRESSES: Please refer to Docket ID NRC–2019–0100 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 *https://www.regulations.gov* and search for Docket ID NRC–2019–0100. Address questions about NRC dockets IDs in *Regulations.gov* to Jennifer Borges; telephone: 301–287–9127; email: *Jennifer.Borges@nrc.gov.* For technical questions, contact the individuals listed in the **FOR FURTHER INFORMATION CONTACT** section of this document.
- *NRC's Agencywide Documents Access and Management System (ADAMS):* You may obtain publicly-available documents online in the ADAMS Public Documents collection at *https://www.nrc.gov/reading-rm/adams.html.* To begin the search, select ''Begin Web-based ADAMS Search.'' For problems with ADAMS, please contact the NRC's Public Document Room (PDR) reference staff at 1–800–397–4209, 301–415–4737, or by email to *pdr.resource@nrc.gov*.

Revision 4 to RG 1.100 and the regulatory analysis may be found in NRC's ADAMS under Accession Nos. ML19312C677 and ML18093A676, respectively.

Regulatory guides are not copyrighted, and NRC approval is not required to reproduce them.

FOR FURTHER INFORMATION CONTACT: Ian Tseng, Office of Nuclear Reactor Regulation, telephone: 301–415–7964, email: *Ian.Tseng@nrc.gov,* and Edward O'Donnell, Office of Nuclear Regulatory Research, telephone: 301–415–3317, email: *Edward.Odonnell@nrc.gov*. Both are staff members of the U.S. Nuclear Regulatory Commission, Washington, DC 20555–0001.

SUPPLEMENTARY INFORMATION:

I. Discussion

The NRC is issuing a revision to an existing guide in the NRC's ''Regulatory Guide'' series. This series was developed to describe and make available to the public information regarding methods that are acceptable to the NRC staff for implementing specific parts of the agency's regulations, techniques that the NRC staff uses in evaluating specific issues or postulated

events, and data that the NRC staff needs in its review of applications for permits and licenses.

Revision 4 of RG 1.100 was issued with a temporary identification of Draft Regulatory Guide, DG–1328. The guide was revised to endorse, with exceptions and clarifications the following industry consensus standards: (1) Institute of Electrical and Electronics Engineers (IEEE) Standard (Std) 344–2013, ''IEEE Standard for Seismic Qualification of Equipment for Nuclear Power Generating Stations,'' (2) IEEE Std C37.98–2013, ''Standard Qualification Testing of Protective Relays and Auxiliaries for Nuclear Facilities,'' and (3) American Society of Mechanical Engineers (ASME) QME–1–2017, ''Qualification of Active Mechanical Equipment Used in Nuclear Facilities.''

II. Additional Information

The NRC published a notice of the availability of DG–1328 in the **Federal Register** on February 27, 2019 (84 FR 6444) for a 60-day public comment period. The public comment period closed on April 29, 2019. Public comments on DG–1328 and the staff responses to the public comments are available in ADAMS under Accession No. ML19312C678.

III. Congressional Review Act

This RG is a rule as defined in the Congressional Review Act (5 U.S.C. 801–808). However, the Office of Management and Budget has not found it to be a major rule as defined in the Congressional Review Act.

IV. Backfitting, Forward Fitting, and Issue Finality

Issuance of this regulatory guide does not constitute backfitting as defined in title 10 of the *Code of Federal Regulations* (10 CFR) section 50.109, ''Backfitting,'' and as described in NRC Management Directive 8.4, ''Management of Backfitting, Forward Fitting, Issue Finality, and Information Requests''; constitute forward fitting as that term is defined and described in Management Directive 8.4; or affect issue finality of any approval issued under 10 CFR part 52, ''Licenses, Certificates, and Approvals for Nuclear Power Plants.'' As explained in this regulatory guide, applicants and licensees are not required to comply with the positions set forth in this regulatory guide.

Dated: May 27, 2020.

For the Nuclear Regulatory Commission.

Harriet Karagiannis,

Acting Chief, Regulatory Guidance and Generic Issues Branch, Division of Engineering, Office of Nuclear Regulatory Research.

[FR Doc. 2020–11759 Filed 6–1–20; 8:45 am]

BILLING CODE 7590–01–P

NUCLEAR REGULATORY COMMISSION

[NRC–2020–0108]

Applications and Amendments to Facility Operating Licenses and Combined Licenses Involving Proposed No Significant Hazards Considerations and Containing Sensitive Unclassified Non-Safeguards Information and Order Imposing Procedures for Access to Sensitive Unclassified Non-Safeguards Information

AGENCY: Nuclear Regulatory Commission.

ACTION: License amendment request; notice of opportunity to comment, request a hearing, and petition for leave to intervene; order imposing procedures.

SUMMARY: The U.S. Nuclear Regulatory Commission (NRC) received and is considering approval of two amendment requests. The amendment requests are for Oconee Nuclear Station, Units 1, 2, and 3; and Watts Bar Nuclear Plant, Units 1 and 2. For each amendment request, the NRC proposes to determine that they involve no significant hazards consideration. Because each amendment request contains sensitive unclassified non-safeguards information (SUNSI) an order imposes procedures to obtain access to SUNSI for contention preparation.

DATES: Comments must be filed by July 2, 2020. A request for a hearing or petitions for leave to intervene must be filed by August 3, 2020. Any potential party as defined in § 2.4 of title 10 of the *Code of Federal Regulations* (10 CFR), who believes access to SUNSI is necessary to respond to this notice must request document access by June 12, 2020.

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

- *Federal Rulemaking Website:* Go to *https://www.regulations.gov* and search for Docket ID NRC–2020–0108. Address questions about NRC 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:* Office of Administration, Mail Stop: TWFN–7–A60M, U.S. Nuclear Regulatory Commission, Washington, DC 20555–0001, ATTN: Program Management, Announcements and Editing Staff.

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: Bernadette Abeywickrama, Office of Nuclear Reactor Regulation, U.S. Nuclear Regulatory Commission, Washington, DC 20555–0001, telephone: 301–415–0481, email: *bernadette.abeywickrama@nrc.gov* .

SUPPLEMENTARY INFORMATION:

I. Obtaining Information and Submitting Comments

A. Obtaining Information

Please refer to Docket ID NRC–2020–0108, facility name, unit number(s), plant docket number(s), application date, and subject when contacting the NRC about the availability of information for this action. You may obtain publicly-available information related to this action by any of the following methods:

- *Federal Rulemaking Website:* Go to *https://www.regulations.gov* and search for Docket ID NRC–2020–0108.
- *NRC's Agencywide Documents Access and Management System (ADAMS):* You may obtain publicly-available documents online in the ADAMS Public Documents collection at *https://www.nrc.gov/reading-rm/adams.html.* To begin the search, select ''Begin Web-based ADAMS Search.'' For problems with ADAMS, please contact the NRC's Public Document Room (PDR) reference staff at 1–800–397–4209, 301–415–4737, or by email to *pdr.resource@nrc.gov.* 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.

B. Submitting Comments

Please include Docket ID NRC–2020–0108, facility name, unit number(s), plant docket number(s), application date, and subject in your comment submission.

The NRC cautions you not to include identifying or contact information that you do not want to be publicly disclosed in your comment submission.

The NRC will post all comment submissions at *https://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. Background

Pursuant to Section 189a.(2) of the Atomic Energy Act of 1954, as amended (the Act), the NRC is publishing this notice. The Act requires the Commission to publish notice of any amendments issued, or proposed to be issued and grants the Commission the authority to issue and make immediately effective any amendment to an operating license or combined license, as applicable, upon a determination by the Commission that such amendment involves no significant hazards consideration, notwithstanding the pendency before the Commission of a request for a hearing from any person.

This notice includes notices of amendments containing SUNSI.

III. Notice of Consideration of Issuance of Amendments to Facility Operating Licenses and Combined Licenses, Proposed No Significant Hazards Consideration Determination, and Opportunity for a Hearing

The Commission has made a proposed determination that the following amendment requests involve no significant hazards consideration. Under the Commission's regulations in 10 CFR 50.92, this means that operation of the facility in accordance with the proposed amendment would not (1) involve a significant increase in the probability or consequences of an accident previously evaluated, or (2) create the possibility of a new or different kind of accident from any accident previously evaluated, or (3) involve a significant reduction in a margin of safety. The basis for this proposed determination for each amendment request is shown below.

The Commission is seeking public comments on this proposed determination. Any comments received within 30 days after the date of publication of this notice will be considered in making any final determination.

Normally, the Commission will not issue the amendment until the expiration of 60 days after the date of publication of this notice. The Commission may issue the license amendment before expiration of the 60-day period provided that its final determination is that the amendment involves no significant hazards consideration. In addition, the Commission may issue the amendment prior to the expiration of the 30-day comment period if circumstances change during the 30-day comment period such that failure to act in a timely way would result, for example, in derating or shutdown of the facility. If the Commission takes action prior to the expiration of either the comment period or the notice period, it will publish a notice of issuance in the **Federal Register**. If the Commission makes a final no significant hazards consideration determination, any hearing will take place after issuance. The Commission expects that the need to take this action will occur very infrequently.

A. Opportunity To Request a Hearing and Petition for Leave To Intervene

Within 60 days after the date of publication of this notice, any persons (petitioner) whose interest may be affected by this action may file a request for a hearing and petition for leave to intervene (petition) with respect to the action. Petitions shall be filed in accordance with the Commission's ''Agency Rules of Practice and Procedure'' in 10 CFR part 2. Interested persons should consult a current copy of 10 CFR 2.309. The NRC's regulations are accessible electronically from the NRC Library on the NRC's website at *https://www.nrc.gov/reading-rm/doc-collections/cfr/.* 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 to be made a party to the proceeding; (3) the nature and extent of the petitioner's property, financial, or other interest in the proceeding; and (4) the possible effect of any decision or order which may be entered in the proceeding on the petitioner's interest.

In accordance with 10 CFR 2.309(f), the petition must also set forth the specific contentions which the petitioner seeks to have litigated in the proceeding. Each contention must consist of a specific statement of the issue of law or fact to be raised or controverted. In addition, the petitioner must provide a brief explanation of the bases for the contention and a concise statement of the alleged facts or expert opinion which support the contention and on which the petitioner intends to rely in proving the contention at the hearing. The petitioner must also provide references to the specific sources and documents on which the petitioner intends to rely to support its position on the issue. The petition must include sufficient information to show that a genuine dispute exists with the applicant or licensee on a material issue of law or fact. Contentions must be limited to matters within the scope of the proceeding. The contention must be one which, if proven, would entitle the petitioner to relief. A petitioner who fails to satisfy the requirements at 10 CFR 2.309(f) with respect to at least one contention will not be permitted to participate as a party.

Those permitted to intervene become parties to the proceeding, subject to any limitations in the order granting leave to intervene. Parties have the opportunity to participate fully in the conduct of the hearing with respect to resolution of that party's admitted contentions, including the opportunity to present evidence, consistent with the NRC's regulations, policies, and procedures.

Petitions must be filed no later than 60 days from the date of publication of this notice. Petitions and motions for leave to file new or amended contentions that are filed after the deadline will not be entertained absent a determination by the presiding officer that the filing demonstrates good cause by satisfying the three factors in 10 CFR 2.309(c)(1)(i) through (iii). The petition must be filed in accordance with the filing instructions in the ''Electronic Submissions (E-Filing)'' section of this document.

If a hearing is requested, and the Commission has not made a final determination on the issue of no significant hazards consideration, the Commission will make a final determination on the issue of no significant hazards consideration. The final determination will serve to establish when the hearing is held. If the final determination is that the amendment request involves no significant hazards consideration, the Commission may issue the amendment and make it immediately effective,

notwithstanding the request for a hearing. Any hearing would take place after issuance of the amendment. If the final determination is that the amendment request involves a significant hazards consideration, then any hearing held would take place before the issuance of the amendment unless the Commission finds an imminent danger to the health or safety of the public, in which case it will issue an appropriate order or rule under 10 CFR part 2.

A State, local governmental body, Federally-recognized Indian Tribe, or agency thereof, may submit a petition to the Commission to participate as a party under 10 CFR 2.309(h)(1). The petition should state the nature and extent of the petitioner's interest in the proceeding. The petition should be submitted to the Commission no later than 60 days from the date of publication of this notice. The petition must be filed in accordance with the filing instructions in the ''Electronic Submissions (E-Filing)'' section of this document, and should meet the requirements for petitions set forth in this section, except that under 10 CFR 2.309(h)(2) a State, local governmental body, or Federally-recognized Indian Tribe, or agency thereof does not need to address the standing requirements in 10 CFR 2.309(d) if the facility is located within its boundaries. Alternatively, a State, local governmental body, Federally-recognized Indian Tribe, or agency thereof may participate as a non-party under 10 CFR 2.315(c).

If a hearing is granted, any person who is not a party to the proceeding and is not affiliated with or represented by a party may, at the discretion of the presiding officer, be permitted to make a limited appearance pursuant to the provisions of 10 CFR 2.315(a). A person making a limited appearance may make an oral or written statement of his or her position on the issues but may not otherwise participate in the proceeding. A limited appearance may be made at any session of the hearing or at any prehearing conference, subject to the limits and conditions as may be imposed by the presiding officer. Details regarding the opportunity to make a limited appearance will be provided by the presiding officer if such sessions are scheduled.

B. Electronic Submissions (E-Filing)

All documents filed in NRC adjudicatory proceedings, including a request for hearing and petition for leave to intervene (petition), any motion or other document filed in the proceeding prior to the submission of a request for hearing or petition to intervene, and documents filed by interested governmental entities that request to participate under 10 CFR 2.315(c), must be filed in accordance with the NRC's E-Filing rule (72 FR 49139; August 28, 2007, as amended at 77 FR 46562; August 3, 2012). The E-Filing process requires participants to submit and serve all adjudicatory documents over the internet, or in some cases to mail copies on electronic storage media. Detailed guidance on making electronic submissions may be found in the Guidance for Electronic Submissions to the NRC and on the NRC website at *https://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 *https://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 *https://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 *https://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.

Duke Energy Carolinas, LLC, Docket Nos. 50–269, 50–270, and 50–287, Oconee Nuclear Station, Units 1, 2, and 3, Oconee County, South Carolina

Date of amendment request: February 19, 2020, as supplemented by letter dated April 6, 2020. Publicly-available versions are available in ADAMS under Accession No. ML20050D379 and Accession No. ML20097E117, respectively.

Description of amendment request: This amendment request contains sensitive unclassified non-safeguards information (SUNSI). The proposed amendment would revise the Renewed Operating Licenses and Technical Specifications (TSs) for each unit at the Oconee Nuclear Station, Units 1, 2, and 3, to support a measurement uncertainty recapture power uprate from 2568 megawatts thermal (MWt) to 2610 MWt.

Basis for proposed no significant hazards consideration determination: As required by 10 CFR 50.91(a), the licensee has provided its analysis of the issue of no significant hazards consideration, which is presented below:

1. Does the proposed amendment involve a significant increase in the probability or consequences of an accident previously evaluated?

Response: No.

The proposed amendment changes the rated thermal power from 2568 megawatts thermal (MWt) to 2610 MWt; an increase of approximately 1.64% Rated Thermal Power. Duke Energy's evaluations have shown that all structures, systems and components (SSCs) are capable of performing their design function at the uprated power of 2610 MWt. A review of station accident analyses found that all acceptance criteria are still met at the uprated power of 2610 MWt.

The radiological consequences of operation at the uprated power conditions have been assessed. The proposed power uprate does not affect release paths, frequency of release, or the analyzed reactor core fission product inventory for any accidents previously evaluated in the Updated Final Safety Analysis Report. Analyses performed to assess the effects of mass and energy releases remain valid. All acceptance criteria for radiological consequences continue to be met at the uprated power level.

The proposed change does not involve any change to the design or functional requirements of the safety and support systems. That is, the increased power level neither degrades the performance of, nor increases the challenges to any safety systems assumed to function in the plant safety analysis.

While power level is an input to accident analyses, it is not an initiator of accidents. The proposed change does not affect any accident precursors and does not introduce any accident initiators. The proposed change does not impact the usefulness of the Surveillance Requirements in evaluating the operability of required systems and components.

In addition, evaluation of the proposed TS changes demonstrates that the ability of equipment and systems required to prevent or mitigate the radiological consequences of an accident is not significantly affected. Since the impact on the systems is minimal, it is concluded that the overall impact on the plant safety analysis is negligible.

Therefore, the proposed TS change does not significantly increase 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.

No new accident scenarios, failure mechanisms, or single failures are introduced as a result of the proposed change. The installation of the Cameron LEFM CheckPlus System has been analyzed and failures of the system will have no adverse effect on any safety-related system or any SSCs required for transient mitigation. SSCs previously required for the mitigation of a transient continue to be capable of fulfilling their intended design functions. The proposed change has no adverse effect on any safety-related system or component and does not change the performance or integrity of any safety-related system.

The proposed change does not adversely affect any current system interfaces or create any new interfaces that could result in an accident or malfunction of a different kind than previously evaluated. Operation at the uprated power level does not create any new accident initiators or precursors. Credible malfunctions are bounded by the current accident analyses of record or recent evaluations demonstrating that applicable criteria are still met with the proposed change.

Therefore, this 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.

Although the proposed amendment increases the ONS [Oconee Nuclear Station] Units 1, 2, and 3 operating power level, the units retain their margin of safety because it is only increasing power by the amount equal to the reduction in uncertainty in the heat balance calculation. The margins of safety associated with the power uprate are those pertaining to core thermal power. These include fuel cladding, reactor coolant system pressure boundary, and containment barriers. Analyses demonstrate that the current design basis continues to be met after the measurement uncertainty recapture power uprate. Components associated with the reactor coolant system pressure boundary structural integrity, including pressure-temperature limits, vessel fluence, and pressurized thermal shock are bounded by the current analyses. Systems will continue to operate within their design parameters and remain capable of performing their intended safety functions.

The current ONS safety analyses including the design basis radiological accident dose calculations, bound the power uprate.

Therefore, the proposed change does not involve a significant reduction in a margin of safety.

The NRC staff has reviewed the licensee's analysis and, based on this review, it appears that the three standards of 10 CFR 50.92(c) are satisfied. Therefore, the NRC staff proposes to determine that the amendment request involves no significant hazards consideration.

Attorney for licensee: Kate Nolan, Deputy General Counsel, Duke Energy Carolinas, 550 South Tryon Street, Charlotte, NC 28202.

NRC Branch Chief: Michael T. Markley.

Tennessee Valley Authority (TVA), Docket Nos. 50–390 and 50–391, Watts Bar Nuclear Plant (WBN), Units 1 and 2, Rhea County, Tennessee

Date of amendment request: January 17, 2020. A publicly-available version is available in ADAMS under Accession No. ML20017A338.

Description of amendment request: This amendment request contains SUNSI. The amendment would revise WBN, Units 1 and 2 TS 5.9.5, ''Core Operating Limits Report,'' to replace the loss-of-coolant accident (LOCA) analysis evaluation model references with reference to the FULL SPECTRUM™ Loss-of-Coolant Accident (FSLOCA™) Evaluation Model analysis applicable to

WBN, Units 1 and 2, with replacement steam generators. The amendments would also revise WBN, Unit 2 Operating License condition 2.C(4) to reflect the implementation of the FSLOCA Evaluation Model methodology. The amendment would also revise WBN, Unit 1 TS 4.2.1, ''Fuel Assemblies,'' to delete discussion of Zircalloy fuel rods. Lastly, the amendment would approve a new LOCA-specific Tritium Producing Burnable Absorber Rod stress analysis methodology.

Basis for proposed no significant hazards consideration determination: As required by 10 CFR 50.91(a), the licensee has provided its analysis of the issue of no significant hazards consideration, which is presented below:

1. Does the proposed amendment involve a significant increase in the probability or consequence of an accident previously evaluated?

Response: No.

The proposed change to WBN Units 1 and 2, TS 5.9.5, ''Core Operating Limits Report,'' to replace the LOCA analysis evaluation model references with reference to the FSLOCA Evaluation Model analysis applicable to both WBN Unit 1 and Unit 2 with replacement steam generators. The proposed change would also revise WBN Unit 1 TS 4.2.1, ''Fuel Assemblies,'' to delete discussion of Zircalloy fuel rods. These changes implement a Nuclear Regulatory Commission (NRC) approved LOCA evaluation model. The analysis results for WBN Units 1 and 2, based on using the new evaluation model meet the regulatory requirements of 10 CFR 50.46. The use of a new NRC-approved LOCA evaluation model will not increase the potential for an accident. Therefore, the possibility of an accident is not increased by the proposed changes. Because the reactor core meets the regulatory requirements of 10 CFR 50.46 after a postulated LOCA, the consequences of an accident are not increased by the proposed changes.

The use of separate simulations performed in accordance with the FSLOCA Evaluation Model as part of the new tritium producing burnable absorber rod (TPBAR) stress analysis methodology developed by Pacific Northwest National Laboratory and Westinghouse provide a recovery of margin in the post-LOCA criticality evaluation in the presence of assumed TPBR failures. The TPBARs were conservatively assumed to rupture due to high cladding temperature and pressure differential during LBLOCA events. TPBAR rupture results in a positive reactivity addition and is a penalty in the post-LOCA criticality evaluation. TVA proposes to use the FSLOCA Evaluation Model methodology and the new LOCA-specific TPBAR stress analysis methodology to evaluate the integrity of the TPBARs. The results show that TPBARs will not rupture (with high probability and confidence). Crediting the continued integrity of the TPBARs results will be utilized in the core reload design process to simplify core designs, increase tritium production, and improve fuel cycle economics. The safety analysis process for each reload design will continue to demonstrate that all regulatory criteria are met. The use of a new TPBAR stress analysis methodology will not increase the potential for an accident. Therefore, the possibility of an accident is not increased by the proposed changes. Because the TPBAR failure analysis results show that TPBARs will not rupture (with high probability and confidence), the consequences of an accident are not increased by the proposed changes.

Based on the above discussions, the proposed changes do not involve an increase in the probability or consequences of an accident previously evaluated.

2. Does the proposed amendment create the possibility of a new or different kind of accident from any accident previously evaluated?

Response: No.

The proposed change to WBN Units 1 and 2 TS 5.9.5 to replace the LOCA analysis evaluation model references with reference to FSLOCA Evaluation Model and the corresponding change to WBN Unit 1 TS 4.2.1 implement an NRC-approved LOCA evaluation model. The use of the new TPBAR stress analysis methodology to analyze the potential for TPBAR failures provides recovery of margin in the post-LOCA criticality evaluation in the presence of assumed TPBAR failures. The use of these two new analytical methodologies will not create the possibility of a new or different kind of accident from any accident previously evaluated.

Therefore, the proposed changes do not create the possibility of a new or different kind of accident from any accident previously evaluated.

3. Does the proposed amendment involve a significant reduction in a margin of safety?

Response: No.

The proposed change to WBN Units 1 and 2 TS 5.9.5 to replace the LOCA analysis evaluation model references with reference to the FSLOCA Evaluation Model and the corresponding change to WBN Unit 1 TS 4.2.1 implement an NRC-approved LOCA evaluation model. The analysis results for WBN Units 1 and 2, based on using the new evaluation model, meet the regulatory requirements of 10 CFR 50.46 with increased margin after a postulated LOCA.

The analysis results for WBN Units 1 and 2, based on using the new LOCA specific TPBAR stress analysis methodology show that TPBARs will not rupture (with high probability and confidence), which provides an increase of margin in the post-LOCA criticality evaluation in the presence of assumed TPBAR failures.

Accordingly, the proposed changes do not involve a significant reduction in a margin of safety.

The NRC staff has reviewed the licensee's analysis and, based on this review, it appears that the three standards of 10 CFR 50.92(c) are satisfied. Therefore, the NRC staff proposes to determine that the amendment request involves no significant hazards consideration.

Attorney for licensee: General Counsel, Tennessee Valley Authority, 400 West Summit Hill Drive, 6A West Tower, Knoxville, TN 37902.

NRC Branch Chief: Undine Shoop.

Order Imposing Procedures for Access to Sensitive Unclassified Non-Safeguards Information for Contention Preparation

Duke Energy Carolinas, LLC, Docket Nos. 50–269, 50–270, and 50–287 Oconee Nuclear Station, Units 1, 2, and 3, Oconee County, South Carolina

Tennessee Valley Authority, Docket Nos. 50–390 and 50–391, Watts Bar Nuclear Plant, Units 1 and 2, Rhea County, Tennessee

A. This Order contains instructions regarding how potential parties to this proceeding may request access to documents containing SUNSI.

B. Within 10 days after publication of this notice of hearing and opportunity to petition for leave to intervene, any potential party who believes access to SUNSI is necessary to respond to this notice may request access to SUNSI. A ''potential party'' is any person who intends to participate as a party by demonstrating standing and filing an admissible contention under 10 CFR 2.309. Requests for access to SUNSI submitted later than 10 days after publication of this notice will not be considered absent a showing of good cause for the late filing, addressing why the request could not have been filed earlier.

C. The requestor shall submit a letter requesting permission to access SUNSI to the Office of the Secretary, U.S. Nuclear Regulatory Commission, Washington, DC 20555–0001, Attention: Rulemakings and Adjudications Staff, and provide a copy to the Deputy General Counsel for Hearings and Administration, Office of the General Counsel, U.S. Nuclear Regulatory Commission, Washington, DC 20555–0001. The expedited delivery or courier mail address for both offices is: U.S. Nuclear Regulatory Commission, 11555 Rockville Pike, Rockville, Maryland 20852. The email address for the Office of the Secretary and the Office of the General Counsel are *Hearing.Docket@nrc.gov* and *RidsOgcMailCenter.Resource@nrc.gov,* respectively.[1] The request must include the following information:

[1] While a request for hearing or petition to intervene in this proceeding must comply with the filing requirements of the NRC's ''E-Filing Rule,'' the initial request to access SUNSI under these

(1) A description of the licensing action with a citation to this **Federal Register** notice;

(2) The name and address of the potential party and a description of the potential party's particularized interest that could be harmed by the action identified in C.(1); and

(3) The identity of the individual or entity requesting access to SUNSI and the requestor's basis for the need for the information in order to meaningfully participate in this adjudicatory proceeding. In particular, the request must explain why publicly available versions of the information requested would not be sufficient to provide the basis and specificity for a proffered contention.

D. Based on an evaluation of the information submitted under paragraph C.(3) the NRC staff will determine within 10 days of receipt of the request whether:

(1) There is a reasonable basis to believe the petitioner is likely to establish standing to participate in this NRC proceeding; and

(2) The requestor has established a legitimate need for access to SUNSI.

E. If the NRC staff determines that the requestor satisfies both D.(1) and D.(2) above, the NRC staff will notify the requestor in writing that access to SUNSI has been granted. The written notification will contain instructions on how the requestor may obtain copies of the requested documents, and any other conditions that may apply to access to those documents. These conditions may include, but are not limited to, the signing of a Non-Disclosure Agreement or Affidavit, or Protective Order [2] setting forth terms and conditions to prevent the unauthorized or inadvertent disclosure of SUNSI by each individual who will be granted access to SUNSI.

F. Filing of Contentions. Any contentions in these proceedings that are based upon the information received as a result of the request made for SUNSI must be filed by the requestor no later than 25 days after receipt of (or access to) that information. However, if more than 25 days remain between the petitioner's receipt of (or access to) the information and the deadline for filing all other contentions (as established in the notice of hearing or opportunity for hearing), the petitioner may file its SUNSI contentions by that later deadline.

G. Review of Denials of Access.

(1) If the request for access to SUNSI is denied by the NRC staff after a determination on standing and requisite need, the NRC staff shall immediately notify the requestor in writing, briefly stating the reason or reasons for the denial.

(2) The requestor may challenge the NRC staff's adverse determination by filing a challenge within 5 days of receipt of that determination with: (a) The presiding officer designated in this proceeding; (b) if no presiding officer has been appointed, the Chief Administrative Judge, or if he or she is unavailable, another administrative judge, or an Administrative Law Judge with jurisdiction pursuant to 10 CFR 2.318(a); or (c) if another officer has been designated to rule on information access issues, with that officer.

(3) Further appeals of decisions under this paragraph must be made pursuant to 10 CFR 2.311.

H. Review of Grants of Access. A party other than the requestor may challenge an NRC staff determination granting access to SUNSI whose release would harm that party's interest independent of the proceeding. Such a challenge must be filed within 5 days of the notification by the NRC staff of its grant of access and must be filed with: (a) The presiding officer designated in this proceeding; (b) if no presiding officer has been appointed, the Chief Administrative Judge, or if he or she is unavailable, another administrative judge, or an Administrative Law Judge with jurisdiction pursuant to 10 CFR 2.318(a); or (c) if another officer has been designated to rule on information access issues, with that officer.

If challenges to the NRC staff determinations are filed, these procedures give way to the normal process for litigating disputes concerning access to information. The availability of interlocutory review by the Commission of orders ruling on such NRC staff determinations (whether granting or denying access) is governed by 10 CFR 2.311.[3]

I. The Commission expects that the NRC staff and presiding officers (and any other reviewing officers) will consider and resolve requests for access to SUNSI, and motions for protective orders, in a timely fashion in order to minimize any unnecessary delays in identifying those petitioners who have standing and who have propounded contentions meeting the specificity and basis requirements in 10 CFR part 2. The attachment to this Order summarizes the general target schedule for processing and resolving requests under these procedures.

It is so ordered.

Dated: May 12, 2020.

For the Nuclear Regulatory Commission.

Annette L. Vietti-Cook,

Secretary of the Commission.

ATTACHMENT 1—GENERAL TARGET SCHEDULE FOR PROCESSING AND RESOLVING REQUESTS FOR ACCESS TO SENSITIVE UNCLASSIFIED NON-SAFEGUARDS INFORMATION IN THIS PROCEEDING

Day	Event/activity
0	Publication of **Federal Register** notice of hearing and opportunity to petition for leave to intervene, including order with instructions for access requests.
10	Deadline for submitting requests for access to Sensitive Unclassified Non-Safeguards Information (SUNSI) with information: Supporting the standing of a potential party identified by name and address; describing the need for the information in order for the potential party to participate meaningfully in an adjudicatory proceeding.
60	Deadline for submitting petition for intervention containing: (i) Demonstration of standing; and (ii) all contentions whose formulation does not require access to SUNSI (+25 Answers to petition for intervention; +7 petitioner/requestor reply).
20	U.S. Nuclear Regulatory Commission (NRC) staff informs the requestor of the staff's determination whether the request for access provides a reasonable basis to believe standing can be established and shows need for SUNSI. (NRC staff also informs any party to the proceeding whose interest independent of the proceeding would be harmed by the release of the information.) If NRC staff makes the finding of need for SUNSI and likelihood of standing, NRC staff begins document processing (preparation of redactions or review of redacted documents).

procedures should be submitted as described in this paragraph.

[2] Any motion for Protective Order or draft Non-Disclosure Affidavit or Agreement for SUNSI must be filed with the presiding officer or the Chief Administrative Judge if the presiding officer has not yet been designated, within 30 days of the deadline for the receipt of the written access request.

[3] Requestors should note that the filing requirements of the NRC's E-Filing Rule (72 FR 49139; August 28, 2007, as amended at 77 FR 46562; August 3, 2012) apply to appeals of NRC staff determinations (because they must be served on a presiding officer or the Commission, as applicable), but not to the initial SUNSI request submitted to the NRC staff under these procedures.

ATTACHMENT 1—GENERAL TARGET SCHEDULE FOR PROCESSING AND RESOLVING REQUESTS FOR ACCESS TO SENSITIVE UNCLASSIFIED NON-SAFEGUARDS INFORMATION IN THIS PROCEEDING—Continued

Day	Event/activity
25	If NRC staff finds no ''need'' or no likelihood of standing, the deadline for petitioner/requestor to file a motion seeking a ruling to reverse the NRC staff's denial of access; NRC staff files copy of access determination with the presiding officer (or Chief Administrative Judge or other designated officer, as appropriate). If NRC staff finds ''need'' for SUNSI, the deadline for any party to the proceeding whose interest independent of the proceeding would be harmed by the release of the information to file a motion seeking a ruling to reverse the NRC staff's grant of access.
30	Deadline for NRC staff reply to motions to reverse NRC staff determination(s).
40	(Receipt +30) If NRC staff finds standing and need for SUNSI, deadline for NRC staff to complete information processing and file motion for Protective Order and draft Non-Disclosure Affidavit. Deadline for applicant/licensee to file Non-Disclosure Agreement for SUNSI.
A	If access granted: Issuance of presiding officer or other designated officer decision on motion for protective order for access to sensitive information (including schedule for providing access and submission of contentions) or decision reversing a final adverse determination by the NRC staff.
A + 3	Deadline for filing executed Non-Disclosure Affidavits. Access provided to SUNSI consistent with decision issuing the protective order.
A + 28	Deadline for submission of contentions whose development depends upon access to SUNSI. However, if more than 25 days remain between the petitioner's receipt of (or access to) the information and the deadline for filing all other contentions (as established in the notice of opportunity to request a hearing and petition for leave to intervene), the petitioner may file its SUNSI contentions by that later deadline.
A + 53	(Contention receipt +25) Answers to contentions whose development depends upon access to SUNSI.
A + 60	(Answer receipt +7) Petitioner/Intervenor reply to answers.
>A + 60	Decision on contention admission.

[FR Doc. 2020–10530 Filed 6–1–20; 8:45 am]

BILLING CODE 7590–01–P

NUCLEAR REGULATORY COMMISSION

[NRC–2019–0218]

Information Collection: Notice of Enforcement Discretion (NOED) for Operating Power Reactors and Gaseous Diffusion Plants (NRC Enforcement Policy)

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, ''Notice of Enforcement Discretion (NOED) for Operating Power Reactors and Gaseous Diffusion Plants (NRC Enforcement Policy).''

DATES: Submit comments by July 2, 2020. 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: Written comments and recommendations for the proposed information collection should be sent within 30 days of publication of this notice to *https://www.reginfo.gov/public/do/PRAMain.* Find this particular information collection by selecting ''Currently under Review—Open for Public Comments'' or by using the search function.

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–2019–0218 when contacting the NRC about the availability of information for this action. You may obtain publicly-available information related to this action by any of the following methods:

- Federal Rulemaking website: Go to *https://www.regulations.gov* and search for Docket ID NRC–2019–0218. A copy of the collection of information and related instructions may be obtained without charge by accessing Docket ID NRC–2019–0218 on this website.
- NRC's Agencywide Documents Access and Management System (ADAMS): You may obtain publicly-available documents online in the ADAMS Public Documents collection at *https://www.nrc.gov/reading-rm/adams.html.* To begin the search, select ''Begin Web-based ADAMS Search.'' For problems with ADAMS, please contact the NRC's Public Document Room (PDR) reference staff at 1–800–397–4209, 301–415–4737, or by email to *pdr.resource@nrc.gov.* The supporting statement is available in ADAMS under Accession No. ML20030A287.
- 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 *https://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, ''Notice of Enforcement Discretion (NOED) for Operating Power Reactors and Gaseous Diffusion Plants (NRC Enforcement Policy).'' 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 December 26, 2019, 84 FR 71006.

1. *The title of the information collection:* Notice of Enforcement Discretion (NOED) for Operating Power Reactors and Gaseous Diffusion Plants (NRC Enforcement Policy).

2. *OMB approval number:* 3150–0136.

3. *Type of submission:* Extension.

4. *The form number if applicable:* N/A.

5. *How often the collection is required or requested:* On Occasion.

6. *Who will be required or asked to respond:* Those licensees that voluntarily request enforcement discretion through the NOED process.

7. *The estimated number of annual responses:* 8 (4 reporting responses + 4 recordkeepers).

8. *The estimated number of annual respondents:* 4.

9. *An estimate of the total number of hours needed annually to comply with the information collection requirement or request:* 680 (600 reporting + 80 recordkeeping).

10. *Abstract:* The NRC's Enforcement Policy includes the circumstances in which the NRC may grant a NOED. On occasion, circumstances arise when a power plant licensee's compliance with a Technical Specification (TS) Limiting Condition for Operation or any other license condition would involve an unnecessary plant shutdown or transient. Similarly, for a gaseous diffusion plant, circumstances may arise where compliance with a Technical Safety Requirement (TSR) or other condition would unnecessarily call for a total plant shutdown, or, compliance would unnecessarily place the plant in a condition where safety, safeguards, or security features were degraded or inoperable.

In these circumstances, a licensee or certificate holder may request that the NRC exercise enforcement discretion, and the NRC staff may choose to not enforce the applicable TS, TSR, or other license or certificate condition. This enforcement discretion is designated as a NOED.

A licensee or certificate holder seeking the issuance of a NOED must justify, in accordance with NRC Enforcement Manual (ADAMS Accession No. ML19193A023), the safety basis for the request, including an evaluation of the safety significance and potential consequences of the proposed request, a description of proposed compensatory measures, a justification for the duration of the request, the basis for the licensee's or certificate holder's conclusion that the request does not have a potential adverse impact on the public health and safety, and does not involve adverse consequences to the environment, and any other information the NRC staff deems necessary before making a decision to exercise discretion.

Dated: May 28, 2020.

For the Nuclear Regulatory Commission.

Kristen E. Benney,

Acting NRC Clearance Officer, Office of the Chief Information Officer.

[FR Doc. 2020–11896 Filed 6–1–20; 8:45 am]

BILLING CODE 7590–01–P

NUCLEAR REGULATORY COMMISSION

[NRC–2020–0123]

Biweekly Notice; Applications and Amendments to Facility Operating Licenses and Combined Licenses Involving No Significant Hazards Considerations

AGENCY: Nuclear Regulatory Commission.

ACTION: Biweekly notice.

SUMMARY: Pursuant to section 189.a.(2) of the Atomic Energy Act of 1954, as amended (the Act), the U.S. Nuclear Regulatory Commission (NRC) is publishing this regular biweekly notice. The Act requires the Commission to publish notice of any amendments issued, or proposed to be issued, and grants the Commission the authority to issue and make immediately effective any amendment to an operating license or combined license, as applicable, upon a determination by the Commission that such amendment involves no significant hazards consideration (NSHC), notwithstanding the pendency before the Commission of a request for a hearing from any person. This biweekly notice includes all amendments issued, or proposed to be issued, from May 5, 2020, to May 15, 2020. The last biweekly notice was published on May 19, 2020.

DATES: Comments must be filed by July 2, 2020. A request for a hearing or petitions for leave to intervene must be filed by August 3, 2020.

ADDRESSES: You may submit comments by any of the following:

- *Federal Rulemaking Website:* Go to *https://www.regulations.gov* and search for Docket ID NRC–2020–0123. Address questions about NRC 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:* Office of Administration, Mail Stop: TWFN–7–A60M, U.S. Nuclear Regulatory Commission, Washington, DC 20555–0001, ATTN: Program Management, Announcements and Editing Staff.

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: Janet Burkhardt, Office of Nuclear Reactor Regulation, telephone: 301–415–1384, email: *Janet.Burkhardt@nrc.gov,* U.S. Nuclear Regulatory Commission, Washington, DC 20555–0001.

SUPPLEMENTARY INFORMATION:

I. Obtaining Information and Submitting Comments

A. Obtaining Information

Please refer to Docket ID NRC–2020–0123, facility name, unit number(s), docket number(s), application date, and subject when contacting the NRC about the availability of information for this action. You may obtain publicly-available information related to this action by any of the following methods:

- *Federal Rulemaking Website:* Go to *https://www.regulations.gov* and search for Docket ID NRC–2020–0123.
- *NRC's Agencywide Documents Access and Management System (ADAMS):* You may obtain publicly-available documents online in the ADAMS Public Documents collection at *https://www.nrc.gov/reading-rm/adams.html.* To begin the search, select ''Begin Web-based ADAMS Search.'' For problems with ADAMS, please contact the NRC's Public Document Room (PDR) reference staff at 1–800–397–4209, 301–415–4737, or by email to *pdr.resource@nrc.gov.* 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.

B. Submitting Comments

Please include Docket ID NRC–2020–0123, facility name, unit number(s), docket number(s), application date, and subject in your comment submission.

The NRC cautions you not to include identifying or contact information that you do not want to be publicly disclosed in your comment submission. The NRC will post all comment submissions at *https://www.regulations.gov* as well as enter the comment submissions into ADAMS. The NRC does not routinely edit comment submissions to remove identifying or contact information.

If you are requesting or aggregating comments from other persons for submission to the NRC, then you should inform those persons not to include identifying or contact information that they do not want to be publicly disclosed in their comment submission. Your request should state that the NRC does not routinely edit comment submissions to remove such information before making the comment submissions available to the public or entering the comment into ADAMS.

II. Notice of Consideration of Issuance of Amendments to Facility Operating Licenses and Combined Licenses and Proposed No Significant Hazards Consideration Determination

For the facility-specific amendment requests shown below, the Commission finds that the licensee's analyses provided, consistent with title 10 of the *Code of Federal Regulations* (10 CFR) section 50.91 is sufficient to support the proposed determination that these amendment requests involve NSHC. Under the Commission's regulations in 10 CFR 50.92, operation of the facility in accordance with the proposed amendment would not (1) involve a significant increase in the probability or consequences of an accident previously evaluated; or (2) create the possibility of a new or different kind of accident from any accident previously evaluated; or (3) involve a significant reduction in a margin of safety.

The Commission is seeking public comments on this proposed determination. Any comments received within 30 days after the date of publication of this notice will be considered in making any final determination.

Normally, the Commission will not issue the amendment until the expiration of 60 days after the date of publication of this notice. The Commission may issue the license amendment before expiration of the 60-day period provided that its final determination is that the amendment involves NSHC. 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 NSHC determination, any hearing will take place after issuance. The Commission expects that the need to take action on an amendment before 60 days have elapsed will occur very infrequently.

A. Opportunity To Request a Hearing and Petition for Leave To Intervene

Within 60 days after the date of publication of this notice, any persons (petitioner) whose interest may be affected by this action may file a request for a hearing and petition for leave to intervene (petition) with respect to the action. Petitions shall be filed in accordance with the Commission's ''Agency Rules of Practice and Procedure'' in 10 CFR part 2. Interested persons should consult a current copy of 10 CFR 2.309. The NRC's regulations are accessible electronically from the NRC Library on the NRC's website at *https://www.nrc.gov/reading-rm/doc-collections/cfr/*. If a petition is filed, the Commission or a presiding officer will rule on the petition and, if appropriate, a notice of a hearing will be issued.

As required by 10 CFR 2.309(d) the petition should specifically explain the reasons why intervention should be permitted with particular reference to the following general requirements for standing: (1) The name, address, and telephone number of the petitioner; (2) the nature of the petitioner's right under the Act to be made a party to the proceeding; (3) the nature and extent of the petitioner's property, financial, or other interest in the proceeding; and (4) the possible effect of any decision or order which may be entered in the proceeding on the petitioner's interest.

In accordance with 10 CFR 2.309(f), the petition must also set forth the specific contentions which the petitioner seeks to have litigated in the proceeding. Each contention must consist of a specific statement of the issue of law or fact to be raised or controverted. In addition, the petitioner must provide a brief explanation of the bases for the contention and a concise statement of the alleged facts or expert opinion which support the contention and on which the petitioner intends to rely in proving the contention at the hearing. The petitioner must also provide references to the specific sources and documents on which the petitioner intends to rely to support its position on the issue. The petition must include sufficient information to show that a genuine dispute exists with the applicant or licensee on a material issue of law or fact. Contentions must be limited to matters within the scope of the proceeding. The contention must be one which, if proven, would entitle the petitioner to relief. A petitioner who fails to satisfy the requirements at 10 CFR 2.309(f) with respect to at least one contention will not be permitted to participate as a party.

Those permitted to intervene become parties to the proceeding, subject to any limitations in the order granting leave to intervene. Parties have the opportunity to participate fully in the conduct of the hearing with respect to resolution of that party's admitted contentions, including the opportunity to present evidence, consistent with the NRC's regulations, policies, and procedures.

Petitions must be filed no later than 60 days from the date of publication of this notice. Petitions and motions for leave to file new or amended contentions that are filed after the deadline will not be entertained absent a determination by the presiding officer that the filing demonstrates good cause by satisfying the three factors in 10 CFR 2.309(c)(1)(i) through (iii). The petition must be filed in accordance with the filing instructions in the ''Electronic Submissions (E-Filing)'' section of this document.

If a hearing is requested, and the Commission has not made a final determination on the issue of no significant hazards consideration, the Commission will make a final determination on the issue of no significant hazards consideration. The final determination will serve to establish when the hearing is held. If the final determination is that the amendment request involves no significant hazards consideration, the Commission may issue the amendment and make it immediately effective, notwithstanding the request for a hearing. Any hearing would take place after issuance of the amendment. If the final determination is that the amendment request involves a significant hazards consideration, then any hearing held would take place before the issuance of the amendment unless the Commission finds an imminent danger to the health or safety of the public, in which case it will issue

an appropriate order or rule under 10 CFR part 2.

A State, local governmental body, Federally-recognized Indian Tribe, or agency thereof, may submit a petition to the Commission to participate as a party under 10 CFR 2.309(h)(1). The petition should state the nature and extent of the petitioner's interest in the proceeding. The petition should be submitted to the Commission no later than 60 days from the date of publication of this notice. The petition must be filed in accordance with the filing instructions in the ''Electronic Submissions (E-Filing)'' section of this document, and should meet the requirements for petitions set forth in this section, except that under 10 CFR 2.309(h)(2) a State, local governmental body, or Federally-recognized Indian Tribe, or agency thereof does not need to address the standing requirements in 10 CFR 2.309(d) if the facility is located within its boundaries. Alternatively, a State, local governmental body, Federally-recognized Indian Tribe, or agency thereof may participate as a non-party under 10 CFR 2.315(c).

If a hearing is granted, any person who is not a party to the proceeding and is not affiliated with or represented by a party may, at the discretion of the presiding officer, be permitted to make a limited appearance pursuant to the provisions of 10 CFR 2.315(a). A person making a limited appearance may make an oral or written statement of his or her position on the issues but may not otherwise participate in the proceeding. A limited appearance may be made at any session of the hearing or at any prehearing conference, subject to the limits and conditions as may be imposed by the presiding officer. Details regarding the opportunity to make a limited appearance will be provided by the presiding officer if such sessions are scheduled.

B. Electronic Submissions (E-Filing)

All documents filed in NRC adjudicatory proceedings, including a request for hearing and petition for leave to intervene (petition), any motion or other document filed in the proceeding prior to the submission of a request for hearing or petition to intervene, and documents filed by interested governmental entities that request to participate under 10 CFR 2.315(c), must be filed in accordance with the NRC's E-Filing rule (72 FR 49139; August 28, 2007, as amended at 77 FR 46562; August 3, 2012). The E-Filing process requires participants to submit and serve all adjudicatory documents over the internet, or in some cases to mail copies on electronic storage media. Detailed guidance on making electronic submissions may be found in the Guidance for Electronic Submissions to the NRC and on the NRC website at *https://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 *https://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 *https://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 *https://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.

The table below provides the plant name, docket number, date of application, ADAMS accession number, and location in the application of the licensee's proposed NSHC determination. For further details with respect to these license amendment applications, see the application for amendment which is available for public inspection in ADAMS and at the NRC's PDR. For additional direction on accessing information related to this document, see the ''Obtaining Information and Submitting Comments'' section of this document.

Energy Harbor Nuclear Corp.; Perry Nuclear Power Plant, Unit 1; Lake County, OH	
Application Date	April 24, 2020.
ADAMS Accession No	ML20115E517.
Location in Application of NSHC	Pages 8–10 of Enclosure.
Brief Description of Amendments	The proposed amendment would modify technical specification requirements related to direct current (DC) electrical systems in accordance with Technical Specifications Task Force (TSTF) Traveler TSTF–500, Revision 2, ''DC Electrical Rewrite—Update to TSTF–360.''
Proposed Determination	NSHC.
Name of Attorney for Licensee, Mailing Address	Rick Giannantonio, General Counsel, Energy Harbor Corp., Mail Stop A–WAC–B3, 341 White Pond Drive, Akron, OH 44320.
Docket Nos	50–440.
NRC Project Manager, Telephone Number	Scott Wall, 301–415–2855.
Indiana Michigan Power Company; Donald C. Cook Nuclear Plant, Unit 1; Berrien County, MI	
Application Date	April 7, 2020.
ADAMS Accession No	ML20108E997.
Location in Application of NSHC	Pages 23–25 of Enclosure 2.
Brief Description of Amendments	The requested amendment would revise the reactor coolant system heatup and cooldown curves and low temperature overpressure protection (LTOP) requirements in Technical Specification (TS) 3.4.3 and 3.4.12, respectively. The proposed changes to the LTOP requirements in TS 3.4.12 will also require changes to be made to TS 3.4.6, 3.4.7, and 3.4.10.
Proposed Determination	NSHC.
Name of Attorney for Licensee, Mailing Address	Robert B. Haemer, Senior Nuclear Counsel, Indiana Michigan Power Company, One Cook Place, Bridgman, MI 49106.
Docket Nos	50–315.
NRC Project Manager, Telephone Number	Scott Wall, 301–415–2855.
Indiana Michigan Power Company; Donald C. Cook Nuclear Plant, Units 1 and 2; Berrien County, MI	
Application Date	April 7, 2020.
ADAMS Accession No	ML20126G456.
Location in Application of NSHC	Pages 4–5 of Enclosure 2.
Brief Description of Amendments	The requested amendment would revise Technical Specification (TS) 5.5.12, ''Technical Specifications (TS) Bases Control Program,'' to coincide with the Updated Final Safety Analysis Report update frequency.
Proposed Determination	NSHC.
Name of Attorney for Licensee, Mailing Address	Robert B. Haemer, Senior Nuclear Counsel, Indiana Michigan Power Company, One Cook Place, Bridgman, MI 49106.
Docket Nos	50–315, 50–316.
NRC Project Manager, Telephone Number	Scott Wall, 301–415–2855.
Southern Nuclear Operating Company, Inc.; Vogtle Electric Generating Plant, Units 3 and 4; Burke County, GA	
Application Date	April 30, 2020.
ADAMS Accession No	ML20121A288.
Location in Application of NSHC	Pages 14–16 of Enclosure 1.
Brief Description of Amendments	The requested amendment would revise the upper limit and frequency of performance of the core makeup tank boron concentration Technical Specification (TS) Surveillance Requirement (SR) 3.5.2.4 and the mass of trisodium phosphate required by TS Limiting Condition for Operation 3.6.8 and associated SR.
Proposed Determination	NSHC.
Name of Attorney for Licensee, Mailing Address	M. Stanford Blanton, Balch & Bingham LLP, 1710 Sixth Avenue North, Birmingham, AL 35203–2015.
Docket Nos	52–025, 52–026.
NRC Project Manager, Telephone Number	Jennivine Rankin, 301–415–1530.
STP Nuclear Operating Company; South Texas Project, Units 1 and 2; Matagorda County, TX	
Application Date	March 30, 2020, as supplemented by letter dated April 29, 2020.
ADAMS Accession No	ML20090B745 and ML20120A618.
Location in Application of NSHC	Pages 39–41 of Enclosure 1 to the letter dated March 30, 2020.
Brief Description of Amendments	The amendments would authorize the revision of the emergency plan, which was rebaselined based on the guidance in NUREG–0654/FEMA–REP–1, ''Criteria for Preparation and Evaluation of Radiological Emergency Response Plans and Preparedness in Support of Nuclear Power Plants,'' Revision 2.
Proposed Determination	NSHC.
Name of Attorney for Licensee, Mailing Address	Kym Harshaw, Vice President and General Counsel, STP Nuclear Operating Company, P.O. Box 289, Wadsworth, TX 77483.
Docket Nos	50–498, 50–499.
NRC Project Manager, Telephone Number	Dennis Galvin, 301–415–6256.
Tennessee Valley Authority; Browns Ferry Nuclear Plant, Units 1, 2, and 3; Limestone County, AL	
Application Date	March 27, 2020.

ADAMS Accession No	ML20087P262.
Location in Application of NSHC	Attachment 6.
Brief Description of Amendments	The amendments would revise the technical specifications (TS) by the adoption, with administrative and technical variations, of Technical Specification Task Force (TSTF) Traveler TSTF–425, Revision 3, ''Relocate Surveillance Frequencies to Licensee Control—Risk Informed Technical Specification Task Force (RITSTF) Initiative 5b.'' TSTF–425, Revision 3, provides for the relocation of specific surveillance frequencies to a licensee-controlled program. Additionally, the change would add a new program, the Surveillance Frequency Control Program, to TS Section 5.0, ''Administrative Controls.''
Proposed Determination	NSHC.
Name of Attorney for Licensee, Mailing Address	Christopher C. Chandler, Attorney, Associate General Counsel, Tennessee Valley Authority, 400 West Summit Hill Drive, WT 6A–K, Knoxville, TN 37902.
Docket Nos	50–259, 50–260, 50–296.
NRC Project Manager, Telephone Number	Michael Wentzel, 301–415–6459.

Vistra Operations Company LLC; Comanche Peak Nuclear Power Plant, Unit Nos. 1 and 2; Somervell County, TX

Application Date	March 31, 2020.
ADAMS Accession No	ML20091H586.
Location in Application of NSHC	Pages 15–17 of the Enclosure.
Brief Description of Amendments	The amendments would revise Technical Specification (TS) 3.8.1, ''AC [Alternating Current] Sources—Operating,'' to change the emergency diesel generator surveillance requirement (SR) steady-state frequency band in multiple SRs from a band from 58.8 hertz (Hz) to 61.2 Hz to a band from 59.9 Hz to 60.1 Hz. The amendments would also remove historical information from TS 3.8.1 and a Note from SR 3.8.1.13.
Proposed Determination	NSHC.
Name of Attorney for Licensee, Mailing Address	Timothy P. Matthews, Esq., Morgan, Lewis and Bockius, 1111 Pennsylvania Avenue NW, Washington, DC 20004.
Docket Nos	50–445, 50–446.
NRC Project Manager, Telephone Number	Dennis Galvin, 301–415–6256.

Wolf Creek Nuclear Operating Corporation; Wolf Creek Generating Station, Unit 1; Coffey County, KS

Application Date	April 20, 2020.
ADAMS Accession No	ML20111A327.
Location in Application of NSHC	Pages 115–118 of Attachment I.
Brief Description of Amendments	The amendment would revise Technical Specification 5.5.16, ''Containment Leakage Rate Testing Program,'' for permanent extension of Type A and Type C Leak Rate Test Frequencies.
Proposed Determination	NSHC.
Name of Attorney for Licensee, Mailing Address	Jay E. Silberg, Pillsbury Winthrop Shaw Pittman LLP, 1200 17th St. NW, Washington, DC 20036.
Docket Nos	50–482.
NRC Project Manager, Telephone Number	Balwant Singal, 301–415–3016.

III. Notice of Issuance of Amendments to Facility Operating Licenses and Combined Licenses

During the period since publication of the last biweekly notice, the Commission has issued the following amendments. The Commission has determined for each of these amendments that the application complies with the standards and requirements of the Atomic Energy Act of 1954, as amended (the Act), and the Commission's rules and regulations. The Commission has made appropriate findings as required by the Act and the Commission's rules and regulations in 10 CFR chapter I, which are set forth in the license amendment.

A notice of consideration of issuance of amendment to facility operating license or combined license, as applicable, proposed NSHC determination, and opportunity for a hearing in connection with these actions, was published in the **Federal Register** as indicated.

Unless otherwise indicated, the Commission has determined that these amendments satisfy the criteria for categorical exclusion in accordance with 10 CFR 51.22. Therefore, pursuant to 10 CFR 51.22(b), no environmental impact statement or environmental assessment need be prepared for these amendments. If the Commission has prepared an environmental assessment under the special circumstances provision in 10 CFR 51.22(b) and has made a determination based on that assessment, it is so indicated.

For further details with respect to the action, see (1) the application for amendment; (2) the amendment; and (3) the Commission's related letter, Safety Evaluation, and/or Environmental Assessment as indicated. All of these items can be accessed as described in the ''Obtaining Information and Submitting Comments'' section of this document.

Exelon Generation Company, LLC; Braidwood Station, Unit 2; Will County, IL

Date Issued	May 1, 2020.
ADAMS Accession No	ML20111A000.
Amendment Nos	209.
Brief Description of Amendments	The amendment revised Technical Specification (TS) 5.5.9, ''Steam Generator (SG) Program,'' for a one-time revision to the frequency for SG tube inspections. The amendment allows deferral of the required inspections until the next Braidwood Station, Unit 2, refueling outage.
Docket Nos	50–457.

Indiana Michigan Power Company; Donald C. Cook Nuclear Plant, Units 1 and 2; Berrien County, MI

Date Issued	May 1, 2020.
ADAMS Accession No	ML20043D304.
Amendment Nos	Unit 1—351; Unit 2—332.
Brief Description of Amendments	The amendments revised the Donald C. Cook Nuclear Plant, Units 1 and 2, Technical Specification 3.8.1, ''AC [Alternating Current] Sources—Operating,'' by deleting Surveillance Requirement 3.8.1.20 which requires verification that diesel generator (DG) availability is not compromised when the DG is tested by connecting to its load test resistor banks.

Docket Nos	50–315, 50–316.

Nebraska Public Power District; Cooper Nuclear Station; Nemaha County, NE

Date Issued	May 12, 2020.
ADAMS Accession No	ML19329B151.
Amendment Nos	265.
Brief Description of Amendments	The amendment revised the Cooper Nuclear Station Technical Specifications (TSs) based on Technical Specifications Task Force (TSTF) Traveler TSTF–564, Revision 2, ''Safety Limit MCPR [Minimum Critical Power Ratio],'' dated October 24, 2018 (ADAMS Accession No. ML18297A361). The amendment revised the TS Safety Limit 2.1.1.2 and TS 5.6.5, ''Core Operating Limits Report (COLR).''
Docket Nos	50–298.

IV. Notice of Issuance of Amendments to Facility Operating Licenses and Combined Licenses and Final Determination of No Significant Hazards Consideration and Opportunity for a Hearing (Exigent Public Announcement or Emergency Circumstances)

During the period since publication of the last biweekly notice, the Commission has issued the following amendments. The Commission has determined for each of these amendments that the application for the amendment complies with the standards and requirements of the Atomic Energy Act of 1954, as amended (the Act), and the Commission's rules and regulations. The Commission has made appropriate findings as required by the Act and the Commission's rules and regulations in 10 CFR chapter I, which are set forth in the license amendment.

Because of exigent or emergency circumstances associated with the date the amendment was needed, there was not time for the Commission to publish, for public comment before issuance, its usual notice of consideration of issuance of amendment, proposed NSHC determination, and opportunity for a hearing.

For exigent circumstances, the Commission has either issued a **Federal Register** notice providing opportunity for public comment or has used local media to provide notice to the public in the area surrounding a licensee's facility of the licensee's application and of the Commission's proposed determination of NSHC. The Commission has provided a reasonable opportunity for the public to comment, using its best efforts to make available to the public means of communication for the public to respond quickly, and in the case of telephone comments, the comments have been recorded or transcribed as appropriate and the licensee has been informed of the public comments.

In circumstances where failure to act in a timely way would have resulted, for example, in derating or shutdown of a nuclear power plant or in prevention of either resumption of operation or of increase in power output up to the plant's licensed power level, the Commission may not have had an opportunity to provide for public comment on its NSHC determination. In such case, the license amendment has been issued without opportunity for comment. If there has been some time for public comment but less than 30 days, the Commission may provide an opportunity for public comment. If comments have been requested, it is so stated. In either event, the State has been consulted by telephone whenever possible.

Under its regulations, the Commission may issue and make an amendment immediately effective, notwithstanding the pendency before it of a request for a hearing from any person, in advance of the holding and completion of any required hearing, where it has determined that NSHC is involved.

The Commission has applied the standards of 10 CFR 50.92 and has made a final determination that the amendment involves NSHC. The basis for this determination is contained in the documents related to this action. Accordingly, the amendments have been issued and made effective as indicated.

Unless otherwise indicated, the Commission has determined that these amendments satisfy the criteria for categorical exclusion in accordance with 10 CFR 51.22. Therefore, pursuant to 10 CFR 51.22(b), no environmental impact statement or environmental assessment need be prepared for these amendments. If the Commission has prepared an environmental assessment under the special circumstances provision in 10 CFR 51.12(b) and has made a determination based on that assessment, it is so indicated.

For further details with respect to the action see (1) the application for amendment, (2) the amendment to Facility Operating License or Combined License, as applicable, and (3) the Commission's related letter, Safety Evaluation and/or Environmental Assessment, as indicated. All of these items can be accessed as described in the ''Obtaining Information and Submitting Comments'' section of this document.

Energy Northwest; Columbia Generating Station; Benton County, WA

Date of Amendment	May 4, 2020.
Brief Description of Amendment	The amendment revised the implementation date for Amendment No. 255 from May 6, 2020, to February 6, 2021.
ADAMS Accession No	ML20113E984.
Amendment Nos	257.
Public Comments Requested as to Proposed NSHC (Yes/No).	Yes.
Docket Nos	50–397.

Energy Northwest; Columbia Generating Station; Benton County, WA

Date of Amendment	May 12, 2020.
Brief Description of Amendment	The amendment revised Technical Specifications (TSs) 3.8.4, ''DC (Direct Current) Sources—Operating,'' and 3.8.7, ''Distribution Systems—Operating,'' TS Required Actions 3.8.4.G.1, 3.8.7.A.1, and 3.8.7.B.1 completion times, on a one-time basis. Additionally, the change removed an existing one-time note to TS 3.8.7.A, which has expired.
ADAMS Accession No	ML20125A080.
Amendment Nos	258.
Public Comments Requested as to Proposed NSHC (Yes/No).	Yes.

Docket Nos	50–397.

Dated: May 20, 2020.

For the Nuclear Regulatory Commission.

Craig G. Erlanger,

Director, Division of Operating Reactor Licensing, Office of Nuclear Reactor Regulation.

[FR Doc. 2020–11233 Filed 6–1–20; 8:45 am]

BILLING CODE 7590–01–P

POSTAL REGULATORY COMMISSION

[Docket Nos. MC2020–140 and CP2020–149; CP2020–150; MC2020–141 and CP2020–151; MC2020–142 and CP2020–152]

New Postal Products

AGENCY: Postal Regulatory Commission.

ACTION: Notice.

SUMMARY: The Commission is noticing a recent Postal Service filing for the Commission's consideration concerning negotiated service agreements. This notice informs the public of the filing, invites public comment, and takes other administrative steps.

DATES: *Comments are due:* June 4, 2020.

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 3011.301.[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 3030, and 39 CFR part 3040, 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 3035, and 39 CFR part 3040, subpart B. Comment deadline(s) for each request appear in section II.

II. Docketed Proceeding(s)

1. *Docket No(s).:* MC2020–140 and CP2020–149; *Filing Title:* USPS Request to Add Priority Mail Express International, Priority Mail International, First-Class Package International Service & Commercial EPacket Contract 1 to Competitive Product List and Notice of Filing Materials Under Seal; *Filing Acceptance Date:* May 27, 2020; *Filing Authority:* 39 U.S.C. 3642, 39 CFR 3040.130 *et seq.,* and 39 CFR 3035.105; *Public Representative:* Curtis E. Kidd; *Comments Due:* June 4, 2020.

2. *Docket No(s).:* CP2020–150; *Filing Title:* Notice of United States Postal Service of Filing a Functionally Equivalent Global Expedited Package Services 10 Negotiated Service Agreement and Application for Non-Public Treatment of Materials Filed Under Seal; *Filing Acceptance Date:* May 27, 2020; *Filing Authority:* 39 CFR 3035.105; *Public Representative:* Kenneth R. Moeller; *Comments Due:* June 4, 2020.

3. *Docket No(s).:* MC2020–141 and CP2020–151; *Filing Title:* USPS Request to Add Priority Mail Contract 619 to Competitive Product List and Notice of Filing Materials Under Seal; *Filing Acceptance Date:* May 27, 2020; *Filing Authority:* 39 U.S.C. 3642, 39 CFR 3040.130 *et seq.,* and 39 CFR 3035.105; *Public Representative:* Christopher C. Mohr; *Comments Due:* June 4, 2020.

4. *Docket No(s).:* MC2020–142 and CP2020–152; *Filing Title:* USPS Request to Add Priority Mail Contract 620 to Competitive Product List and Notice of Filing Materials Under Seal; *Filing Acceptance Date:* May 27, 2020; *Filing Authority:* 39 U.S.C. 3642, 39 CFR 3040.130 *et seq.,* and 39 CFR 3035.105; *Public Representative:* Christopher C. Mohr; *Comments Due:* June 4, 2020.

This Notice will be published in the **Federal Register**.

Erica A. Barker,

Secretary.

[FR Doc. 2020–11882 Filed 6–1–20; 8:45 am]

BILLING CODE 7710–FW–P

[1] *See* Docket No. RM2018–3, Order Adopting Final Rules Relating to Non-Public Information, June 27, 2018, Attachment A at 19–22 (Order No. 4679).

SECURITIES AND EXCHANGE COMMISSION

[Release No. 34–88961; File No. SR–NYSEArca–2020–47]

Self-Regulatory Organizations; NYSE Arca, Inc.; Notice of Filing and Immediate Effectiveness of Proposed Rule Change To Extend the Temporary Waiver of the Co-Location Hot Hands Fee

May 27, 2020.

Pursuant to Section 19(b)(1)[1] of the Securities Exchange Act of 1934 (the ''Act'')[2] and Rule 19b–4 thereunder,[3] notice is hereby given that, on May 14, 2020, NYSE Arca, Inc. (''NYSE Arca'' or the ''Exchange'') filed with the Securities and Exchange Commission (the ''Commission'') the proposed rule change as described in Items I, II, and III below, which Items have been prepared by the self-regulatory organization. The Commission is publishing this notice to solicit comments on the proposed rule change from interested persons.

[1] 15 U.S.C. 78s(b)(1).

[2] 15 U.S.C. 78a.

[3] 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 extend the temporary waiver of the co-location ''Hot Hands'' fee. The proposed rule change is available on the Exchange's website at *www.nyse.com,* at the principal office of the Exchange, and at the Commission's Public Reference Room.

II. Self-Regulatory Organization's Statement of the Purpose of, and Statutory Basis for, the Proposed Rule Change

In its filing with the Commission, the self-regulatory organization included statements concerning the purpose of, and basis for, the proposed rule change and discussed any comments it received on the proposed rule change. The text of those statements may be examined at the places specified in Item IV below. The Exchange has prepared summaries, set forth in sections A, B, and C below, of the most significant parts of such statements.

A. Self-Regulatory Organization's Statement of the Purpose of, and the Statutory Basis for, the Proposed Rule Change

1. Purpose

The Exchange proposes to extend of the temporary waiver of the co-location [4] ''Hot Hands'' fee through the earlier of the reopening of the Mahwah, New Jersey data center (''Data Center'') or June 30, 2020. The waiver of the Hot Hands fee is scheduled to expire on May 15, 2020.[5]

The Exchange is an indirect subsidiary of Intercontinental Exchange, Inc. (''ICE''). Through its ICE Data Services (''IDS'') business, ICE operates the Mahwah, New Jersey data center (''Data Center''), from which the Exchange provides co-location services to Users.[6] Among those services is a ''Hot Hands'' service, which allows Users to use on-site Data Center personnel to maintain User equipment, support network troubleshooting, rack and stack a server in a User's cabinet; power recycling; and install and document the fitting of cable in a User's cabinet(s).[7] The Hot Hands fee is $100 per half hour.

ICE previously announced to Users that the Data Center would be closed to third parties for the period from March 16, 2020 through May 15, 2020 (the ''Initial Closure''), to help avoid the spread of COVID–19, which could negatively impact Data Center functions. Prior to the closure of the Data Center, the Chief Executive Officer of the Exchange took the actions required under NYSE Arca Rules 7.1–E and 7.1–O to close the co-location facility of the Exchange to third parties.

ICE has now announced to Users that, because the concerns that led to the Initial Closure still apply, the closure of the Data Center will be extended, with the date of the reopening announced through a customer notice.

If a User's equipment requires work while a Rules 7.1–E and 7.1–O closure is in effect, the User has to use the Hot Hands service and, absent a waiver, incurs Hot Hands fees for the work. Given that, the Exchange waived all Hot Hands fees for the duration of the Initial Closure.[8] Because the period has been extended, the Exchange proposes to extend the waiver of the Hot Hands Fee for the length of the period. To that end, the Exchange proposes to revise the footnote to the Hot Hands Fee in the Fee Schedules as follows (deletions bracketed, additions italicized):

† Fees for Hot Hands Services will be waived beginning on March 16, 2020 through the earlier of *June 30, 2020 and* the reopening of the Mahwah, New Jersey data center [or May 15, 2020].

The Exchange believes that there will be sufficient Data Center staff on-site to comply with User requests for Hot Hands service.

The proposed extension of the waiver would apply equally to all Users. The proposed extension of the fee waiver would not apply differently to distinct types or sizes of market participants. Rather, it would continue to apply uniformly to all Users.

The proposed change is not otherwise intended to address any other issues relating to co-location services and/or related fees, and the Exchange is not aware of any problems that Users would have in complying with the proposed change.

2. Statutory Basis

The Exchange believes that the proposed rule change is consistent with Section 6(b) of the Act,[9] in general, and furthers the objectives of Sections 6(b)(4) and (5) of the Act,[10] in particular, because it provides for the equitable allocation of reasonable dues, fees, and other charges among its members, issuers and other persons using its facilities and does not unfairly discriminate between customers, issuers, brokers or dealers. In addition, it is designed 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.

The Proposed Rule Change Is Reasonable

The Exchange believes that the proposed rule change is reasonable for the following reasons.

Given that the closure of the Data Center has been extended, the Exchange believes that it is reasonable to grant the proposed corresponding extension of the waiver of the Hot Hands Fee. While a Rules 7.1–E and 7.1–O closure is in effect, User representatives are not allowed access to the Data Center. If a User's equipment requires work during such period, the User has to use the Hot Hands service. Absent a waiver, the User would incur Hot Hands fees for the work.

The proposed extension of the waiver would allow a User to have work carried out on its equipment notwithstanding

[4] The Exchange initially filed rule changes relating to its co-location services with the Securities and Exchange Commission (''Commission'') in 2010. *See* Securities Exchange Act Release No. 63275 (November 8, 2010), 75 FR 70048 (November 16, 2010) (SR–NYSEArca–2010–100).

[5] *See* Securities Exchange Act Release Nos. 88398 (March 17, 2020), 85 FR 16398 (March 23, 2020) (SR–NYSEArca–2020–22), and 88520 (March 31, 2020), 85 FR 19208 (April 6, 2020) (SR–NYSEArca–2020–26).

[6] For purposes of the Exchange's co-location services, a ''User'' means any market participant that requests to receive co-location services directly from the Exchange. *See* Securities Exchange Act Release No. 76010 (September 29, 2015), 80 FR 60197 (October 5, 2015) (SR–NYSEArca–2015–82). As specified in the NYSE Arca Options Fees and Charges and the NYSE Arca Equities Fees and Charges (together, the ''Fee Schedules''), a User that incurs co-location fees for a particular co-location service pursuant thereto would not be subject to co-location fees for the same co-location service charged by the Exchange's affiliates the New York Stock Exchange LLC (''NYSE''), NYSE American LLC (''NYSE American''), NYSE Chicago, Inc. (''NYSE Chicago''), and NYSE National, Inc. (''NYSE National'' and together, the ''Affiliate SROs''). *See* Securities Exchange Act Release No. 70173 (August 13, 2013), 78 FR 50459 (August 19, 2013) (SR–NYSEArca–2013–80). Each Affiliate SRO has submitted substantially the same proposed rule change to propose the changes described herein. *See* SR–NYSE–2020–44, SR–NYSEAmer–2020–39, SR–NYSECHX–2020–15, and SR–NYSENAT–2020–18.

[7] *See* Securities Exchange Act Release No. 72720 (July 30, 2014), 79 FR 45577 (August 5, 2014) (SR–NYSEArca-2014–81).

[8] *See* 85 FR 16398 and 85 FR 19208, *supra* note 5.

[9] 15 U.S.C. 78f(b).

[10] 15 U.S.C. 78f(b)(4) and (5).

the closure of the Data Center without incurring Hot Hands fees.

The Proposed Rule Change Is Equitable

The Exchange believes the proposed rule change is an equitable allocation of its fees and credits for the following reasons.

The proposed extension of the waiver would apply equally to all Users. The proposed extension would not apply differently to distinct types or sizes of market participants. Rather, it would apply uniformly to all Users.

The Exchange believes that the proposal is equitable because the extension of the waiver would mean that for the duration of the closure of the Data Center all similarly-situated Users would not be charged a fee to use the Hot Hands service.

The Proposed Change Is Not Unfairly Discriminatory and Would Protect Investors and the Public Interest

The Exchange believes that the proposed change is not unfairly discriminatory for the following reasons.

The proposed extension of the waiver would not apply differently to distinct types or sizes of market participants. Rather, all Users whose equipment requires work during the extension of the Data Center closure would have the resulting fees waived, and the extension of the waiver would apply uniformly to all Users during the period. For the reasons above, the proposed changes do not unfairly discriminate between or among market participants.

In addition, the Exchange believes that the proposed rule change would perfect the mechanisms of a free and open market and a national market system and, in general, protect investors and the public interest because it would allow a User to have work carried out on its equipment notwithstanding a Rules 7.1–E and 7.1–O closure without incurring Hot Hands fees. Accordingly, the Exchange believes that the requested extension of the waiver is designed to perfect the mechanisms of a free and open market and a national market system and, in general, protect investors and the public interest by facilitating the uninterrupted availability of Users' equipment.

For all of the above 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,[11] 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.

Intramarket Competition

The Exchange does not believe that the proposed change would place any burden on intramarket competition that is not necessary or appropriate.

The proposed extension of the waiver is not designed to affect competition, but rather to provide relief to Users that, while a Rules 7.1–E and 7.1–O closure is in effect, have no option but to use the Hot Hands service.

The proposed extension of the waiver would not apply differently to distinct types or sizes of market participants. Rather, all Users whose equipment requires work during the extension of the Data Center closure would have the resulting fees waived, and the extension of the waiver would apply uniformly to all Users during the period.

Intermarket Competition

The Exchange does not believe that the proposed change would impose any burden on intermarket competition that is not necessary or appropriate.

The Exchange believes that the proposed change would not affect the competitive landscape among the national securities exchanges, as the Hot Hands service is solely charged within co-location to existing Users, and would be temporary.

For the reasons described above, the Exchange believes that the proposed rule change reflects this competitive environment.

C. Self-Regulatory Organization's Statement on Comments on the Proposed Rule Change Received From Members, Participants, or Others

No written comments were solicited or received with respect to the proposed rule change.

III. Date of Effectiveness of the Proposed Rule Change and Timing for Commission Action

The foregoing rule change is effective upon filing pursuant to Section 19(b)(3)(A)[12] of the Act and subparagraph (f)(2) of Rule 19b–4[13] thereunder, because it establishes a due, fee, or other charge imposed by the Exchange.

At any time within 60 days of the filing of such proposed rule change, the Commission summarily may temporarily suspend such rule change if it appears to the Commission that such action is necessary or appropriate in the public interest, for the protection of investors, or otherwise in furtherance of the purposes of the Act. If the Commission takes such action, the Commission shall institute proceedings under Section 19(b)(2)(B)[14] of the Act to determine whether the proposed rule change should be approved or disapproved.

IV. Solicitation of Comments

Interested persons are invited to submit written data, views, and arguments concerning the foregoing, including whether the proposed rule change is consistent with the Act. Comments may be submitted by any of the following methods:

Electronic Comments

- Use the Commission's internet comment form (*http://www.sec.gov/rules/sro.shtml*); or
- Send an email to *rule-comments@sec.gov.* Please include File Number SR–NYSEArca–2020–47 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–2020–47. 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

[11] 15 U.S.C. 78f(b)(8).

[12] 15 U.S.C. 78s(b)(3)(A).

[13] 17 CFR 240.19b–4(f)(2).

[14] 15 U.S.C. 78s(b)(2)(B).

comment submissions. You should submit only information that you wish to make available publicly. All submissions should refer to File Number SR–NYSEArca–2020–47 and should be submitted on or before June 23, 2020.

For the Commission, by the Division of Trading and Markets, pursuant to delegated authority.[15]

J. Matthew DeLesDernier,

Assistant Secretary.

[FR Doc. 2020–11784 Filed 6–1–20; 8:45 am]

BILLING CODE 8011–01–P

SECURITIES AND EXCHANGE COMMISSION

[Release No. 34–88955; File No. SR–NYSE–2020–44]

Self-Regulatory Organizations; New York Stock Exchange LLC; Notice of Filing and Immediate Effectiveness of Proposed Rule Change To Extend the Temporary Waiver of the Co-Location Hot Hands Fee

May 27, 2020.

Pursuant to Section 19(b)(1)[1] of the Securities Exchange Act of 1934 (the ''Act'')[2] and Rule 19b–4 thereunder,[3] notice is hereby given that, on May 14, 2020, New York Stock Exchange LLC (''NYSE'' or the ''Exchange'') filed with the Securities and Exchange Commission (the ''Commission'') the proposed rule change as described in Items I, II, and III below, which Items have been prepared by the self-regulatory organization. The Commission is publishing this notice to solicit comments on the proposed rule change from interested persons.

I. Self-Regulatory Organization's Statement of the Terms of Substance of the Proposed Rule Change

The Exchange proposes to extend the temporary waiver of the co-location ''Hot Hands'' fee. The proposed rule change is available on the Exchange's website at *www.nyse.com,* at the principal office of the Exchange, and at the Commission's Public Reference Room.

II. Self-Regulatory Organization's Statement of the Purpose of, and Statutory Basis for, the Proposed Rule Change

In its filing with the Commission, the self-regulatory organization included statements concerning the purpose of, and basis for, the proposed rule change and discussed any comments it received on the proposed rule change. The text of those statements may be examined at the places specified in Item IV below. The Exchange has prepared summaries, set forth in sections A, B, and C below, of the most significant parts of such statements.

A. Self-Regulatory Organization's Statement of the Purpose of, and the Statutory Basis for, the Proposed Rule Change

1. Purpose

The Exchange proposes to extend of the temporary waiver of the co-location[4] ''Hot Hands'' fee through the earlier of the reopening of the Mahwah, New Jersey data center (''Data Center'') or June 30, 2020. The waiver of the Hot Hands fee is scheduled to expire on May 15, 2020.[5]

The Exchange is an indirect subsidiary of Intercontinental Exchange, Inc. (''ICE''). Through its ICE Data Services (''IDS'') business, ICE operates the Mahwah, New Jersey data center (''Data Center''), from which the Exchange provides co-location services to Users.[6] Among those services is a ''Hot Hands'' service, which allows Users to use on-site Data Center personnel to maintain User equipment, support network troubleshooting, rack and stack a server in a User's cabinet; power recycling; and install and document the fitting of cable in a User's cabinet(s).[7] The Hot Hands fee is $100 per half hour.

ICE previously announced to Users that the Data Center would be closed to third parties for the period from March 16, 2020 through May 15, 2020 (the ''Initial Closure''), to help avoid the spread of COVID–19, which could negatively impact Data Center functions. Prior to the closure of the Data Center, the Chief Executive Officer of the Exchange took the actions required under NYSE Rule 7.1 to close the co-location facility of the Exchange to third parties.

ICE has now announced to Users that, because the concerns that led to the Initial Closure still apply, the closure of the Data Center will be extended, with the date of the reopening announced through a customer notice.

If a User's equipment requires work while a Rule 7.1 closure is in effect, the User has to use the Hot Hands service and, absent a waiver, incurs Hot Hands fees for the work. Given that, the Exchange waived all Hot Hands fees for the duration of the Initial Closure.[8] Because the period has been extended, the Exchange proposes to extend the waiver of the Hot Hands Fee for the length of the period. To that end, the Exchange proposes to revise the footnote to the Hot Hands Fee in the Price List as follows (deletions bracketed, additions underlined):

[15] 17 CFR 200.30–3(a)(12).

[1] 15 U.S.C. 78s(b)(1).

[2] 15 U.S.C. 78a.

[3] 17 CFR 240.19b–4.

[4] The Exchange initially filed rule changes relating to its co-location services with the Securities and Exchange Commission (''Commission'') in 2010. *See* Securities Exchange Act Release No. 62960 (September 21, 2010), 75 FR 59310 (September 27, 2010) (SR–NYSE–2010–56).

[5] *See* Securities Exchange Act Release Nos. 88397 (March 17, 2020), 85 FR 16406 (March 23, 2020) (SR–NYSE–2020–18), and 88518 (March 31, 2020), 85 FR 19187 (April 6, 2020) (SR–NYSE–2020–25).

[6] For purposes of the Exchange's co-location services, a ''User'' means any market participant that requests to receive co-location services directly from the Exchange. *See* Securities Exchange Act Release No. 76008 (September 29, 2015), 80 FR 60190 (October 5, 2015) (SR–NYSE–2015–40). As specified in the Price List, a User that incurs co-location fees for a particular co-location service pursuant thereto would not be subject to co-location fees for the same co-location service charged by the Exchange's affiliates NYSE American LLC (''NYSE American''), NYSE Arca, Inc. (''NYSE Arca''), NYSE Chicago, Inc. (''NYSE Chicago''), and NYSE National, Inc. (''NYSE National'' and together, the ''Affiliate SROs''). *See* Securities Exchange Act Release No. 70206 (August 15, 2013), 78 FR 51765 (August 21, 2013) (SR–NYSE–2013–59). Each Affiliate SRO has submitted substantially the same proposed rule change to propose the changes described herein. *See* SR–NYSEAmer–2020–39, SR–NYSEArca–2020–47, SR–NYSECHX–2020–15, and SR–NYSENAT–2020–18.

[7] *See* Securities Exchange Act Release No. 72721 (July 30, 2014), 79 FR 45562 (August 5, 2014) (SR–NYSE–2014–37).

[8] *See* 85 FR 16406 and 85 FR 19187, *supra* note 5.

† Fees for Hot Hands Services will be waived beginning on March 16, 2020 through the earlier of June 30, 2020 and the reopening of the Mahwah, New Jersey data center[or May 15, 2020].

The Exchange believes that there will be sufficient Data Center staff on-site to comply with User requests for Hot Hands service.

The proposed extension of the waiver would apply equally to all Users. The proposed extension of the fee waiver would not apply differently to distinct types or sizes of market participants. Rather, it would continue to apply uniformly to all Users.

The proposed change is not otherwise intended to address any other issues relating to co-location services and/or related fees, and the Exchange is not aware of any problems that Users would have in complying with the proposed change.

2. Statutory Basis

The Exchange believes that the proposed rule change is consistent with Section 6(b) of the Act,[9] in general, and furthers the objectives of Sections 6(b)(4) and (5) of the Act,[10] in particular, because it provides for the equitable allocation of reasonable dues, fees, and other charges among its members, issuers and other persons using its facilities and does not unfairly discriminate between customers, issuers, brokers or dealers. In addition, it is designed 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.

The Proposed Rule Change Is Reasonable

The Exchange believes that the proposed rule change is reasonable for the following reasons.

Given that the closure of the Data Center has been extended, the Exchange believes that it is reasonable to grant the proposed corresponding extension of the waiver of the Hot Hands Fee. While a Rule 7.1 closure is in effect, User representatives are not allowed access to the Data Center. If a User's equipment requires work during such period, the User has to use the Hot Hands service. Absent a waiver, the User would incur Hot Hands fees for the work.

The proposed extension of the waiver would allow a User to have work carried out on its equipment notwithstanding the closure of the Data Center without incurring Hot Hands fees.

The Proposed Rule Change Is Equitable

The Exchange believes the proposed rule change is an equitable allocation of its fees and credits for the following reasons.

The proposed extension of the waiver would apply equally to all Users. The proposed extension would not apply differently to distinct types or sizes of market participants. Rather, it would apply uniformly to all Users.

The Exchange believes that the proposal is equitable because the extension of the waiver would mean that for the duration of the closure of the Data Center all similarly-situated Users would not be charged a fee to use the Hot Hands service.

The Proposed Change Is Not Unfairly Discriminatory and Would Protect Investors and the Public Interest

The Exchange believes that the proposed change is not unfairly discriminatory for the following reasons.

The proposed extension of the waiver would not apply differently to distinct types or sizes of market participants. Rather, all Users whose equipment requires work during the extension of the Data Center closure would have the resulting fees waived, and the extension of the waiver would apply uniformly to all Users during the period. For the reasons above, the proposed changes do not unfairly discriminate between or among market participants.

In addition, the Exchange believes that the proposed rule change would perfect the mechanisms of a free and open market and a national market system and, in general, protect investors and the public interest because it would allow a User to have work carried out on its equipment notwithstanding a Rule 7.1 closure without incurring Hot Hands fees. Accordingly, the Exchange believes that the requested extension of the waiver is designed to perfect the mechanisms of a free and open market and a national market system and, in general, protect investors and the public interest by facilitating the uninterrupted availability of Users' equipment.

For all of the above 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,[11] 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.

Intramarket Competition

The Exchange does not believe that the proposed change would place any burden on intramarket competition that is not necessary or appropriate.

The proposed extension of the waiver is not designed to affect competition, but rather to provide relief to Users that, while a Rule 7.1 closure is in effect, have no option but to use the Hot Hands service.

The proposed extension of the waiver would not apply differently to distinct types or sizes of market participants. Rather, all Users whose equipment requires work during the extension of the Data Center closure would have the resulting fees waived, and the extension of the waiver would apply uniformly to all Users during the period.

Intermarket Competition

The Exchange does not believe that the proposed change would impose any burden on intermarket competition that is not necessary or appropriate.

The Exchange believes that the proposed change would not affect the competitive landscape among the national securities exchanges, as the Hot Hands service is solely charged within co-location to existing Users, and would be temporary.

For the reasons described above, the Exchange believes that the proposed rule change reflects this competitive environment.

[9] 15 U.S.C. 78f(b).

[10] 15 U.S.C. 78f(b)(4) and (5).

[11] 15 U.S.C. 78f(b)(8).

C. Self-Regulatory Organization's Statement on Comments on the Proposed Rule Change Received From Members, Participants, or Others

No written comments were solicited or received with respect to the proposed rule change.

III. Date of Effectiveness of the Proposed Rule Change and Timing for Commission Action

The foregoing rule change is effective upon filing pursuant to Section 19(b)(3)(A) [12] of the Act and subparagraph (f)(2) of Rule 19b–4 [13] thereunder, because it establishes a due, fee, or other charge imposed by the Exchange.

At any time within 60 days of the filing of such proposed rule change, the Commission summarily may temporarily suspend such rule change if it appears to the Commission that such action is necessary or appropriate in the public interest, for the protection of investors, or otherwise in furtherance of the purposes of the Act. If the Commission takes such action, the Commission shall institute proceedings under Section 19(b)(2)(B) [14] of the Act to determine whether the proposed rule change should be approved or disapproved.

IV. Solicitation of Comments

Interested persons are invited to submit written data, views, and arguments concerning the foregoing, including whether the proposed rule change is consistent with the Act. Comments may be submitted by any of the following methods:

Electronic Comments

- Use the Commission's internet comment form (*http://www.sec.gov/rules/sro.shtml*); or
- Send an email to *rule-comments@sec.gov.* Please include File Number SR–NYSE–2020–44 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–NYSE–2020–44. 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–NYSE–2020–44 and should be submitted on or before June 23, 2020.

For the Commission, by the Division of Trading and Markets, pursuant to delegated authority.[15]

J. Matthew DeLesDernier,

Assistant Secretary.

[FR Doc. 2020–11779 Filed 6–1–20; 8:45 am]

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[12] 15 U.S.C. 78s(b)(3)(A).

[13] 17 CFR 240.19b–4(f)(2).

[14] 15 U.S.C. 78s(b)(2)(B).

[15] 17 CFR 200.30–3(a)(12).

SECURITIES AND EXCHANGE COMMISSION

[Release No. 34–88956; File No. SR–NYSEAMER–2020–39]

Self-Regulatory Organizations; NYSE American LLC; Notice of Filing and Immediate Effectiveness of Proposed Change To Extend the Temporary Waiver of the Co-Location Hot Hands Fee

May 27, 2020.

Pursuant to Section 19(b)(1) [1] of the Securities Exchange Act of 1934 (the ''Act'') [2] and Rule 19b–4 thereunder,[3] notice is hereby given that, on May 14, 2020, NYSE American LLC (''NYSE American'' or the ''Exchange'') filed with the Securities and Exchange Commission (the ''Commission'') the proposed rule change as described in Items I, II, and III below, which Items have been prepared by the self-regulatory organization. The Commission is publishing this notice to solicit comments on the proposed rule change from interested persons.

I. Self-Regulatory Organization's Statement of the Terms of Substance of the Proposed Rule Change

The Exchange proposes to extend the temporary waiver of the co-location ''Hot Hands'' fee. The proposed change is available on the Exchange's website at *www.nyse.com,* at the principal office of the Exchange, and at the Commission's Public Reference Room.

II. Self-Regulatory Organization's Statement of the Purpose of, and Statutory Basis for, the Proposed Rule Change

In its filing with the Commission, the self-regulatory organization included statements concerning the purpose of, and basis for, the proposed rule change and discussed any comments it received on the proposed rule change. The text of those statements may be examined at the places specified in Item IV below. The Exchange has prepared summaries, set forth in sections A, B, and C below, of the most significant parts of such statements.

A. Self-Regulatory Organization's Statement of the Purpose of, and the Statutory Basis for, the Proposed Rule Change

1. Purpose

The Exchange proposes to extend of the temporary waiver of the co-location [4] ''Hot Hands'' fee through the earlier of the reopening of the Mahwah, New Jersey data center (''Data Center'') or June 30, 2020. The waiver of the Hot Hands fee is scheduled to expire on May 15, 2020.[5]

The Exchange is an indirect subsidiary of Intercontinental Exchange, Inc. (''ICE''). Through its ICE Data Services (''IDS'') business, ICE operates the Mahwah, New Jersey data center (''Data Center''), from which the Exchange provides co-location services to Users.[6] Among those services is a

[1] 15 U.S.C. 78s(b)(1).

[2] 15 U.S.C. 78a.

[3] 17 CFR 240.19b–4.

[4] The Exchange initially filed rule changes relating to its co-location services with the Securities and Exchange Commission (''Commission'') in 2010. *See* Securities Exchange Act Release No. 62961 (September 21, 2010), 75 FR 59299 (September 27, 2010) (SR–NYSEAmex–2010–80).

[5] *See* Securities Exchange Act Release No. 88403 (March 17, 2020), 85 FR 16400 (March 23, 2020) (SR–NYSEAMER–2020–19), and 88523 (March 31, 2020), 85 FR 19179 (April 6, 2020) (SR–NYSEAMER–2020–23).

[6] For purposes of the Exchange's co-location services, a ''User'' means any market participant that requests to receive co-location services directly from the Exchange. *See* Securities Exchange Act

''Hot Hands'' service, which allows Users to use on-site Data Center personnel to maintain User equipment, support network troubleshooting, rack and stack a server in a User's cabinet; power recycling; and install and document the fitting of cable in a User's cabinet(s).[7] The Hot Hands fee is $100 per half hour.

ICE previously announced to Users that the Data Center would be closed to third parties for the period from March 16, 2020 through May 15, 2020 (the ''Initial Closure''), to help avoid the spread of COVID–19, which could negatively impact Data Center functions. Prior to the closure of the Data Center, the Chief Executive Officer of the Exchange took the actions required under NYSE American Rules 7.1E and 901NY to close the co-location facility of the Exchange to third parties.

ICE has now announced to Users that, because the concerns that led to the Initial Closure still apply, the closure of the Data Center will be extended, with the date of the reopening announced through a customer notice.

If a User's equipment requires work while a Rules 7.1E and 901NY closure is in effect, the User has to use the Hot Hands service and, absent a waiver, incurs Hot Hands fees for the work. Given that, the Exchange waived all Hot Hands fees for the duration of the Initial Closure.[8] Because the period has been extended, the Exchange proposes to extend the waiver of the Hot Hands Fee for the length of the period. To that end, the Exchange proposes to revise the footnote to the Hot Hands Fee in the Price List and Fee Schedule as follows (deletions bracketed, additions underlined):

† Fees for Hot Hands Services will be waived beginning on March 16, 2020 through the earlier of June 30, 2020 and the reopening of the Mahwah, New Jersey data center[or May 15, 2020].

The Exchange believes that there will be sufficient Data Center staff on-site to comply with User requests for Hot Hands service.

The proposed extension of the waiver would apply equally to all Users. The proposed extension of the fee waiver would not apply differently to distinct types or sizes of market participants. Rather, it would continue to apply uniformly to all Users.

The proposed change is not otherwise intended to address any other issues relating to co-location services and/or related fees, and the Exchange is not aware of any problems that Users would have in complying with the proposed change.

2. Statutory Basis

The Exchange believes that the proposed rule change is consistent with Section 6(b) of the Act,[9] in general, and furthers the objectives of Sections 6(b)(4) and (5) of the Act,[10] in particular, because it provides for the equitable allocation of reasonable dues, fees, and other charges among its members, issuers and other persons using its facilities and does not unfairly discriminate between customers, issuers, brokers or dealers. In addition, it is designed 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.

The Proposed Rule Change Is Reasonable

The Exchange believes that the proposed rule change is reasonable for the following reasons.

Given that the closure of the Data Center has been extended, the Exchange believes that it is reasonable to grant the proposed corresponding extension of the waiver of the Hot Hands Fee. While a Rules 7.1E and 901NY closure is in effect, User representatives are not allowed access to the Data Center. If a User's equipment requires work during such period, the User has to use the Hot Hands service. Absent a waiver, the User would incur Hot Hands fees for the work.

The proposed extension of the waiver would allow a User to have work carried out on its equipment notwithstanding the closure of the Data Center without incurring Hot Hands fees.

The Proposed Rule Change Is Equitable

The Exchange believes the proposed rule change is an equitable allocation of its fees and credits for the following reasons.

The proposed extension of the waiver would apply equally to all Users. The proposed extension would not apply differently to distinct types or sizes of market participants. Rather, it would apply uniformly to all Users.

The Exchange believes that the proposal is equitable because the extension of the waiver would mean that for the duration of the closure of the Data Center all similarly-situated Users would not be charged a fee to use the Hot Hands service.

The Proposed Change Is Not Unfairly Discriminatory and Would Protect Investors and the Public Interest

The Exchange believes that the proposed change is not unfairly discriminatory for the following reasons.

The proposed extension of the waiver would not apply differently to distinct types or sizes of market participants. Rather, all Users whose equipment requires work during the extension of

Release No. 76009 (September 29, 2015), 80 FR 60213 (October 5, 2015) (SR–NYSEMKT–2015–67). As specified in the NYSE American Equities Price List and Fee Schedule and the NYSE American Options Fee Schedule (together, the ''Price List and Fee Schedule''), a User that incurs co-location fees for a particular co-location service pursuant thereto would not be subject to co-location fees for the same co-location service charged by the Exchange's affiliates the New York Stock Exchange LLC (''NYSE''), NYSE Arca, Inc. (''NYSE Arca''), NYSE Chicago, Inc. (''NYSE Chicago''), and NYSE National, Inc. (''NYSE National'' and together, the ''Affiliate SROs''). *See* Securities Exchange Act Release No. 70176 (August 13, 2013), 78 FR 50471 (August 19, 2013) (SR–NYSEMKT–2013–67). Each Affiliate SRO has submitted substantially the same proposed rule change to propose the changes described herein. *See* SR–NYSE–2020–44, SR–NYSEArca-2020–47, SR–NYSECHX–2020–15, and SR–NYSENAT–2020–18.

[7] *See* Securities Exchange Act Release No. 72719 (July 30, 2014), 79 FR 45502 (August 5, 2014) (SR–NYSEMKT–2014–61).

[8] *See* 85 FR 16400 and 85 FR 19179, *supra* note 5.

[9] 15 U.S.C. 78f(b).

[10] 15 U.S.C. 78f(b)(4) and (5).

the Data Center closure would have the resulting fees waived, and the extension of the waiver would apply uniformly to all Users during the period. For the reasons above, the proposed changes do not unfairly discriminate between or among market participants.

In addition, the Exchange believes that the proposed rule change would perfect the mechanisms of a free and open market and a national market system and, in general, protect investors and the public interest because it would allow a User to have work carried out on its equipment notwithstanding a Rules 7.1E and 901NY closure without incurring Hot Hands fees. Accordingly, the Exchange believes that the requested extension of the waiver is designed to perfect the mechanisms of a free and open market and a national market system and, in general, protect investors and the public interest by facilitating the uninterrupted availability of Users' equipment.

For all of the above 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,[11] 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.

Intramarket Competition

The Exchange does not believe that the proposed change would place any burden on intramarket competition that is not necessary or appropriate.

The proposed extension of the waiver is not designed to affect competition, but rather to provide relief to Users that, while a Rules 7.1E and 901NY closure is in effect, have no option but to use the Hot Hands service.

The proposed extension of the waiver would not apply differently to distinct types or sizes of market participants. Rather, all Users whose equipment requires work during the extension of the Data Center closure would have the resulting fees waived, and the extension of the waiver would apply uniformly to all Users during the period.

Intermarket Competition

The Exchange does not believe that the proposed change would impose any burden on intermarket competition that is not necessary or appropriate.

The Exchange believes that the proposed change would not affect the competitive landscape among the national securities exchanges, as the Hot Hands service is solely charged within co-location to existing Users, and would be temporary.

For the reasons described above, the Exchange believes that the proposed rule change reflects this competitive environment.

C. Self-Regulatory Organization's Statement on Comments on the Proposed Rule Change Received From Members, Participants, or Others

No written comments were solicited or received with respect to the proposed rule change.

III. Date of Effectiveness of the Proposed Rule Change and Timing for Commission Action

The foregoing rule change is effective upon filing pursuant to Section 19(b)(3)(A)[12] of the Act and subparagraph (f)(2) of Rule 19b–4[13] thereunder, because it establishes a due, fee, or other charge imposed by the Exchange.

At any time within 60 days of the filing of such proposed rule change, the Commission summarily may temporarily suspend such rule change if it appears to the Commission that such action is necessary or appropriate in the public interest, for the protection of investors, or otherwise in furtherance of the purposes of the Act. If the Commission takes such action, the Commission shall institute proceedings under Section 19(b)(2)(B)[14] of the Act to determine whether the proposed rule change should be approved or disapproved.

IV. Solicitation of Comments

Interested persons are invited to submit written data, views, and arguments concerning the foregoing, including whether the proposed rule change is consistent with the Act. Comments may be submitted by any of the following methods:

Electronic Comments

- Use the Commission's internet comment form (*http://www.sec.gov/rules/sro.shtml*); or
- Send an email to *rule-comments@sec.gov.* Please include File Number SR–NYSEAMER–2020–39 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–NYSEAMER–2020–39. 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–NYSEAMER–2020–39 and should be submitted on or before June 23, 2020.

For the Commission, by the Division of Trading and Markets, pursuant to delegated authority.[15]

J. Matthew DeLesDernier,

Assistant Secretary.

[FR Doc. 2020–11780 Filed 6–1–20; 8:45 am]

BILLING CODE 8011–01–P

[11] 15 U.S.C. 78f(b)(8).

[12] 15 U.S.C. 78s(b)(3)(A).

[13] 17 CFR 240.19b–4(f)(2).

[14] 15 U.S.C. 78s(b)(2)(B).

[15] 17 CFR 200.30–3(a)(12).

SECURITIES AND EXCHANGE COMMISSION

[Release No. 34–88954; File No. SR–ICC–2020–007]

Self-Regulatory Organizations; ICE Clear Credit LLC; Order Approving Proposed Rule Change Relating to the ICC Clearing Rules

May 27, 2020.

I. Introduction

On April 10, 2020, ICE Clear Credit LLC (''ICC'') filed with the Securities and Exchange Commission (''Commission''), pursuant to Section

19(b)(1) of the Securities Exchange Act of 1934 (the ''Act''),[1] and Rule 19b–4,[2] a proposed rule change to amend Chapter 2 of the ICC Rules relating to requirements applicable to ICC's Clearing Participants. The proposed rule change was published for comment in the **Federal Register** on April 20, 2020.[3] The Commission did not receive comments regarding the proposed rule change. For the reasons discussed below, the Commission is approving the proposed rule change.

II. Description of the Proposed Rule Change

As discussed below, the proposed rule change would amend Chapter 2 of the ICC Rules, which relates to requirements applicable to ICC's Clearing Participants.

The proposed rule change would amend ICC Rule 201(b), which sets out the standards that each of ICC's Clearing Participants must meet, to add a new standard in standard in subparagraph (xiv). New subparagraph (xiv) would require that a Clearing Participant participate in default management simulations, new technology testing and other exercises, as notified by ICE Clear Credit from time to time.

The proposed rule change would also amend Rule 206(a), which requires that each Clearing Participant immediately notify ICC, orally and in writing, upon the occurrence of certain specified events. The proposed rule change would amend Rule 206(a) to delete the requirement that Clearing Participants provide notices orally, so that instead Clearing Participants would only be required to provide notice in writing.

Finally, the proposed rule change would amend Rule 206(c), which requires a Clearing Participant that is a broker-dealer to notify ICC of, among other things, any matter of which the Clearing Participant must notify FINRA under FINRA Rule 3070. The proposed rule change would replace ''FINRA Rule 3070'' with ''FINRA Rule 4530(a)(1)(A),(C),(E) and 4530(b) (or any similar rules),'' as FINRA Rule 3070 is no longer applicable and has been superseded by FINRA Rule 4530.[4]

[1] 15 U.S.C. 78s(b)(1).

[2] 17 CFR 240.19b–4.

[3] Self-Regulatory Organizations; ICE Clear Credit LLC; Notice of Proposed Rule Change Relating to the ICC Clearing Rules, Exchange Act Release No. 88628 (Apr. 14, 2020); 85 FR 21907 (Apr. 20, 2020) (SR–ICC–2020–007).

[4] FINRA Rule 4530 generally requires that its members promptly report to FINRA after the member or an associated person of the member has been found to have violated any securities or other rules and regulations of a regulatory body, is named as a defendant or respondent in any proceeding brought by a domestic or foreign regulatory body, or is indicted, or convicted of, or pleads guilty to any felony or any misdemeanor that involves the purchase or sale of any security, etc. Further, this rule also generally requires that each member shall promptly report to FINRA after the member has concluded or reasonably should have concluded that an associated person of the member or the member itself has violated any securities or other rules and regulations of a regulatory body.

III. Discussion and Commission Findings

Section 19(b)(2)(C) of the Act directs the Commission to approve a proposed rule change of a self-regulatory organization if it finds that such proposed rule change is consistent with the requirements of the Act and the rules and regulations thereunder applicable to such organization.[5] For the reasons given below, the Commission finds that the proposed rule change is consistent with Section 17A(b)(3)(F) of the Act[6] and Rule 17Ad–22(d)(2).[7]

A. Consistency With Section 17A(b)(3)(F) of the Act

Section 17A(b)(3)(F) of the Act requires, among other things, that the rules of ICC be designed to promote the prompt and accurate clearance and settlement of securities transactions and, to the extent applicable, derivative agreements, contracts, and transactions, as well as to assure the safeguarding of securities and funds which are in the custody or control of ICC or for which it is responsible.[8] By updating the standards for membership applicable to Clearing Participants as discussed above, the proposed rule change should help to ensure that ICC's Clearing Participants participate in default testing and other testing conducted by ICC. In addition, the proposed rule change should help to ensure that all of ICC's Clearing Participants are prepared for, and ready to take actions in response to, a Clearing Participant default, thereby helping to improve ICC's management of a Clearing Participant default. Because the Commission believes that a Clearing Participant default, if not properly managed, could cause ICC to incur losses which could hinder its clearance and settlement of securities transactions and safeguarding of securities and funds in its custody or control, the Commission believes this aspect of the proposed rule change should help to promote the prompt and accurate clearance and settlement of securities transactions and assure the safeguarding of securities and funds in ICC's custody and control.

[5] 15 U.S.C. 78s(b)(2)(C).

[6] 15 U.S.C. 78q–1(b)(3)(F).

[7] 17 CFR 240.17Ad–22(d)(2).

[8] 15 U.S.C. 78q–1(b)(3)(F).

Similarly, by eliminating the requirement for oral notices and updating the reference to the current FINRA rulerequiring notification by a Clearing Participant that is a broker-dealer of violations of regulatory rules and regulations, the proposed rule change should help to ensure that ICC receives notice from a Clearing Participant of events or situations which could affect the Clearing Participant's ability to satisfy the standards and obligations applicable to it as a participant in ICC. The proposed rule change would allow ICC to respond as needed to mitigate any potential negative effects to ICC arising from such events or situations that could hinder ICC's clearance and settlement of securities transactions and safeguarding of securities and funds in its custody or control. Consequently, the Commission believes this aspect of the proposed rule change should help to promote the prompt and accurate clearance and settlement of securities transactions and assure the safeguarding of securities and funds in ICC's custody and control.

Therefore, the Commission finds that the proposed rule change should promote the prompt and accurate clearance and settlement of securities transactions and assure the safeguarding of securities and funds in ICC's custody and control, consistent with Section 17A(b)(3)(F) of the Act.[9]

B. Consistency With Rule 17Ad–22(d)(2)

Rule 17Ad–22(d)(2) requires that ICC establish, implement, maintain and enforce written policies and procedures reasonably designed to require participants to have sufficient financial resources and robust operational capacity to meet obligations arising from participation in ICC; have procedures in place to monitor that participation requirements are met on an ongoing basis; and have participation requirements that are objective and publicly disclosed, and permit fair and open access.[10] The adoption of a new standard applicable to Clearing Participants—participation in default management simulations, new technology testing and other exercises, as notified by ICE Clear Credit from time to time—should establish a participation requirement that is objective in that it applies to all Clearing Participants equally, and is publicly disclosed, in that it would be part of ICC's publicly available rulebook. Moreover, this new participation standard should allow ICC to test a Clearing Participant's operational

[9] 15 U.S.C. 78q–1(b)(3)(F).

[10] 15 U.S.C. 17Ad–22(d)(2).

response to a simulated default, thereby helping to ensure that a Clearing Participant has robust operational capacity to meet obligations arising from participation in ICC. Finally, the elimination of the requirement for oral notices and updating of the reference to the current FINRA rule should help to ensure that ICC receives notice from a Clearing Participant of events or situations which could affect the Clearing Participant's ability to satisfy the standards and obligations applicable to it as a participant in ICC. Taken together, the Commission believes that the proposed rule change should help ICC to monitor that Clearing Participants are meeting their participation requirements on an ongoing basis. For these reasons, the Commission finds that the proposed rule change is consistent with Rule 17Ad–22(d)(2).[11]

IV. Conclusion

On the basis of the foregoing, the Commission finds that the proposed rule change is consistent with the requirements of the Act, and in particular, with the requirements of Section 17A(b)(3)(F) of the Act[12] and Rules 17Ad–22(d)(2).[13]

It is therefore ordered pursuant to Section 19(b)(2) of the Act[14] that the proposed rule change (SR–ICC–2020–007), be, and hereby is, approved.[15]

For the Commission, by the Division of Trading and Markets, pursuant to delegated authority.[16]

J. Matthew DeLesDernier,

Assistant Secretary.

[FR Doc. 2020–11777 Filed 6–1–20; 8:45 am]

BILLING CODE 8011–01–P

[11] 15 U.S.C. 17Ad–22(d)(2).

[12] 15 U.S.C. 78q–1(b)(3)(F).

[13] 17 CFR 240.17Ad–22(d)(2).

[14] 15 U.S.C. 78s(b)(2).

[15] In approving the proposed rule change, the Commission considered the proposal's impact on efficiency, competition, and capital formation. 15 U.S.C. 78c(f).

[16] 17 CFR 200.30–3(a)(12).

SECURITIES AND EXCHANGE COMMISSION

[Release No. 34–88958; File No. SR–NYSENAT–2020–18]

Self-Regulatory Organizations; NYSE National, Inc.; Notice of Filing and Immediate Effectiveness of Proposed Rule Change To Extend the Temporary Waiver of the Co-location Hot Hands Fee

May 27, 2020.

Pursuant to Section 19(b)(1)[1] of the Securities Exchange Act of 1934 (the ''Act'')[2] and Rule 19b–4 thereunder,[3] notice is hereby given that, on May 14, 2020, NYSE National, Inc. (''NYSE National'' or the ''Exchange'') filed with the Securities and Exchange Commission (the ''Commission'') the proposed rule change as described in Items I, II, and III below, which Items have been prepared by the self-regulatory organization. The Commission is publishing this notice to solicit comments on the proposed rule change from interested persons.

I. Self-Regulatory Organization's Statement of the Terms of Substance of the Proposed Rule Change

The Exchange proposes to extend the temporary waiver of the co-location ''Hot Hands'' fee. The proposed rule change is available on the Exchange's website at *www.nyse.com,* at the principal office of the Exchange, and at the Commission's Public Reference Room.

II. Self-Regulatory Organization's Statement of the Purpose of, and Statutory Basis for, the Proposed Rule Change

In its filing with the Commission, the self-regulatory organization included statements concerning the purpose of, and basis for, the proposed rule change and discussed any comments it received on the proposed rule change. The text of those statements may be examined at the places specified in Item IV below. The Exchange has prepared summaries, set forth in sections A, B, and C below, of the most significant parts of such statements.

A. Self-Regulatory Organization's Statement of the Purpose of, and the Statutory Basis for, the Proposed Rule Change

1. Purpose

The Exchange proposes to extend of the temporary waiver of the co-location[4] ''Hot Hands'' fee through the earlier of the reopening of the Mahwah, New Jersey data center (''Data Center'') or June 30, 2020. The waiver of the Hot Hands fee is scheduled to expire on May 15, 2020.[5]

The Exchange is an indirect subsidiary of Intercontinental Exchange, Inc. (''ICE''). Through its ICE Data Services (''IDS'') business, ICE operates the Mahwah, New Jersey data center (''Data Center''), from which the Exchange provides co-location services to Users.[6] Among those services is a ''Hot Hands'' service, which allows Users to use on-site Data Center personnel to maintain User equipment, support network troubleshooting, rack and stack a server in a User's cabinet; power recycling; and install and document the fitting of cable in a User's cabinet(s).[7] The Hot Hands fee is $100 per half hour.

ICE previously announced to Users that the Data Center would be closed to third parties for the period from March 16, 2020 through May 15, 2020 (the ''Initial Closure''), to help avoid the spread of COVID–19, which could negatively impact Data Center functions. Prior to the closure of the Data Center, the Chief Executive Officer of the Exchange took the actions required under NYSE National Rule 7.1 to close the co-location facility of the Exchange to third parties.

ICE has now announced to Users that, because the concerns that led to the Initial Closure still apply, the closure of the Data Center will be extended, with the date of the reopening announced through a customer notice.

[1] 15 U.S.C. 78s(b)(1).

[2] 15 U.S.C. 78a.

[3] 17 CFR 240.19b–4.

[4] The Exchange initially filed rule changes relating to its co-location services with the Securities and Exchange Commission (''Commission'') in May 2018. *See* Securities Exchange Act Release No. 83351 (May 31, 2018), 83 FR 26314 (June 6, 2018) (SR–NYSENAT–2018–07).

[5] *See* Securities Exchange Act Release Nos. 88399 (March 17, 2020), 85 FR 16428 (March 23, 2020) (SR–NYSENAT–2020–10), and 88521 (March 31, 2020), 85 FR 19194 (April 6, 2020) (SR–NYSENAT–2020–14).

[6] For purposes of the Exchange's co-location services, a ''User'' means any market participant that requests to receive co-location services directly from the Exchange. *See* 83 FR 26314, *supra* note 4, at note 9. As specified in the Exchange's Price List, a User that incurs co-location fees for a particular co-location service pursuant thereto would not be subject to co-location fees for the same co-location service charged by the Exchange's affiliates the New York Stock Exchange LLC (''NYSE''), NYSE American LLC (''NYSE American''), NYSE Arca, Inc. (''NYSE Arca''), and NYSE Chicago, Inc. (''NYSE Chicago'' and together, the ''Affiliate SROs''). *See id.* at note 11. Each Affiliate SRO has submitted substantially the same proposed rule change to propose the changes described herein. *See* SR–NYSE–2020–44, SR–NYSEAmer–2020–39, SR–NYSEArca–2020–47, and SR–NYSECHX–2020–15.

[7] *See* 83 FR 26314, *supra* note 4.

If a User's equipment requires work while a Rule 7.1 closure is in effect, the User has to use the Hot Hands service and, absent a waiver, incurs Hot Hands fees for the work. Given that, the Exchange waived all Hot Hands fees for the duration of the Initial Closure.[8] Because the period has been extended, the Exchange proposes to extend the waiver of the Hot Hands Fee for the length of the period. To that end, the Exchange proposes to revise the footnote to the Hot Hands Fee in the Price List as follows (deletions bracketed, additions underlined):

† Fees for Hot Hands Services will be waived beginning on March 16, 2020 through the earlier of June 30, 2020 and the reopening of the Mahwah, New Jersey data center[or May 15, 2020].

The Exchange believes that there will be sufficient Data Center staff on-site to comply with User requests for Hot Hands service.

The proposed extension of the waiver would apply equally to all Users. The proposed extension of the fee waiver would not apply differently to distinct types or sizes of market participants. Rather, it would continue to apply uniformly to all Users.

The proposed change is not otherwise intended to address any other issues relating to co-location services and/or related fees, and the Exchange is not aware of any problems that Users would have in complying with the proposed change.

2. Statutory Basis

The Exchange believes that the proposed rule change is consistent with Section 6(b) of the Act,[9] in general, and furthers the objectives of Sections 6(b)(4) and (5) of the Act,[10] in particular, because it provides for the equitable allocation of reasonable dues, fees, and other charges among its members, issuers and other persons using its facilities and does not unfairly discriminate between customers, issuers, brokers or dealers. In addition, it is designed 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.

The Proposed Rule Change Is Reasonable

The Exchange believes that the proposed rule change is reasonable for the following reasons.

Given that the closure of the Data Center has been extended, the Exchange believes that it is reasonable to grant the proposed corresponding extension of the waiver of the Hot Hands Fee. While a Rule 7.1 closure is in effect, User representatives are not allowed access to the Data Center. If a User's equipment requires work during such period, the User has to use the Hot Hands service. Absent a waiver, the User would incur Hot Hands fees for the work.

The proposed extension of the waiver would allow a User to have work carried out on its equipment notwithstanding the closure of the Data Center without incurring Hot Hands fees.

The Proposed Rule Change Is Equitable

The Exchange believes the proposed rule change is an equitable allocation of its fees and credits for the following reasons.

The proposed extension of the waiver would apply equally to all Users. The proposed extension would not apply differently to distinct types or sizes of market participants. Rather, it would apply uniformly to all Users.

The Exchange believes that the proposal is equitable because the extension of the waiver would mean that for the duration of the closure of the Data Center all similarly-situated Users would not be charged a fee to use the Hot Hands service.

The Proposed Change Is Not Unfairly Discriminatory and Would Protect Investors and the Public Interest

The Exchange believes that the proposed change is not unfairly discriminatory for the following reasons.

The proposed extension of the waiver would not apply differently to distinct types or sizes of market participants. Rather, all Users whose equipment requires work during the extension of the Data Center closure would have the resulting fees waived, and the extension of the waiver would apply uniformly to all Users during the period. For the reasons above, the proposed changes do not unfairly discriminate between or among market participants.

In addition, the Exchange believes that the proposed rule change would perfect the mechanisms of a free and open market and a national market system and, in general, protect investors and the public interest because it would allow a User to have work carried out on its equipment notwithstanding a Rule 7.1 closure without incurring Hot Hands fees. Accordingly, the Exchange believes that the requested extension of the waiver is designed to perfect the mechanisms of a free and open market and a national market system and, in general, protect investors and the public interest by facilitating the uninterrupted availability of Users' equipment.

For all of the above 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,[11] 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.

Intramarket Competition

The Exchange does not believe that the proposed change would place any burden on intramarket competition that is not necessary or appropriate.

The proposed extension of the waiver is not designed to affect competition, but rather to provide relief to Users that, while a Rule 7.1 closure is in effect, have no option but to use the Hot Hands service.

The proposed extension of the waiver would not apply differently to distinct types or sizes of market participants. Rather, all Users whose equipment requires work during the extension of

[8] *See* 85 FR 16428 and 85 FR 19194, *supra* note 5.

[9] 15 U.S.C. 78f(b).

[10] 15 U.S.C. 78f(b)(4) and (5).

[11] 15 U.S.C. 78f(b)(8).

the Data Center closure would have the resulting fees waived, and the extension of the waiver would apply uniformly to all Users during the period.

Intermarket Competition

The Exchange does not believe that the proposed change would impose any burden on intermarket competition that is not necessary or appropriate.

The Exchange believes that the proposed change would not affect the competitive landscape among the national securities exchanges, as the Hot Hands service is solely charged within co-location to existing Users, and would be temporary.

For the reasons described above, the Exchange believes that the proposed rule change reflects this competitive environment.

C. Self-Regulatory Organization's Statement on Comments on the Proposed Rule Change Received From Members, Participants, or Others

No written comments were solicited or received with respect to the proposed rule change.

III. Date of Effectiveness of the Proposed Rule Change and Timing for Commission Action

The foregoing rule change is effective upon filing pursuant to Section 19(b)(3)(A) [12] of the Act and subparagraph (f)(2) of Rule 19b–4 [13] thereunder, because it establishes a due, fee, or other charge imposed by the Exchange.

At any time within 60 days of the filing of such proposed rule change, the Commission summarily may temporarily suspend such rule change if it appears to the Commission that such action is necessary or appropriate in the public interest, for the protection of investors, or otherwise in furtherance of the purposes of the Act. If the Commission takes such action, the Commission shall institute proceedings under Section 19(b)(2)(B) [14] of the Act to determine whether the proposed rule change should be approved or disapproved.

IV. Solicitation of Comments

Interested persons are invited to submit written data, views, and arguments concerning the foregoing, including whether the proposed rule change is consistent with the Act. Comments may be submitted by any of the following methods:

Electronic Comments

- Use the Commission's internet comment form (*http://www.sec.gov/rules/sro.shtml*); or
- Send an email to *rule-comments@sec.gov.* Please include File Number SR–NYSENAT–2020–18 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–NYSENAT–2020–18. 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–NYSENAT–2020–18 and should be submitted on or before June 23, 2020.

For the Commission, by the Division of Trading and Markets, pursuant to delegated authority.[15]

J. Matthew DeLesDernier,

Assistant Secretary.

[FR Doc. 2020–11782 Filed 6–1–20; 8:45 am]

BILLING CODE 8011–01–P

[12] 15 U.S.C. 78s(b)(3)(A).

[13] 17 CFR 240.19b–4(f)(2).

[14] 15 U.S.C. 78s(b)(2)(B).

[15] 17 CFR 200.30–3(a)(12).

SECURITIES AND EXCHANGE COMMISSION

[Release No. 34–88957; File No. SR–NYSECHX–2020–15]

Self-Regulatory Organizations; NYSE Chicago, Inc.; Notice of Filing and Immediate Effectiveness of Proposed Rule Change To Extend the Temporary Waiver of the Co-Location Hot Hands Fee

May 27, 2020.

Pursuant to Section 19(b)(1) [1] of the Securities Exchange Act of 1934 (the ''Act'') [2] and Rule 19b–4 thereunder,[3] notice is hereby given that, on May 14, 2020 the NYSE Chicago, Inc. (''NYSE Chicago'' or the ''Exchange'') filed with the Securities and Exchange Commission (the ''Commission'') the proposed rule change as described in Items I, II, and III below, which Items have been prepared by the self-regulatory organization. The Commission is publishing this notice to solicit comments on the proposed rule change from interested persons.

I. Self-Regulatory Organization's Statement of the Terms of Substance of the Proposed Rule Change

The Exchange proposes to extend the temporary waiver of the co-location ''Hot Hands'' fee. The proposed rule change is available on the Exchange's website at *www.nyse.com,* at the principal office of the Exchange, and at the Commission's Public Reference Room.

II. Self-Regulatory Organization's Statement of the Purpose of, and Statutory Basis for, the Proposed Rule Change

In its filing with the Commission, the self-regulatory organization included statements concerning the purpose of, and basis for, the proposed rule change and discussed any comments it received on the proposed rule change. The text of those statements may be examined at the places specified in Item IV below. The Exchange has prepared summaries, set forth in sections A, B, and C below, of the most significant parts of such statements.

A. Self-Regulatory Organization's Statement of the Purpose of, and the Statutory Basis for, the Proposed Rule Change

1. Purpose

The Exchange proposes to extend of the temporary waiver of the co-

[1] 15 U.S.C. 78s(b)(1).

[2] 15 U.S.C. 78a.

[3] 17 CFR 240.19b–4.

location [4] ''Hot Hands'' fee through the earlier of the reopening of the Mahwah, New Jersey data center (''Data Center'') or June 30, 2020. The waiver of the Hot Hands fee is scheduled to expire on May 15, 2020.[5]

The Exchange is an indirect subsidiary of Intercontinental Exchange, Inc. (''ICE''). Through its ICE Data Services (''IDS'') business, ICE operates the Mahwah, New Jersey data center (''Data Center''), from which the Exchange provides co-location services to Users.[6] Among those services is a ''Hot Hands'' service, which allows Users to use on-site Data Center personnel to maintain User equipment, support network troubleshooting, rack and stack a server in a User's cabinet; power recycling; and install and document the fitting of cable in a User's cabinet(s).[7] The Hot Hands fee is $100 per half hour.

ICE previously announced to Users that the Data Center would be closed to third parties for the period from March 16, 2020 through May 15, 2020 (the ''Initial Closure''), to help avoid the spread of COVID–19, which could negatively impact Data Center functions. Prior to the closure of the Data Center, the Chief Executive Officer of the Exchange took the actions required under NYSE Chicago Rule 7.1 to close the co-location facility of the Exchange to third parties.

ICE has now announced to Users that, because the concerns that led to the Initial Closure still apply, the closure of the Data Center will be extended, with the date of the reopening announced through a customer notice.

If a User's equipment requires work while a Rule 7.1 closure is in effect, the User has to use the Hot Hands service and, absent a waiver, incurs Hot Hands fees for the work. Given that, the Exchange waived all Hot Hands fees for the duration of the Initial Closure.[8] Because the period has been extended, the Exchange proposes to extend the waiver of the Hot Hands Fee for the length of the period. To that end, the Exchange proposes to revise the footnote to the Hot Hands Fee in the Fee Schedule as follows (deletions bracketed, additions underlined):

† Fees for Hot Hands Services will be waived beginning on March 16, 2020 through the earlier of June 30, 2020 and the reopening of the Mahwah, New Jersey data center[or May 15, 2020].

The Exchange believes that there will be sufficient Data Center staff on-site to comply with User requests for Hot Hands service.

The proposed extension of the waiver would apply equally to all Users. The proposed extension of the fee waiver would not apply differently to distinct types or sizes of market participants. Rather, it would continue to apply uniformly to all Users.

The proposed change is not otherwise intended to address any other issues relating to co-location services and/or related fees, and the Exchange is not aware of any problems that Users would have in complying with the proposed change.

2. Statutory Basis

The Exchange believes that the proposed rule change is consistent with Section 6(b) of the Act,[9] in general, and furthers the objectives of Sections 6(b)(4) and (5) of the Act,[10] in particular, because it provides for the equitable allocation of reasonable dues, fees, and other charges among its members, issuers and other persons using its facilities and does not unfairly discriminate between customers, issuers, brokers or dealers. In addition, it is designed 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.

The Proposed Rule Change Is Reasonable

The Exchange believes that the proposed rule change is reasonable for the following reasons.

Given that the closure of the Data Center has been extended, the Exchange believes that it is reasonable to grant the proposed corresponding extension of the waiver of the Hot Hands Fee. While a Rule 7.1 closure is in effect, User representatives are not allowed access to the Data Center. If a User's equipment requires work during such period, the User has to use the Hot Hands service. Absent a waiver, the User would incur Hot Hands fees for the work.

The proposed extension of the waiver would allow a User to have work carried out on its equipment notwithstanding the closure of the Data Center without incurring Hot Hands fees.

The Proposed Rule Change Is Equitable

The Exchange believes the proposed rule change is an equitable allocation of its fees and credits for the following reasons.

The proposed extension of the waiver would apply equally to all Users. The proposed extension would not apply differently to distinct types or sizes of market participants. Rather, it would apply uniformly to all Users.

The Exchange believes that the proposal is equitable because the extension of the waiver would mean that for the duration of the closure of the

[4] The Exchange initially filed rule changes relating to its co-location services with the Securities and Exchange Commission (''Commission'') in October 2019. *See* Securities Exchange Act Release No. 87408 (October 28, 2019), 84 FR 58778 (November 1, 2019) (SR–NYSECHX–2019–27).

[5] *See* Securities Exchange Act Release Nos. 88400 (March 17, 2020), 85 FR 16434 (March 23, 2020) (SR–NYSECHX–2020–07), and 88522 (March 31, 2020), 85 FR 19191 (April 6, 2020) (SR–NYSECHX–2020–10).

[6] For purposes of the Exchange's co-location services, a ''User'' means any market participant that requests to receive co-location services directly from the Exchange. *See* 84 FR 58778, *supra* note 4, at note 6. As specified in the Fee Schedule of NYSE Chicago, Inc. (''Fee Schedule''), a User that incurs co-location fees for a particular co-location service pursuant thereto would not be subject to co-location fees for the same co-location service charged by the Exchange's affiliates the New York Stock Exchange LLC (''NYSE''), NYSE American LLC (''NYSE American''), NYSE Arca, Inc. (''NYSE Arca''), and NYSE National, Inc. (''NYSE National'' and together, the ''Affiliate SROs''). *See id.* at 58779. Each Affiliate SRO has submitted substantially the same proposed rule change to propose the changes described herein. *See* SR–NYSE–2020–44, SR–NYSEAmer–2020–39, SR–NYSEArca–2020–47, and SR–NYSENAT–2020–18.

[7] *See* 84 FR 58778, *supra* note 4.

[8] *See* 85 FR 16434 and 85 FR 19191, *supra* note 5.

[9] 15 U.S.C. 78f(b).

[10] 15 U.S.C. 78f(b)(4) and (5).

Data Center all similarly-situated Users would not be charged a fee to use the Hot Hands service.

The Proposed Change Is Not Unfairly Discriminatory and Would Protect Investors and the Public Interest

The Exchange believes that the proposed change is not unfairly discriminatory for the following reasons.

The proposed extension of the waiver would not apply differently to distinct types or sizes of market participants. Rather, all Users whose equipment requires work during the extension of the Data Center closure would have the resulting fees waived, and the extension of the waiver would apply uniformly to all Users during the period. For the reasons above, the proposed changes do not unfairly discriminate between or among market participants.

In addition, the Exchange believes that the proposed rule change would perfect the mechanisms of a free and open market and a national market system and, in general, protect investors and the public interest because it would allow a User to have work carried out on its equipment notwithstanding a Rule 7.1 closure without incurring Hot Hands fees. Accordingly, the Exchange believes that the requested extension of the waiver is designed to perfect the mechanisms of a free and open market and a national market system and, in general, protect investors and the public interest by facilitating the uninterrupted availability of Users' equipment.

For all of the above 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,[11] 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.

Intramarket Competition

The Exchange does not believe that the proposed change would place any burden on intramarket competition that is not necessary or appropriate.

The proposed extension of the waiver is not designed to affect competition, but rather to provide relief to Users that, while a Rule 7.1 closure is in effect, have no option but to use the Hot Hands service.

The proposed extension of the waiver would not apply differently to distinct types or sizes of market participants. Rather, all Users whose equipment requires work during the extension of the Data Center closure would have the resulting fees waived, and the extension of the waiver would apply uniformly to all Users during the period.

Intermarket Competition

The Exchange does not believe that the proposed change would impose any burden on intermarket competition that is not necessary or appropriate.

The Exchange believes that the proposed change would not affect the competitive landscape among the national securities exchanges, as the Hot Hands service is solely charged within co-location to existing Users, and would be temporary.

For the reasons described above, the Exchange believes that the proposed rule change reflects this competitive environment.

C. Self-Regulatory Organization's Statement on Comments on the Proposed Rule Change Received From Members, Participants, or Others

No written comments were solicited or received with respect to the proposed rule change.

III. Date of Effectiveness of the Proposed Rule Change and Timing for Commission Action

The foregoing rule change is effective upon filing pursuant to Section 19(b)(3)(A)[12] of the Act and subparagraph (f)(2) of Rule 19b–4[13] thereunder, because it establishes a due, fee, or other charge imposed by the Exchange.

At any time within 60 days of the filing of such proposed rule change, the Commission summarily may temporarily suspend such rule change if it appears to the Commission that such action is necessary or appropriate in the public interest, for the protection of investors, or otherwise in furtherance of the purposes of the Act. If the Commission takes such action, the Commission shall institute proceedings under Section 19(b)(2)(B)[14] of the Act to determine whether the proposed rule change should be approved or disapproved.

IV. Solicitation of Comments

Interested persons are invited to submit written data, views, and arguments concerning the foregoing, including whether the proposed rule change is consistent with the Act. Comments may be submitted by any of the following methods:

Electronic Comments

- Use the Commission's internet comment form (*http://www.sec.gov/rules/sro.shtml*); or
- Send an email to *rule-comments@sec.gov.* Please include File Number SR–NYSECHX–2020–15 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–NYSECHX–2020–15. 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–NYSECHX–2020–15 and should be submitted on or before June 23, 2020.

For the Commission, by the Division of Trading and Markets, pursuant to delegated authority.[15]

J. Matthew DeLesDernier,

Assistant Secretary.

[FR Doc. 2020–11781 Filed 6–1–20; 8:45 am]

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[11] 15 U.S.C. 78f(b)(8).

[12] 15 U.S.C. 78s(b)(3)(A).

[13] 17 CFR 240.19b–4(f)(2).

[14] 15 U.S.C. 78s(b)(2)(B).

[15] 17 CFR 200.30–3(a)(12).

SECURITIES AND EXCHANGE COMMISSION

[Release No. 34–88959; File No. SR–BOX–2020–17]

Self-Regulatory Organizations; BOX Exchange LLC; Notice of Filing and Immediate Effectiveness of a Proposed Rule Change To Replace BOX Rule 7260 (Penny Pilot Program) To Conform the Rule to Section 3.1 of the Plan for the Purpose of Developing and Implementing Procedures Designed To Facilitate the Listing and Trading of Standardized Options and Make Other Non Substantive Changes to References to the Penny Pilot Program

May 27, 2020.

Pursuant to Section 19(b)(1)T [1] of the Securities Exchange Act of 1934 (''Act'') [2] and Rule 19b–4 thereunder,[3] notice is hereby given that, on May 26, 2020, BOX Exchange LLC (''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 self-regulatory organization. The Commission is publishing this notice to solicit comments on the proposed rule change from interested persons.

I. Self-Regulatory Organization's Statement of the Terms of Substance of the Proposed Rule Change

The Exchange proposes to replace BOX Rule 7260 (Penny Pilot Program) with BOX Rule 7260 (Requirements for Penny Interval Program) to conform the rule to Section 3.1 of the Plan for the Purpose of Developing and Implementing Procedures Designed to Facilitate the Listing and Trading of Standardized Options (the ''OLPP'') and make other non-substantive changes to references to the Penny Pilot Program. The text of the proposed rule change is available from the principal office of the Exchange, at the Commission's Public Reference Room and also on the Exchange's internet website at *http://boxoptions.com.*

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 these statements may be examined at the places specified in Item IV below. The self-regulatory organization 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 the Statutory Basis for, the Proposed Rule Change

1. Purpose

The purpose of this rule change is to delete BOX Rule 7260 (Penny Pilot Program) in order to rename the rule as BOX Rule 7260 (Requirements for Penny Interval Program) and replace the rule text to conform to Section 3.1 of the OLPP. The Exchange also proposes to replace references to the Penny Pilot with references to the Penny Interval Program in IM–5050–10 (Mini Option Contracts), Rule 7050 (Minimum Trading Increments), and IM–7620–1 (Sub-Penny Cabinet).

Background

On January 23, 2007, the Commission approved on a limited basis a Penny Pilot in option classes in certain issues (''Penny Pilot''). The Penny Pilot was designed to determine whether investors would benefit from options being quoted in penny increments, and in which classes the benefits were most significant. The Penny Pilot was expanded and extended numerous times over the last 13 years.[4] In each instance, these approvals relied upon the consideration of data periodically provided by the Exchanges that analyzed how quoting options in penny increments affects spreads, liquidity, quote traffic, and volume. Today, the Penny Pilot includes 363 option classes, which are among the most actively traded, multiply listed option classes. The Penny Pilot is scheduled to expire by its own terms on June 30, 2020.[5]

In light of the imminent expiration of the Penny Pilot on June 30, 2020, the Exchange, together with other participating exchanges, filed, on July 18, 2019 a proposal to amend the OLPP.[6] On April 1, 2020 the Commission approved the amendment to the OLPP to make permanent the Pilot Program (the ''OLPP Program'').[7]

The OLPP Program replaces the Penny Pilot by instituting a permanent program that would permit quoting in penny increments for certain option classes. Under the terms of the OLPP Program, designated option classes would continue to be quoted in $0.01 and $0.05 increments according to the same parameters for the Penny Pilot. In addition, the OLPP Program would: (i) Establish an annual review process to add option classes to, or to remove option classes from, the OLPP Program; (ii) to allow an option class to be added to the OLPP Program if it is a newly listed option class and it meets certain criteria; (iii) to allow an option class to be added to the OLPP Program if it is an option class that has seen a significant growth in activity; (iv) to provide that if a corporate action involves one or more option classes in the OLPP Program, all adjusted and unadjusted series and classes emerging as a result of the corporate action will be included in the OLPP Program; and (v) to provide that any series in an option class participating in the OLPP Program that have been delisted, or are identified by OCC as ineligible for opening Customer transactions, will

[1] 15 U.S.C. 78s(b)(1).

[2] 15 U.S.C. 78a.

[3] 17 CFR 240.19b–4.

[4] *See* Securities Exchange Act Release Nos. 55156 (January 23, 2007) 72 FR 4759 (February 1, 2007) (NYSEArca–2006–73); 56150 (July 26, 2007) 72 FR 42460 (August 2, 2007) (NYSEArca–2007–56); 56568 (September 27, 2007) 72 FR 56422 (October 3, 2007) (NYSEArca–2007–88); 59628 (March 26, 2009) 74 FR 15025 (NYSEArca–2009–26); 60224 (July 1, 2009) 74 FR 32991 (July 9, 2009) (NYSEArca–2009–61); 60711 (September 23, 2009) 74 FR 49419 (September 28, 2009) (NYSEArca–2009–44); 61061 (November 24, 2009) 74 FR 62857 (December 1, 2009) (NYSEArca–2009–44); 63376 (November 24, 2010) 75 FR 75527 (December 3, 2010) (NYSEArca–2010–104); 65977 (December 15, 2011) 76 FR 79234 (NYSEArca–2011–93). The Penny Pilot Program has been in effect on the Exchange since its inception in May 2012. *See* Securities Exchange Act Release Nos. 66871 (April 27, 2012), 77 FR 26323 (May 3, 2012) (File No.10–206, In the Matter of the Application of BOX Options Exchange LLC for Registration as a National Securities Exchange Findings, Opinion, and Order of the Commission), 67328 (June 29, 2012), 77 FR 40123 (July 6, 2012) (SR–BOX–2012–007), 68425 (December 13, 2012), 77 FR 75234 (December 19, 2013) (SR–BOX–2012–021), 69789 (June 18, 2013), 78 FR 37854 (June 24, 2013) (SR–BOX–2013–31), 71056 (December 12, 2013), 78 FR 76691 (December 18, 2013) (SR–BOX–2013–56), 72348 (June 9, 2014), 79 FR 33976 (June 13, 2014) (SR–BOX–2014–17), 73822 (December 11, 2014), 79 FR 75606 (December 18, 2014) (SR–BOX–2014–29), 75295 (June 25, 2015), 80 FR 37690 (July 1, 2015)(SR–BOX–2015–23), 78172 (June 28, 2016), 81 FR 43325 (July 1, 2016)(SR–BOX–2016–24), 79429 (November 30, 2016), 81 FR 87991 (December 6, 2016)(SR–BOX–2016–55), 80828 (May 31, 2017), 82 FR 26175 (June 6, 2017)(SR–BOX–2017–18), 82353 (December 19, 2017) 82 FR 61087 (December 26, 2017)(SR–BOX–2017–37), 83500 (June 22, 2018), 83 FR 30471 (June 28, 2018)(SR–BOX–2018–23), 84869 (December 19, 2018), 83 FR 66806 (December 27, 2018)(SR–BOX–2018–38), 86053 (June 6, 2019), 84 FR 27388 (June 12, 2019)(SR–BOX–2019–20), 87632 (November 26, 2019), 84 FR 66255 (December 3, 2019)(SR–BOX–2019–34).

[5] *See* Securities Exchange Act Release No. 34–87632 (November 26, 2019) 84 FR 66255 (December 3, 2019) (SR–BOX–2019–34).

[6] *See* Securities Exchange Act Release No. 87681 (December 9, 2019), 84 FR 68960 (December 17, 2019) (''Notice'').

[7] *See* Securities Exchange Act Release No. 88532 (April 1, 2020), 85 FR 19545 (April 7, 2020) (File No. 4–443) (''Approval Order'').

continue to trade pursuant to the OLPP Program until they expire.

To conform its Rules to the OLPP Program, the Exchange proposes to delete BOX Rule 7260 (Penny Pilot Program) to rename the rule as BOX Rule 7620 (''Requirements for Penny Interval Program'') and replace the rule text, which is described below, and to replace references to ''Penny Pilot'' in the Exchange rules with ''Penny Interval Program.''

Penny Interval Program

The Exchange proposes to codify the OLPP Program in new Rule 7260 (Requirements for Penny Interval Program) (the ''Penny Program''), which will replace the Penny Pilot Program and permanently permit the Exchange to quote certain option classes in minimum increments of one cents ($0.01) and five cents ($0.05)(''penny increments''). The penny increments that currently apply under the Penny Pilot will continue to apply for option classes included in the Penny Program. Specifically, (i) the minimum quoting increment for all series in the QQQ, SPY, and IWM would continue to be $0.01, regardless of price; [8] (ii) all series of an option class included in the Penny Program with a price of less than $3.00 would be quoted in $0.01 increments; and (iii) all series of an option class included in the Penny Program with a price of $3.00 or higher would be quoted in $0.05 increments.

The Penny Program would initially apply to the 363 most actively traded multiply listed option classes, based on National Cleared Volume at The Options Clearing Corporation (''OCC'') in the six full calendar months ending in the month of approval (*i.e.,* November 2019–April 2020) that currently quote in penny increments, or overlie securities priced below $200, or any index at an index level below $200. Eligibility for inclusion in the Penny Program will be determined at the close of trading on the monthly Expiration Friday of the second full month following April 1, 2020 (*i.e.,* June 19, 2020).

Once in the Penny Program, an option class will remain included until it is no longer among the 425 most actively traded option classes at the time the annual review is conducted (described below), at which point it will be removed from the Penny Program. As described in more detail below, the removed class will be replaced by the next most actively traded multiply listed option class overlying securities priced below $200 per share, or any index at an index level below $200, and not yet in the Penny Program. Advanced notice regarding the option classes included, added, or removed from the Penny Program will be provided to the Exchange's Participants via Regulatory Circular and published by the Exchange on its website.

Annual Review

The Penny Program would include an annual review process that applies objective criteria to determine option classes to be added to, or removed from, the Penny Program. Specifically, on an annual basis beginning in December 2020 and occurring every December thereafter, the Exchange will review and rank all multiply listed option classes based on National Cleared Volume at OCC for the six full calendar months from June 1st through November 30th for determination of the most actively traded option classes. Any option classes not yet in the Penny Program may be added to the Penny Program if the class is among the 300 most actively traded multiply listed option classes and priced below $200 per share or any index at an index level below $200.

Following the annual review, option classes to be added to the Penny Program would begin quoting in penny increments (*i.e.,* $0.01 if trading at less than $3; and $0.05 if trading at $3 and above) on the first trading day of January.[9] In addition, following the annual review, any option class in the Penny Program that falls outside of the 425 most actively traded option classes would be removed from the Penny Program. After the annual review, option classes that are removed from the Penny Program will be subject to the minimum trading increments set forth in Rule 7050, effective on the first trading day of April.

Changes to the Composition of the Penny Program Outside of the Annual Review

Newly Listed Option Classes and Option Classes With Significant Growth in Activity

The Penny Program would specify a process and parameters for including option classes in the Program outside the annual review process in two circumstances. These provisions are designed to provide objective criteria to add to the Penny Program new option classes in issues with the most demonstrated trading interest from market participants and investors on an expedited basis prior to the annual review, with the benefit that market participants and investors will then be able to trade these new option classes based upon quotes expressed in finer trading increments.

First, the Penny Program provides for certain newly listed option classes to be added to the Penny Program outside of the annual review process, provided that (i) the class is among the 300 most actively traded, multiply listed option classes, as ranked by National Cleared Volume at OCC, in its first full calendar month of trading; and (ii) the underlying security is priced below $200 or the underlying index is at an index level below $200. Such newly listed option classes added to the Penny Program pursuant to this process would remain in the Penny Program for one full calendar year and then would be subject to the annual review process.

Second, the Penny Program would allow an option class to be added to the Penny Program outside of the annual review process if it is an option class that meets certain specific criteria. Specifically, new option classes may be added to the Penny Program if: (i) the option class is among the 75 most actively traded multiply listed option classes, as ranked by National Cleared Volume at OCC, in the prior six full calendar months of trading and (ii) the underlying security is priced below $200 or the underlying index is at an index level below $200. Any option class added under this provision will be added on the first trading day of the second full month after it qualifies and will remain in the Penny Program for the rest of the calendar year, after which it will be subject to the annual review process.

Corporate Actions

The Penny Program would also specify a process to address option classes in the Penny Program that undergo a corporate action and is designed to ensure continuous liquidity in the affected option classes. Specifically, if a corporate action involves one or more option classes in the Penny Program, all adjusted and unadjusted series of an option class would continue to be included in the Penny Program.[10] Furthermore, neither the trading volume threshold, nor the initial price test would apply to option classes added to the Penny Program as a result of the corporate action. Finally,

[8] *See* Rule 7050(a)(3)(A)–(C).

[9] *See id.* (providing that the minimum quoting increment for all series in the QQQ, SPY, and IWM would continue to be $0.01, regardless of price).

[10] For example, if Company A acquires Company B and Company A is not in the Penny Program but Company B is in the Penny Program, once the merger is consummated and an options contract adjustment is effective, then Company A would be added to the Penny Program and remain in the Penny Program for one calendar year.

the newly added adjusted and unadjusted series of the option class would remain in the Penny Program for one full calendar year and then would become subject to the annual review process.

Delisted or Ineligible Option Classes

Finally, the Penny Program would provide a mechanism to address option classes that have been delisted or those that are no longer eligible for listing. Specifically, any series in an option class participating in the Penny Program in which the underlying has been delisted, or is identified by OCC as ineligible for opening customer transactions, would continue to quote pursuant to the terms of the Penny Program until all options series have expired.

Technical Changes

The Exchange proposes to replace reference to the Penny Pilot with reference to the Penny Interval Program in Rules 7050(a), IM–7620–1, and IM–5050–10. The Exchange believes these technical changes would add clarity, transparency and internal consistency to Exchange rules making them easier to navigate.

Implementation

The Exchange proposes to implement the Penny Program on July 1, 2020, which is the first trading day of the third month following the Approval Order issued on April 1, 2020—*i.e.,* July 1, 2020. While the rule changes pursuant to this proposal will be effective upon filing, the changes will not become operative until July 1, 2020.

2. Statutory Basis

The Exchange believes that the proposal is consistent with the requirements of Section 6(b) of the Securities Exchange Act of 1934 (the ''Act''),[11] in general, and Section 6(b)(5) of the Act,[12] in particular, in that 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 facilitating transactions in securities, to remove impediments to and perfect the mechanism of a free and open market and a national market system, and, in general to protect investors and the public interest. In particular, the proposed rule change, which conforms the Exchange rules to the recently adopted OLPP Program, allows the Exchange to provide market participants with a permanent Penny Program for quoting options in penny increments, which maximizes the benefit of quoting in a finer quoting increment to investors while minimizing the burden that a finer quoting increment places on quote traffic.

Accordingly, the Exchange believes that the proposal is consistent with the Act because, in conforming the Exchange rules to the OLPP Program, the Penny Program would employ processes, based upon objective criteria, that would rebalance the composition of the Penny Program, thereby helping to ensure that the most actively traded option classes are included in the Penny Program, which helps facilitate the maintenance of a fair and orderly market.

Technical Changes

The Exchange notes that the proposed change to Rules 7050(a), IM–7620–1, and IM–5050–10 to replace references to the Penny Pilot with references to the Penny Interval Program would provide clarity and transparency to the Exchange rules and would promote just and equitable principles of trade and remove impediments to, and perfect the mechanism of, a free and open market and a national market system. The proposed rule changes would also provide internal consistency within Exchange rules and operate to protect investors and the investing public by making the Exchange rules easier to navigate and comprehend.

B. Self-Regulatory Organization's Statement on Burden on Competition

The Exchange does not believe that the proposed rule change will impose any burden on competition not necessary or appropriate in furtherance of the purposes of the Act. The proposed Penny Program, which modifies the exchange's rules to align them with the Commission approved OLPP Program, is not designed to be a competitive filing nor does it impose an undue burden on intermarket competition as the Exchange anticipates that the options exchanges will adopt substantially identical rules. Moreover, the Exchange believes that by conforming Exchange rules to the OLPP Program, the Exchange would promote regulatory clarity and consistency, thereby reducing burdens on the marketplace and facilitating investor protection. To the extent that there is a competitive burden on those option classes that do not qualify for the Penny Program, the Exchange believes that it is appropriate because the proposal should benefit all market participants and investors by maximizing the benefit of a finer quoting increment in those option classes with the most trading interest while minimizing the burden of greater quote traffic in option classes with less trading interest. The Exchange believes that adopting rules, which it anticipates will likewise be adopted by all option exchanges that are participants in the OLPP, would allow for continued competition between Exchange market participants trading similar products as their counterparts on other exchanges, while at the same time allowing the Exchange to continue to compete for order flow with other exchanges.

C. Self-Regulatory Organization's Statement on Comments on the Proposed Rule Change Received From Members, Participants, or Others

The Exchange has neither solicited nor received comments on the proposed rule change.

III. Date of Effectiveness of the Proposed Rule Change and Timing for Commission Action

The Exchange has filed the proposed rule change pursuant to Section 19(b)(3)(A)(iii) of the Act[13] and Rule 19b–4(f)(6) thereunder.[14] Because the proposed rule change does not: (i) Significantly affect the protection of investors or the public interest; (ii) impose any significant burden on competition; and (iii) become operative prior to 30 days from the date on which it was filed, or such shorter time as the Commission may designate, if consistent with the protection of investors and the public interest, the proposed rule change has become effective pursuant to Section 19(b)(3)(A) of the Act and Rule 19b–4(f)(6)(iii) thereunder.[15]

At any time within 60 days of the filing of such proposed rule change, the Commission summarily may temporarily suspend such rule change if it appears to the Commission that such action is necessary or appropriate in the public interest, for the protection of investors, or otherwise in furtherance of the purposes of the Act. If the Commission takes such action, the Commission shall institute proceedings under Section 19(b)(2)(B)[16] of the Act to

[11] 15 U.S.C. 78f(b).

[12] 15 U.S.C. 78f(b)(5).

[13] 15 U.S.C. 78s(b)(3)(A)(iii).

[14] 17 CFR 240.19b–4(f)(6).

[15] 15 U.S.C. 78s(b)(3)(A)(iii). 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 at least five business days prior to the date of filing of the proposed rule change, or such shorter time as designated by the Commission. The Commission notes that the Exchange satisfied this requirement.

[16] 15 U.S.C. 78s(b)(2)(B).

determine whether the proposed rule change should be approved or disapproved.

IV. Solicitation of Comments

Interested persons are invited to submit written data, views, and arguments concerning the foregoing, including whether the proposed rule change is consistent with the Act. Comments may be submitted by any of the following methods:

Electronic Comments

- Use the Commission's internet comment form (*http://www.sec.gov/rules/sro.shtml*); or
- Send an email to *rule-comments@sec.gov.* Please include File Number SR–BOX–2020–17 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–BOX–2020–17. 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–BOX–2020–17 and should be submitted on or before June 23, 2020.

For the Commission, by the Division of Trading and Markets, pursuant to delegated authority.[17]

J. Matthew DeLesDernier,

Assistant Secretary.

[FR Doc. 2020–11783 Filed 6–1–20; 8:45 am]

BILLING CODE 8011–01–P

SMALL BUSINESS ADMINISTRATION

[Disaster Declaration #16471 and #16472; Alabama Disaster Number AL–00106]

Presidential Declaration of a Major Disaster for Public Assistance Only for the State of Alabama

AGENCY: U.S. Small Business Administration.

ACTION: Notice.

SUMMARY: This is a Notice of the Presidential declaration of a major disaster for Public Assistance Only for the State of Alabama (FEMA–4546–DR), dated 05/21/2020.

Incident: Severe Storms and Flooding.

Incident Period: 02/05/2020 through 03/06/2020.

DATES: Issued on 05/21/2020.

Physical Loan Application Deadline Date: 07/20/2020.

Economic Injury (EIDL) Loan Application Deadline Date: 02/22/2021.

ADDRESSES: Submit completed loan applications to: U.S. Small Business Administration, Processing and Disbursement Center, 14925 Kingsport Road, Fort Worth, TX 76155.

FOR FURTHER INFORMATION CONTACT: A. Escobar, Office of Disaster Assistance, U.S. Small Business Administration, 409 3rd Street SW, Suite 6050, Washington, DC 20416, (202) 205–6734.

SUPPLEMENTARY INFORMATION: Notice is hereby given that as a result of the President's major disaster declaration on 05/21/2020, Private Non-Profit organizations that provide essential services of a governmental nature may file disaster loan applications at the address listed above or other locally announced locations.

The following areas have been determined to be adversely affected by the disaster:

Primary Counties: Butler, Chambers, Choctaw, Colbert, Covington, Crenshaw, Cullman, Dallas, Fayette, Greene, Lamar, Limestone, Macon, Marion, Perry, Randolph, Tuscaloosa, Wilcox

The Interest Rates are:

	Percent
For Physical Damage:	
Non-Profit Organizations With Credit Available Elsewhere ...	2.750
Non-Profit Organizations Without Credit Available Elsewhere ...	2.750
For Economic Injury:	
Non-Profit Organizations Without Credit Available Elsewhere ...	2.750

The number assigned to this disaster for physical damage is 164716 and for economic injury is 164720.

(Catalog of Federal Domestic Assistance Number 59008)

Cynthia Pitts,

Acting Associate Administrator for Disaster Assistance.

[FR Doc. 2020–11767 Filed 6–1–20; 8:45 am]

BILLING CODE 8026–03–P

DEPARTMENT OF STATE

[Public Notice 11131]

Determination and Certification of Countries Not Cooperating Fully With Antiterrorism Efforts

Pursuant to section 40A of the Arms Export Control Act (22 U.S.C. 2781), and Executive Order 13637, as amended, I hereby determine and certify to the Congress the following countries are no cooperating fully with United States antiterrorism efforts: Iran, Democratic People's Republic of Korea (DPRK, or North Korea), Syria, Venezuela, and Cuba.

This determination and certification shall be transmitted to the Congress and published in the **Federal Register.**

Dated: May 11, 2020.

Michael R. Pompeo,

Secretary of State.

[FR Doc. 2020–11858 Filed 6–1–20; 8:45 am]

BILLING CODE 4710–AD–P

DEPARTMENT OF STATE

[Public Notice 11122]

30-Day Notice of Proposed Information Collection: Public Charge Questionnaire

ACTION: Notice of request for public comment and submission to OMB of proposed collection of information.

SUMMARY: The Department of State (''Department'') is seeking Office of Management and Budget (''OMB'') approval for the information collection described below. In accordance with the Paperwork Reduction Act of 1995 and

[17] 17 CFR 200.30–3(a)(12).

OMB procedures, we are requesting comments on this collection from all interested individuals and organizations. The purpose of this notice is to allow 30 days for public comment preceding submission of the collection to OMB.

DATES: Submit comments up to July 2, 2020.

ADDRESSES: Written comments and recommendations for the proposed information collection should be sent within 30 days of publication of this notice to *www.reginfo.gov/public/do/PRAMain.* Find this particular information collection by selecting ''Currently under 30-day Review—Open for Public Comments'' or by using the search function.

FOR FURTHER INFORMATION CONTACT: Direct requests for additional information regarding the collection listed in this notice may be submitted to Taylor Beaumont, who may be reached over telephone at (202) 485–7586 or email at *PRA_BurdenComments@state.gov.*

SUPPLEMENTARY INFORMATION: The Department published a ''Notice of Intent to Request Emergency Processing of Information Collection: Public Charge Questionnaire'' (''DS–5540''), notifying the public of the Department's intent to seek emergency processing of the DS–5540 on February 12, 2020. 85 FR 8087. Consistent with the Paperwork Reduction Act of 1995 (''PRA'') and OMB procedures, the Department requested approval after emergency processing of the DS–5540. On October 24, 2019, the Department had published a Notice of Request for Public Comment for the DS–5540, initiating a 60-day period for the public to submit comments on the information collection. 84 FR 5712. The 60-day comment period ended on December 23, 2019, and the Department received 92 comments. On February 12, in the Supporting Statement for the Department's request for OMB emergency processing and approval of the DS–5540, the Department responded to public comments received during the 60-day comment period, as well as comments received in response to the emergency notice for the separate DS–5541, Immigrant Health Insurance Coverage (''DS–5541'') (84 FR 58199) that are pertinent to the DS–5540. On February 20, 2020, OMB approved the DS–5540, based on emergency processing. While the Department is currently enjoined from implementing Presidential Proclamation 9945 and therefore cannot utilize the DS–5541, *see* Doe v. Trump, 418 F. Supp. 3d 573 (D. Or. 2019), the health-insurance related questions in the DS–5540 are also relevant for the purposes of making a public-charge assessment.[1] The Department is completing the ongoing PRA process for three-year approval of the DS–5540, because the approval based on emergency processing under the PRA expires August 31, 2020.

- *Title of Information Collection:* Public Charge Questionnaire.
- *OMB Control Number:* 1405–0234.
- *Type of Request:* Extension of a Previously Approved Collection.
- *Originating Office:* Bureau of Consular Affairs, Visa Office (CA/VO).
- *Form Number:* DS–5540.
- *Respondents:* Immigrant visa applicants, including diversity visa applicants, and certain nonimmigrant visa applicants.
- *Estimated Number of Respondents:* 397,814.
- *Estimated Number of Responses:* 397,814.
- *Average Time Per Response:* 4.5 hours.
- *Total Estimated Burden Time:* 1,790,163 hours.
- *Frequency:* Once per respondent's application.
- *Obligation to respond:* Required to Obtain or Retain a Benefit.

We are soliciting public comments that assist the Department in:

- Evaluating whether the proposed information collection is necessary for the proper functions of the Department;
- Evaluating the accuracy of our estimate of the time and cost burden of this proposed collection, including the validity of the methodology and assumptions used;
- Enhancing the quality, utility, and clarity of the information to be collected; and,
- Minimizing the reporting burden on those who are to respond, including the use of automated collection techniques or other forms of information technology.

Please note that comments submitted in response to this Notice are public record. Before including any detailed personal information, you should be aware that your comments as submitted, including your personal information, will be available for public review.

Abstract of Proposed Collection

Aliens who seek a visa, application for admission, or adjustment of status must establish that they are not likely at any time after admission to become a public charge, unless Congress has expressly exempted them from this ground of ineligibility or if the alien obtained a waiver. Consular officers will use completed DS–5540 forms to assess whether an alien is more likely than not to become a public charge, and consequently, whether the alien is ineligible for a visa under section 212(a)(4)(A) of the Immigration and Nationality Act (''INA''), 8 U.S.C. 1182(a)(4), and 22 CFR 40.41. This collection will assist applicants in meeting the burden of proof on aliens under section 291 of the INA, 8 U.S.C. 1361, to establish that they are eligible to receive a visa, including that they are not inadmissible under any provision of the INA. This information collection is consistent with the statutory requirement in section 212(a)(4)(B), 8 U.S.C. 1182(a)(4)(B), and regulatory requirement in 22 CFR 40.41, that consular officers must consider an alien's age; health; family status; assets, resources, and financial status; and education and skills in determining whether a visa applicant is more likely than not to become a public charge. The Department published an interim final rule amending 22 CFR 40.41 on October 11, 2019, to incorporate new standards for assessing eligibility on public charge grounds. The interim final rule invited public comment for 30 days. 84 FR 54996. The Department will separately address public comments to the interim final rule in the publication of the final rule. The DS–5540 collects information relating to the visa applicant's age; health; family status; assets, resources, and financial status; and education and skills. The DS–5540 also will require visa applicants to provide information on whether they have received certain specified public benefits from a U.S. federal, state, territorial, or local government entity.

Among the purposes of the public charge ground of inadmissibility is to ensure that aliens entering the United States are self-sufficient and will not rely on public resources to meet their needs, but rather, will rely on their own capabilities, as well as the resources of sponsors. Through the DS–5540, as approved on an emergency basis, the Department collects information in a standardized format regarding applicants' ability to financially support themselves following entry into the United States, without depending on government assistance. Fields in the DS–5540 primarily pertain to the applicant's health; family status; assets, resources, and financial status; education and skills; health insurance coverage; and tax history. The DS–5540 also requires applicants to provide

[1] The government is also challenging the injunction of the Proclamation before the Ninth Circuit and is awaiting a ruling. See Doe v. Trump, No. 19–36020 (9th Cir.).

information on whether they have received certain specified public benefits from a U.S. Federal, state, local or tribal government entity on or after February 24, 2020. Consular officers use the completed forms in assessing whether an applicant is likely to become a public charge, and is thus ineligible for a visa under section 212(a)(4)(A) of the INA. This collection will assist applicants in meeting the burden of proof on applicants under section 291 of the INA to establish that they are eligible to receive a visa, including that they are not inadmissible under any provision of the INA.

Sponsors of immigrant visa applicants must currently provide information regarding their ability to financially support the applicant on the I–864, Affidavit of Support, which consular officers use in considering whether the applicant is likely to depend on certain forms of government assistance. Visa applicants provide limited optional input on the I–864 regarding their assets. The DS–5540 collects more detailed information on an applicant's ability to support himself or herself. Consular officers use the information to assess whether the applicant is likely to become a public charge, based on the totality of the circumstances.

Applicants for immigrant visas, including diversity visas, are required to complete the DS–5540, except for categories of applicants that are exempt from the public charge ground of inadmissibility. The exempted categories are listed in 8 CFR 212.23(a). Exempted categories include applicants seeking immigrant visas based on qualified service to the U.S. government as an interpreter in Afghanistan or Iraq, visas based on a self-petition under the Violence Against Women Act, and visas for special immigrant juveniles. Additionally, a consular officer has discretion to require a nonimmigrant visa applicant to complete the DS–5540, when the officer determines the information is needed, for example, if the officer is not satisfied, based on other available information, that the applicant would be self-sufficient during his or her period of stay. In the 60-day notice, the Department explained that a consular officer could also request any immigrant visa applicant not subject to public charge, but subject to *The Presidential Proclamation on the Suspension of Entry of Immigrants Who Will Financially Burden the United States Healthcare System* (''Presidential Proclamation 9945'') (Oct. 4, 2019), to complete questions 4 and 4A from Form DS–5540 to establish that the applicant will be covered by an approved health insurance plan within 30 days of entry into the United States, or that the applicant possesses sufficient financial resources to cover reasonably foreseeable medical costs. As noted above, the Proclamation is currently enjoined, but the Department has retained those questions in the DS–5540 because they are also relevant for making a public charge assessment. As long as the injunction exists, officers will be instructed that they can rely on the answers to these questions only to the extent that it is relevant to the public charge assessment and not to implement Presidential Proclamation 9945.

Ongoing PRA Process

On October 24, 2019, the Department published a notice in the **Federal Register** to announce that it was seeking OMB approval of the DS–5540, and invited public comment for a 60-day period. The 60-day comment period ended on December 23, 2019, and the Department received 92 comments. The Department's responses to those comments are in the associated Supporting Statement for this notice.

On February 12, 2020, the Department published a notice of intent to request emergency processing and OMB approval in the **Federal Register** for the DS–5540, because the Department needed to align its standards with those that the Department of Homeland Security (''DHS'') was set to implement on February 24, 2020. The Department of Homeland Security announced that it would begin implementation of its final rule on the public charge ground of inadmissibility on February 24, 2020. Following conclusion of the 60-day public comment period for the DS–5540, there was insufficient time for the Department to complete the ongoing process for OMB approval of the DS–5540 under standard procedures pursuant to 5 CFR 1320 prior to February 24, 2020. OMB granted emergency processing and approval of the DS–5540 pursuant to 5 CFR 1320.13 in order for the DS–5540 to be used by consular officers beginning 12:01 a.m. Eastern Standard Time February 24, 2020. OMB granted approval for six months, until August 31, 2020. On March 9, 2020, the Department published a second notice in the **Federal Register** announcing approval of the DS–5540 to the public.

The Department now seeks three-year approval of the DS–5540 to ensure continued alignment of the Department's standards with those of DHS, to avoid situations where a consular officer will evaluate a visa applicant's circumstances and conclude that the applicant is not likely at any time to become a public charge, only to have a DHS officer subsequently evaluate the same individual under the same facts and find the individual inadmissible on public charge grounds when he or she seeks admission to the United States.

Methodology

The DS–5540 will be available online in fillable PDF format. Immigrant visa applicants will download the completed form and then upload and submit the completed DS–5540 and other supporting documentation as a part of their immigrant visa application through the Consular Electronic Application Center (CEAC). Nonimmigrant visa applicants who are required to submit this form will be able to do so via email or in hard copy.

Carl C. Risch,

Assistant Secretary, Bureau of Consular Affairs, Department of State.

[FR Doc. 2020–11889 Filed 6–1–20; 8:45 am]

BILLING CODE 4710–06–P

TENNESSEE VALLEY AUTHORITY

Webinar Meeting of the Regional Energy Resource Council

AGENCY: Tennessee Valley Authority (TVA).

ACTION: Notice of meeting.

SUMMARY: The TVA Regional Energy Resource Council (RERC) has scheduled a webinar meeting to discuss the impacts of the COVID 19 pandemic on the TVA energy system. The RERC was established to advise TVA on its energy resource activities and the priority to be placed among competing objectives and values. Notice of this webinar meeting is given under the Federal Advisory Committee Act (FACA).

DATES: The webinar meeting will be held on Tuesday, June 23, 2020, from 10:30 a.m. to 2:15 p.m., EDT. There will be a break in the webinar between the hours of 12:00 p.m. and 1:00 p.m. EDT.

ADDRESSES: The meeting will be conducted by webinar only. An Individual requiring special accommodation for a disability should let the contact below know at least a week in advance.

FOR FURTHER INFORMATION CONTACT: Liz Upchurch, *efupchurch@tva.gov,* 865–632–8305.

SUPPLEMENTARY INFORMATION:

The meeting agenda includes the following:

1. Introductions and Webinar Logistics
2. Remarks of RERC Chair

3. Remarks of RERC Designated Federal Officer
4. Overview of the impacts of COVID 19 on the TVA Energy System
5. Council Discussion
6. Public Comments

The webinar meeting is open to the public. Please register in advance at: *https://bit.ly/2ZwlVoK.* Oral comments from the public will be accepted during a 30-minute webinar session beginning at 1:00 p.m. EDT. In order to make oral comments, the public must pre-register by 5:00 p.m. EDT on Monday June 22, 2020 by emailing *efupchurch@tva.gov.* Due to time limitations, oral comments will be limited to two minutes per speaker. The public is also invited to provide written comments to the RERC at any time through links on TVA's website at *www.tva.com/rerc* or by emailing written comments to the Regional Energy Resource Council, care of Liz Upchurch, *efupchurch@tva.gov.*

Dated: May 26, 2020.

Joseph J. Hoagland,

Vice President, Innovation and Research, Tennessee Valley Authority.

[FR Doc. 2020–11890 Filed 6–1–20; 8:45 am]

BILLING CODE 8120–08–P

OFFICE OF THE UNITED STATES TRADE REPRESENTATIVE

Notice of Product Exclusion Extensions: China's Acts, Policies, and Practices Related to Technology Transfer, Intellectual Property, and Innovation

AGENCY: Office of the United States Trade Representative.

ACTION: Notice of product exclusion extensions.

SUMMARY: Effective July 6, 2018, the U.S. Trade Representative imposed additional duties on goods of China with an annual trade value of approximately $34 billion as part of the action in the Section 301 investigation of China's acts, policies, and practices related to technology transfer, intellectual property, and innovation. The U.S. Trade Representative initiated the exclusion process in July 2018 and to date, has granted 10 sets of exclusions under the $34 billion action. The fifth set of exclusions was published in June 2019 and will expire in June 2020. On March 20, 2020, the U.S. Trade Representative established a process for the public to comment on whether to extend particular exclusions granted in June 2019 for up to 12 months. This notice announces the U.S. Trade Representative's determination to extend certain exclusions through December 31, 2020.

DATES: The product exclusion extensions announced in this notice will apply as of June 4, 2020, and extend through December 31, 2020. U.S. Customs and Border Protection will issue instructions on entry guidance and implementation.

FOR FURTHER INFORMATION CONTACT: For general questions about this notice, contact Assistant General Counsels Philip Butler or Benjamin Allen, or Director of Industrial Goods Justin Hoffmann at (202) 395–5725. For specific questions on customs classification or implementation of the product exclusions identified in the Annex to this notice, contact *traderemedy@cbp.dhs.gov.*

SUPPLEMENTARY INFORMATION:

A. Background

For background on the proceedings in this investigation, please see prior notices including: 82 FR 40213 (August 23, 2017), 83 FR 14906 (April 6, 2018), 83 FR 28710 (June 20, 2018), 83 FR 32181 (July 11, 2018), 83 FR 67463 (December 28, 2018), 84 FR 11152 (March 25, 2019), 84 FR 16310 (April 18, 2019), 84 FR 21389 (May 14, 2019), 84 FR 25895 (June 4, 2019), 84 FR 32821 (July 9, 2019), 84 FR 43304 (August 20, 2019), 84 FR 46212 (September 3, 2019), 84 FR 49564 (September 20, 2019), 84 FR 52567 (October 2, 2019), 84 FR 58427 (October 31, 2019), 84 FR 70616 (December 23, 2019), 84 FR 72102 (December 30, 2019), 85 FR 6687 (February 5, 2020), 85 FR 12373 (March 2, 2020), 85 FR 16181 (March 20, 2020), and 85 FR 24081 (April 30, 2020).

Effective July 6, 2018, the U.S. Trade Representative imposed additional 25 percent duties on goods of China classified in 818 eight-digit subheadings of the Harmonized Tariff Schedule of the United States (HTSUS), with an approximate annual trade value of $34 billion. *See* 83 FR 28710 (the $34 billion action). The U.S. Trade Representative's determination included a decision to establish a process by which U.S. stakeholders could request exclusion of particular products classified within an eight-digit HTSUS subheading covered by the $34 billion action from the additional duties. The U.S. Trade Representative issued a notice setting out the process for the product exclusions and opened a public docket. *See* 83 FR 32181 (the July 11 notice).

In June 2019, the U.S. Trade Representative granted a set of exclusion requests, which expire on June 4, 2020. *See* 84 FR 25895 (the June 4 notice). On March 20, 2020, the U.S. Trade Representative invited the public to comment on whether to extend by up to 12 months, particular exclusions granted in the June 4 notice. *See* 85 FR 16181 (the March 20 notice).

Under the March 20 notice, commenters were asked to address whether the particular product and/or a comparable product is available from sources in the United States and/or in third countries; any changes in the global supply chain since July 2018 with respect to the particular product, or any other relevant industry developments; and efforts, if any, importers or U.S. purchasers have undertaken since July 2018 to source the product from the United States or third countries.

In addition, commenters who were importers and/or purchasers of the products covered by an exclusion were asked to provide information regarding their efforts since July 2018 to source the product from the United States or third countries; the value and quantity of the Chinese-origin product covered by the specific exclusion request purchased in 2018, the first half of 2018, and the first half of 2019, and whether these purchases are from a related company; whether Chinese suppliers have lowered their prices for products covered by the exclusion following the imposition of duties; the value and quantity of the product covered by the exclusion purchased from domestic and third country sources in 2018, the first half of 2018 and the first half of 2019; the commenter's gross revenue for 2018, the first half of 2018, and the first half of 2019; whether the Chinese-origin product of concern is sold as a final product or as an input; whether the imposition of duties on the products covered by the exclusion will result in severe economic harm to the commenter or other U.S. interests; and any additional information in support or in opposition of the extending the exclusion.

The March 20 notice required the submission of comments no later than April 30, 2020.

B. Determination To Extend Certain Exclusions

Based on evaluation of the factors set out in the July 11 notice and March 20 notice, which are summarized above, pursuant to sections 301(b), 301(c), and 307(a) of the Trade Act of 1974, as amended, and in accordance with the advice of the interagency Section 301 Committee, the U.S. Trade Representative has determined to extend certain product exclusions covered by the June 4 notice, as set out in the Annex to this notice.

The March 20 notice provided that the U.S. Trade Representative would consider extensions of up to 12 months. In light of the cumulative effect of current and possible future exclusions or extensions of exclusions on the effectiveness of the action taken in this investigation, the U.S. Trade Representative has determined to extend the exclusions in the Annex to this notice for less than 12 months—through December 31, 2020. To date, the U.S. Trade Representative has granted more than 6,200 exclusion requests, has extended some of these exclusions, and may consider further extensions of exclusions. Furthermore, more than 8,600 requests are pending on the products covered by the action taken on August 20, 2019. The U.S. Trade Representative will take account of the cumulative effect of exclusions in considering the possible further extension of the exclusions covered by this notice, as well as possible extensions of exclusions of other products covered by the action in this investigation. The U.S. Trade Representative's determination also takes into account advice from advisory committees and any public comments concerning extension of the pertinent exclusion.

In accordance with the July 11 notice, the exclusions are available for any product that meets the description in the Annex, regardless of whether the importer filed an exclusion request. Further, the scope of each exclusion is governed by the scope of the ten-digit HTSUS headings and product descriptions in the Annex to this notice, and not by the product descriptions set out in any particular request for exclusion.

As set out in the Annex, the U.S. Trade Representative has determined to extend, through December 31, 2020, the following exclusions granted under the June 4, 2019 notice under heading 9903.88.10 and under U.S. note 20(m) to subchapter III of chapter 99 of the HTSUS: (3), (6), (9), (13), (14), (22), (24), (28), (34), (42), (50), (51), (52), (53), (62), and (88).

Joseph Barloon,

General Counsel, Office of the United States Trade Representative.

BILLING CODE 3290–F0–P

ANNEX FOR EXTENSIONS OF CERTAIN PRODUCT EXCLUSIONS FROM THE FIFTH ROUND OF EXCLUSIONS FROM TRANCHE 1

A. Effective with respect to goods entered for consumption, or withdrawn from warehouse for consumption, on or after 12:01 a.m. eastern daylight time on June 4, 2020 and before 11:59 p.m. eastern daylight time on December 31, 2020, subchapter III of chapter 99 of the Harmonized Tariff Schedule of the United States (HTSUS) is modified:

1. by inserting the following new heading 9903.88.50 in numerical sequence, with the material in the new heading inserted in the columns of the HTSUS labeled "Heading/Subheading", "Article Description", and "Rates of Duty 1-General", respectively:

Heading/ Subheading	Article Description	Rates of Duty		
		1		2
		General	Special	
"9903.88.50	Effective with respect to entries on or after June 4, 2020, and through December 31, 2020, articles the product of China, as provided for in U.S. note 20(ccc) to this subchapter, each covered by an exclusion granted by the U.S. Trade Representative	The duty provided in the applicable subheading"		

2. by inserting the following new U.S. note 20(ccc) to subchapter III of chapter 99 in numerical sequence:

"(ccc) The U.S. Trade Representative determined to establish a process by which particular products classified in heading 9903.88.01 and provided for in U.S. notes 20(a) and 20(b) to this subchapter could be excluded from the additional duties imposed by heading 9903.88.01. See 83 Fed. Reg. 28710 (June 20, 2018) and 83 Fed. Reg. 32181 (July 11, 2018). Pursuant to the product exclusion process, the U.S. Trade Representative has determined that, as provided in heading 9903.88.50, the additional duties provided for in heading 9903.88.01 shall not apply to the following particular products, which are provided for in the enumerated statistical reporting numbers:

(1) Oil well and oil field crank-balanced, long-stroke and beam pumps (described in statistical reporting number 8413.50.0010)
(2) Centrifugal pumps, submersible, other than for use with machines for making cellulosic pulp, paper or paperboard; the foregoing pumps rated not over 15 kW (described in statistical reporting number 8413.70.2004)
(3) Submersible pump incorporating a magnetic drive motor (described in statistical reporting number 8413.70.2004)

(4) Centrifugal pumps designed for eliminating condensate, the foregoing not elsewhere specified or included (described in statistical reporting number 8413.70.2090)
(5) Housings for water pumps of subheading 8413.30.90 (described in statistical reporting number 8413.91.9010)
(6) Solar water heaters incorporating glass tube heat collectors and including glass tubes and stands with tanks (described in statistical reporting number 8419.19.0040)
(7) Heat exchanger plates, cores, finned tubes, cones, shells, bonnets, flanges and baffles (described in statistical reporting number 8419.90.3000)
(8) Garage door opener/closers (described in statistical reporting number 8428.90.0290)
(9) Pile drivers, diesel powered (described in statistical reporting number 8430.10.0000)
(10) Welded frames designed to support conveyor rollers (described in statistical reporting number 8431.39.0010)
(11) Coupling covers, including center members, flanged hubs, sleeves and shoes (described in statistical reporting number 8483.90.8010)
(12) AC multi-phase motors, each of an output exceeding 300 kW but not exceeding 310 kW, fitted with pulleys and brakes to raise and lower passenger elevators (described in statistical reporting number 8501.53.8040)
(13) Regenerative speed drive controllers for controlling speed of electric motors for elevators (described in statistical reporting number 8504.40.4000)
(14) Speed drive controllers for electric motors, each such controller measuring 100 mm or more but not over 130 mm in length, 40 mm or more but not over 125 mm in width and 24 mm or more but not over 85 mm in height (described in statistical reporting number 8504.40.4000)
(15) Projector parts (described in statistical reporting number 8529.90.9900)
(16) Disposable surface electrodes for intra-operative neuromonitoring ("IONM") systems, each composed of a surface electrode pad, an insulated wire, and a standard DIN 42802 connector (described in statistical reporting number 9018.19.9560)"

3. by amending the last sentence of the first paragraph of U.S. note 20(a) to subchapter III of chapter 99 by:

a. by deleting "or (8)" and by inserting "(8)" in lieu thereof; and

b. by inserting "; or (9) heading 9903.88.50 and U.S. note 20(ccc) to subchapter III of chapter 99" after the phrase "U.S. note 20(x) to subchapter III of chapter 99", where it appears at the end of the sentence.

4. by amending the first sentence of U.S. note 20(b) to subchapter III of chapter 99 by:

c. by deleting "or (8)" and by inserting "(8)" in lieu thereof; and

d. by inserting "; or (9) heading 9903.88.50 and U.S. note 20(ccc) to subchapter III of chapter 99" after the phrase "U.S. note 20(x) to subchapter III of chapter 99", where it appears at the end of the sentence.

5. by amending the Article Description of heading 9903.88.01:

e. by deleting "9903.88.14, or";

f. by inserting in lieu thereof "9903.88.14,"; and

g. by inserting "or 9903.88.50," after "9903.88.19,".

[FR Doc. 2020–11833 Filed 6–1–20; 8:45 am]
BILLING CODE 3290–F0–C

DEPARTMENT OF TRANSPORTATION

Federal Aviation Administration

[Docket No. FAA–2020–0430]

FAA Advisory Circular 142–1, Standardized Curricula Delivered by Part 142 Training Centers

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

ACTION: Notice of availability of agency guidance.

SUMMARY: This notice announces the availability of FAA Advisory Circular (AC) 142–1, Standardized Curricula Delivered by Part 142 Training Centers. The AC introduces the standardized curriculum concept for training provided by part 142 training centers and describes the associated benefits of this voluntary approach. This AC provides guidance to part 142 training centers on how to obtain approval to deliver a standardized curriculum to part 135 operators, including guidance on how a part 142 training center may qualify its personnel as instructors and check pilots under part 135. This AC also provides guidance on how a part 135 operator may obtain approval to use a standardized curriculum as part of its training program. Voluntary use of standardized curricula for part 135 training promotes safety and increases administrative efficiency for industry. Based on these benefits, the FAA believes that most part 135 training provided by part 142 training centers will occur through standardized curricula after implementation.

DATES: The guidance in AC 142–1 became effective April 27, 2020.

FOR FURTHER INFORMATION CONTACT: Mary Thompson, Flight Standards, Air Transportation Division, Policy Integration Branch (AFS–270), Federal Aviation Administration, 800 Independence Avenue SW, Washington, DC 20591; 404–904–2995, *Mary.Thompson@faa.gov.*

SUPPLEMENTARY INFORMATION: The standardized curriculum concept provides a means to standardize curricula offered by part 142 training centers to part 135 operators. Under the standardized curriculum concept, the Aviation Rulemaking Advisory Committee will use formalized stakeholder input to develop and recommend standardized curricula for each aircraft fleet to the FAA. The FAA will review the recommendations and, if acceptable, publish the standardized curricula at a national level. The standardized curriculum concept aims to provide an efficient means for approving training curricula offered by part 142 training centers while increasing the consistency of training, testing, and checking delivered to part 135 operators. The standardized curriculum concept supports the overarching goals to enhance training and checking and promote safer operational practices and is consistent with applicable regulations. AC 142–1 may be found at *https://www.faa.gov/pilots/training/standardized_curriculum/.*

Issued in Washington, DC.

Robert Carty,

Deputy Executive Director, Flight Standards Service.

[FR Doc. 2020–11894 Filed 6–1–20; 8:45 am]
BILLING CODE 4910–13–P

DEPARTMENT OF TRANSPORTATION

Federal Aviation Administration

[Summary Notice No. PE–2020–31]

Petition for Exemption; Summary of Petition Received; Airlines for America

Correction

In notice document 2020–11288, appearing on page 31850 in the issue of Wednesday, May 27, 2020 make the following correction.

On page 31850, in the first column, in the **DATES** section, ''June 3, 2024'' should read ''June 3, 2020''.

[FR Doc. C1–2020–11288 Filed 5–29–20; 4:15 pm]
BILLING CODE 1300–01–D

DEPARTMENT OF TRANSPORTATION

Federal Motor Carrier Safety Administration

[Docket No. FMCSA–2012–0122; FMCSA–2012–0123; FMCSA–2012–0332; FMCSA–2013–0122; FMCSA–2013–0124; FMCSA–2015–0327; FMCSA–2017–0057; FMCSA–2017–0059]

Qualification of Drivers; Exemption Applications; Hearing

AGENCY: Federal Motor Carrier Safety Administration (FMCSA), DOT.

ACTION: Notice of final disposition.

SUMMARY: FMCSA announces its decision to renew exemptions for 27 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: Each group of renewed exemptions were applicable on the dates stated in the discussions below

and will expire on the dates provided 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 Operations, (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–2012–0122, FMCSA–2012–0123, FMCSA–2012–0332, FMCSA–2013–0122, FMCSA–2013–0124, FMCSA–2015–0327, FMCSA–2017–0057, or FMCSA–2017–0059, 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 Operations 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. To be sure someone is there to help you, please call (202) 366–9317 or (202) 366–9826 before visiting Docket Operations.

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.dottransportation.gov/privacy.*

II. Background

On April 6, 2020, FMCSA published a notice announcing its decision to renew exemptions for 27 individuals from the hearing standard in 49 CFR 391.41(b)(11) to operate a CMV in interstate commerce and requested comments from the public

(85 FR 19218). The public comment period ended on May 6, 2020, and no comments were received.

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 § 391.41(b)(11).

The physical qualification standard for drivers regarding hearing found in § 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).

III. Discussion of Comments

FMCSA received no comments in this proceeding.

IV. Conclusion

Based upon its evaluation of the 27 renewal exemption applications, FMCSA announces its decision to exempt the following drivers from the hearing requirement in § 391.41 (b)(11).

In accordance with 49 U.S.C. 31136(e) and 31315(b), the following groups of drivers received renewed exemptions in the month of April and are discussed below:

As of April 2, 2020, and in accordance with 49 U.S.C. 31136(e) and 31315(b), the following 15 individuals have satisfied the renewal conditions for obtaining an exemption from the hearing requirement in the FMCSRs for interstate CMV drivers (85 FR 19218):

Kathleen Abenchuchan (IA)
Roger Boge (IA)
Johnny Brewer (OH)
Jada Hart (IA)
Sean Hunt (TX)
Paul Klug (IA)
Dayton Lawson, Jr. (MI)
Scott Miller (IA)
Calvin Payne (MD)
Kiley Peterson (IA)
Samuel Sherman (MN)
Darren Talley (NC)
Thomas Warner, II (WA)
Allen Whitener (TX)
Johnny Wu (DE)

The drivers were included in docket number FMCSA–2013–0124, FMCSA–2015–0327, FMCSA–2017–0057, and FMCSA–2017–0059. Their exemptions are applicable as of April 2, 2020, and will expire on April 2, 2022.

As of April 21, 2020, and in accordance with 49 U.S.C. 31136(e) and 31315(b), the following seven individuals have satisfied the renewal conditions for obtaining an exemption from the hearing requirement in the FMCSRs for interstate CMV drivers (85 FR 19218):

Andrew Alcozer (IL)
Roman Landa (CA)
Darren Nordquist (WI)
Jacob Paullin (WI)
Ryan Pope (CA)
Ronald Rutter (CA)
Russell Smith, (OH)

The drivers were included in docket number FMCSA–2012–0122 and FMCSA–2012–0123. Their exemptions are applicable as of April 21, 2020, and will expire on April 21, 2022.

As of April 23, 2020, and in accordance with 49 U.S.C. 31136(e) and 31315(b), the following two individuals have satisfied the renewal conditions for obtaining an exemption from the hearing requirement in the FMCSRs for interstate CMV drivers (85 FR 19218):

Donald Lynch (AR) and Zachary Rietz (TX)

The drivers were included in docket number FMCSA–2012–0332. Their exemptions are applicable as of April 23, 2020, and will expire on April 23, 2022.

As of April 24, 2020, and in accordance with 49 U.S.C. 31136(e) and 31315(b), the following three individuals have satisfied the renewal conditions for obtaining an exemption from the hearing requirement in the FMCSRs for interstate CMV drivers (85 FR 19218):

Kwinton Carpenter (OH); Quinton Murphy (WI); and Andrey Shevchenko (MN)

The drivers were included in docket number FMCSA–2013–0122 and FMCSA–2013–0124. Their exemptions are applicable as of April 24, 2020, and will expire on April 24, 2022.

In accordance with 49 U.S.C. 31315(b), each exemption will be valid for 2 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(b).

Larry W. Minor,

Associate Administrator for Policy.

[FR Doc. 2020–11849 Filed 6–1–20; 8:45 am]

BILLING CODE 4910–EX–P

DEPARTMENT OF TRANSPORTATION

Federal Motor Carrier Safety Administration

[Docket No. FMCSA–1999–6480; FMCSA–2000–8398; FMCSA–2002–11714; FMCSA–2002–12844; FMCSA–2003–15268; FMCSA–2003–16564; FMCSA–2004–19477; FMCSA–2005–23238; FMCSA–2006–23773; FMCSA–2006–24015; FMCSA–2006–24783; FMCSA–2007–0071; FMCSA–2008–0021; FMCSA–2009–0011; FMCSA–2009–0291; FMCSA–2009–0321; FMCSA–2010–0050; FMCSA–2011–0057; FMCSA–2011–0365; FMCSA–2011–0379; FMCSA–2011–0380; FMCSA–2012–0039; FMCSA–2013–0027; FMCSA–2013–0030; FMCSA–2013–0166; FMCSA–2013–0169; FMCSA–2013–0174; FMCSA–2014–0003; FMCSA–2014–0004; FMCSA–2015–0070; FMCSA–2015–0072; FMCSA–2015–0345; FMCSA–2015–0350; FMCSA–2015–0351; FMCSA–2016–0024; FMCSA–2016–0025; FMCSA–2017–0026; FMCSA–2017–0028; FMCSA–2018–0007; FMCSA–2018–0008; FMCSA–2018–0010]

Qualification of Drivers; Exemption Applications; Vision

AGENCY: Federal Motor Carrier Safety Administration (FMCSA), DOT.

ACTION: Notice of final disposition.

SUMMARY: FMCSA announces its decision to renew exemptions for 114 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 requirement 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 provided 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 Operations, (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–1999–6480; FMCSA–2000–8398; FMCSA–2002–11714; FMCSA–2002–12844; FMCSA–2003–15268; FMCSA–2003–16564; FMCSA–2004–19477; FMCSA–2005–23238; FMCSA–2006–23773; FMCSA–2006–24015; FMCSA–2006–24783; FMCSA–2007–0071; FMCSA–2008–0021; FMCSA–2009–0011; FMCSA–2009–0291; FMCSA–2009–0321; FMCSA–2010–0050; FMCSA–2011–0057; FMCSA–2011–0365; FMCSA–2011–0379; FMCSA–2011–0380; FMCSA–2012–0039; FMCSA–2013–0027; FMCSA–2013–0030; FMCSA–2013–0166; FMCSA–2013–0169; FMCSA–2013–0174; FMCSA–2014–0003; FMCSA–2014–0004; FMCSA–2015–0070; FMCSA–2015–0072; FMCSA–2015–0345; FMCSA–2015–0350; FMCSA–2015–0351; FMCSA–2016–0024; FMCSA–2016–0025; FMCSA–2017–0026; FMCSA–2017–0028; FMCSA–2018–0007; FMCSA–2018–0008; FMCSA–2018–0010, 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 Operations 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. To be sure someone is there to help you, please call (202) 366–9317 or (202) 366–9826 before visiting Docket Operations.

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.transportation.gov/privacy.*

II. Background

On April 20, 2020, FMCSA published a notice announcing its decision to renew exemptions for 114 individuals from the vision requirement in 49 CFR 391.41(b)(10) to operate a CMV in interstate commerce and requested comments from the public (85 FR 21919). The public comment period ended on May 20, 2020, and no comments were received.

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 § 391.41(b)(10).

The physical qualification standard for drivers regarding vision found in § 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.

III. Discussion of Comments

FMCSA received no comments in this proceeding.

IV. Conclusion

Based on its evaluation of the 114 renewal exemption applications and comments received, FMCSA confirms its decision to exempt the following drivers from the vision requirement in § 391.41(b)(10).

In accordance with 49 U.S.C. 31136(e) and 31315(b), the following groups of drivers received renewed exemptions in the month of May and are discussed below. As of May 7, 2020, and in accordance with 49 U.S.C. 31136(e) and 31315, the following 35 individuals have satisfied the renewal conditions for obtaining an exemption from the vision requirement in the FMCSRs for interstate CMV drivers (65 FR 78256; 66 FR 16311; 68 FR 13360; 68 FR 37197; 68 FR 48989; 69 FR 64806; 70 FR 2705; 70 FR 25878; 70 FR 42615; 71 FR 5105; 71 FR 6826; 71 FR 19600; 71 FR 19602; 71 FR 32183; 71 FR 41310; 72 FR 1054; 72 FR 28093; 72 FR 40360; 73 FR 6242; 73 FR 11989; 73 FR 16950; 73 FR 60398; 74 FR 26464; 74 FR 34632; 74 FR 49069; 74 FR 65842; 75 FR 1835; 75 FR 9477; 75 FR 9480; 75 FR 9482; 75 FR 13653; 75 FR 22176; 76 FR 18824; 76 FR 29024; 76 FR 34135; 76 FR 62143; 76 FR 70212; 76 FR 78729; 77 FR 3552; 77 FR 10604; 77 FR 13689; 77 FR 13691; 77 FR 17107; 77 FR 17108; 78 FR 24798; 78 FR 34140; 78 FR 41975; 78 FR 46407; 78 FR 56986; 78 FR 62935; 78 FR 64274; 78 FR 76395; 78 FR 77778; 78 FR 77782; 79 FR 1908; 79 FR 2247; 79 FR 14331; 79 FR 14333; 79 FR 17641; 79 FR 17642; 79 FR 17643; 79 FR 18391; 79 FR 24298; 80 FR 26320

80 FR 33009; 80 FR 59225; 80 FR 63839; 80 FR 67476; 80 FR 67481; 80 FR 70060; 80 FR 79414; 80 FR 80443; 81 FR 14190; 81 FR 15401; 81 FR 15404; 81 FR 16265; 81 FR 17237; 81 FR 20433; 81 FR 20435; 81 FR 39100; 81 FR 44680; 81 FR 52516; 81 FR 91239; 82 FR 18949; 82 FR 47312; 83 FR 2311; 83 FR 4537; 83 FR 6681; 83 FR 6919; 83 FR 15195; 83 FR 18648; 83 FR 24146; 83 FR 24151; 83 FR 24571):

David R. Alford (UT)
Bradley T. Alspach (IL)
Otto J. Ammer, Jr. (PA)
Nick D. Bacon (KY)
Terry L. Baker (KY)
Morris R. Beebe II (CO)
James A. Champion (WA)
Loren D. Chapman (MN)
Larry Chinn (WI)
Kevin J. Cobb (PA)
Charles W. Cox (AR)
Walter F. Crean III (CT)
John T. Edmondson (AL)
Kenneth J. Fisk (MI)
Matt A. Guilmain (NH)
Steven W. Halsey (MO)
Volga Kirkwood (MO)
Paul K. Leger (NH)
Spencer E. Leonard (OH)
Juan J. Luna (CA)
Phillip P. Mazza (WI)
Dale A. McCoy (ME)
Cole W. McLaughlin (SD)
John D. Morgan (PA)
Russell L. Moyers, Sr. (WV)
Dakota J. Papsun (PA)
Jose R. Ponce Roman (TX)
Martin L. Reyes (IL)
Steven C. Sheeder (IA)
Robert D. Smith (OH)
Eric Taniguchi (HI)
Hany A. Wagieh (NJ)
Eddie Walker (NC)
Alan T. Watterson (MA)
Kenneth E. Wheland (PA)

The drivers were included in docket numbers FMCSA–2000–8398; FMCSA–2003–15268; FMCSA–2004–19477; FMCSA–2005–23238; FMCSA–2006–23773; FMCSA–2006–24783; FMCSA–2007–0071; FMCSA–2009–0011; FMCSA–2009–0291; FMCSA–2009–0321; FMCSA–2011–0057; FMCSA–2011–0365; FMCSA–2013–0027; FMCSA–2013–0030; FMCSA–2013–0166; FMCSA–2013–0169; FMCSA–2013–0174; FMCSA–2015–0070; FMCSA–2015–0072; FMCSA–2015–0345; FMCSA–2015–0350; FMCSA–2015–0351; FMCSA–2017–0026; and FMCSA–2017–0028. Their exemptions are applicable as of May 7, 2020, and will expire on May 7, 2022.

As of May 10, 2020, and in accordance with 49 U.S.C. 31136(e) and 31315, the following 15 individuals have satisfied the renewal conditions for obtaining an exemption from the vision requirement in the FMCSRs for interstate CMV drivers (83 FR 15214; 83 FR 15216; 83 FR 28323; 83 FR 28328):

Ahmed Abukhatwa (MI)
Jerome DeFabo (PA)
Jason P. Dostal (IN)
John C. Duncan (FL)
Kenneth M. Emerson (ID)
Steven W. Kyman (OR)
Jeffrey T. Landry (NC)
Trent C. McCain (KS)
David M. McCarty (OR)
Ermanno M. Santucci (IL)
Michael B. Sauseda (IL)
Jesse P. Schuster (ND)
Joseph L. Smith (WV)
Justin L. Tidyman (AR)
Timothy L. Tucker (KY)

The drivers were included in docket numbers FMCSA–2018–0007; and FMCSA–2018–0008. Their exemptions are applicable as of May 10, 2020, and will expire on May 10, 2022.

As of May 11, 2020, 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 15184; 77 FR 27850; 79 FR 21996; 81 FR 91239; 83 FR 24146):

Robert L. Brauns (IA)
Clifford W. Doran, Jr. (NC)
Glenn C. Grimm (NJ)
Richard A. Pucker (WI)
John M. Riley (AL)
Jeffery A. Sheets (AR)

The drivers were included in docket numbers FMCSA–2011–0379; and FMCSA–2011–0380. Their exemptions are applicable as of May 11, 2020, and will expire on May 11, 2022.

As of May 12, 2020, 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 (67 FR 68719; 68 FR 2629; 68 FR 74699; 69 FR 10503; 69 FR 71100; 71 FR 6829; 72 FR 1053; 73 FR 11989; 73 FR 15567; 73 FR 27015; 73 FR 76440; 75 FR 19674; 77 FR 23797; 79 FR 23797; 81 FR 91239; 83 FR 24146):

Leo G. Becker (KS)
Stanley W. Davis (TX)
Ray L. Emert (PA)
Neil W. Jennings (MO)
Aaron S. Taylor (WI)

The drivers were included in docket numbers FMCSA–2022–12844; FMCSA–2003–1656; and FMCSA–2008–0021. Their exemptions are applicable as of May 12, 2020, and will expire on May 12, 2022.

As of May 13, 2020, 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 (81 FR 21647; 81 FR 21655; 81 FR 66718; 83 FR 24146):

James T. Curtis (NM)
Mark E. Dow (VT)
Danny R. Floyd (OH)
Bradley K. Linde (IA)
Colby T. Smith (UT)
Carl J. Warnecke (OH)

The drivers were included in docket numbers FMCSA–2016–0024; and FMCSA–2016–0025. Their exemptions are applicable as of May 13, 2020, and will expire on May 13, 2022.

As of May 16, 2020, and in accordance with 49 U.S.C. 31136(e) and 31315, the following 18 individuals have satisfied the renewal conditions for obtaining an exemption from the vision requirement in the FMCSRs for interstate CMV drivers (79 FR 14571; 79 FR 28588; 81 FR 91239; 83 FR 24146):

Luis A. Agudo (MN)
Dmitriy D. Bayda (WA)
Billy D. Devine (WA)
James G. Donze (MO)
Dennis A. Feather (SC)
Robert E. Johnston, Jr. (WA)
David W. Leach (IL)
Jason S. Logue (GA)
David F. Martin (NJ)
Martin L. Mayes (GA)
Daniel A. McNabb, Jr. (KS)
Robert L. Murray (IL)
Bradley W. Reed (AL)
Erik M. Rice (TX)
Tatum R. Schmidt (IA)
Harry J. Scholl (PA)
Jacob A. Shaffer (PA)
James S. Smith (AR)

The drivers were included in docket number FMCSA–2014–0003. Their exemptions are applicable as of May 16, 2020, and will expire on May 16, 2022.

As of May 21, 2020, and in accordance with 49 U.S.C. 31136(e) and 31315, the following three individuals have satisfied the renewal conditions for obtaining an exemption from the vision requirement in the FMCSRs for interstate CMV drivers (75 FR 9480; 75 FR 14656; 75 FR 22176; 75 FR 28684; 77 FR 23800; 79 FR 22000; 81 FR 91239; 83 FR 24146):

Herbert C. Hirsch (MO); Douglas L. Norman (NC); and Wayne J. Savage (VA)

The drivers were included in docket numbers FMCSA–2009–0011; and FMCSA–201–0050. Their exemptions are applicable as of May 21, 2020, and will expire on May 21, 2022.

As of May 22, 2020, 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 (79 FR 18392; 79 FR 29498; 81 FR 91239; 83 FR 24146):

James E. Baker (OH)
Aaron D. Barnett (IA)
James P. Griffin (WA)
Dennis P. Hart (OR)
James D. Kessler (SD)
Rodney J. McMorran (IA)
John L. Meese (MO)
Elmer F. Winters (NC)

The drivers were included in docket number FMCSA–2014–0004. Their exemptions are applicable as of May 22, 2020, and will expire on May 22, 2022.

As of May 25, 2020, 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 (64 FR 68195; 65 FR 20251; 67 FR 17102; 69 FR 17267; 71 FR 14566; 71 FR 16410; 71 FR 30227; 73 FR 27014; 75 FR 27622; 77 FR 20879; 77 FR 26816; 77 FR 31427; 81 FR 91239; 83 FR 24146):

Jose A. Lopez (CT)
Earl E. Martin (VA)
Joseph C. Powell (VA)
David L. Schachle (PA)
Mark Sobczyk (WI)

The drivers were included in docket numbers FMCSA–1999–6480; FMCSA–2006–24015; and FMCSA–2012–0039. Their exemptions are applicable as of May 25, 2020, and will expire on May 25, 2022.

As of May 30, 2020, and in accordance with 49 U.S.C. 31136(e) and 31315, the following 13 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; 71 FR 26602; 73 FR 27017; 75 FR 27621; 77 FR 27849; 81 FR 91239; 83 FR 18644; 83 FR 24146; 83 FR 28342):

Zachary A. Abbotts (CT)
Joseph J. Amatulli (NY)
Joe W. Brewer (SC)
Jimmy L. Burgi (TX)
Gordon C. Canfield (MI)
Tammy J. Duval (NH)
James W. Ellis, 4th (NJ)
Brian K. LaJoie (MI)
James V. Latess (PA)
Kevin R. Stoner (PA)
John A. Thomas (NC)
Jerry L. Womble (AR)
Kevin Young (NJ)

The drivers were included in docket numbers FMCSA–2002–11714; and FMCSA–2018–0010. Their exemptions are applicable as of May 30, 2020, and will expire on May 30, 2022.

In accordance with 49 U.S.C. 31315(b), each exemption will be valid for 2 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(b).

Larry W. Minor,

Associate Administrator for Policy.

[FR Doc. 2020–11850 Filed 6–1–20; 8:45 am]

BILLING CODE 4910–EX–P

DEPARTMENT OF TRANSPORTATION

Federal Motor Carrier Safety Administration

[Docket No. FMCSA–2020–0046]

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 seven 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 May 15, 2020. The exemptions expire on May 15, 2022.

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 Operations, (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/docket?D=FMCSA-2020-0046* 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 Operations 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. To be sure someone is there to help you, please call (202) 366–9317 or (202) 366–9826 before visiting Docket Operations.

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.transportation.gov/privacy.*

II. Background

On April 7, 2020, FMCSA published a notice announcing receipt of applications from seven individuals requesting an exemption from the epilepsy and seizure disorders prohibition in 49 CFR 391.41(b)(8) and requested comments from the public (85 FR 19568). The public comment period ended on May 7, 2020, and no 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 § 391.41(b)(8).

The physical qualification standard for drivers regarding epilepsy found in § 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

[1] These criteria may be found in APPENDIX A TO PART 391—MEDICAL ADVISORY CRITERIA, section H. Epilepsy: § 391.41(b)(8), paragraphs 3, 4, and 5, which is available on the internet at *https://*

Continued

assist medical examiners (MEs) in determining whether drivers with certain medical conditions are qualified to operate a CMV in interstate commerce.

III. Discussion of Comments

FMCSA received no comments in this proceeding.

IV. Basis for Exemption Determination

Under 49 U.S.C. 31136(e) and 31315(b), FMCSA may grant an exemption from the FMCSRs for no longer than a 5-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 5-year period. FMCSA grants medical exemptions from the FMCSRs for a 2-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 2007 recommendations of the Agency's Medical Expert Panel (MEP). The Agency conducted 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 for commercial driver's license (CDL) holders, and interstate and intrastate inspections recorded in the Motor Carrier Management Information System. 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 April 7, 2020, **Federal Register** notice (85 FR 19568) and will not be repeated in this notice.

These seven applicants have been seizure-free over a range of 11 years while taking anti-seizure medication and maintained a stable medication treatment regimen for the last 2 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 § 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 2-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 ME, as defined by § 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.

VII. Conclusion

Based upon its evaluation of the seven exemption applications, FMCSA exempts the following drivers from the epilepsy and seizure disorder prohibition, § 391.41(b)(8), subject to the requirements cited above:

Jason Allie (CA)
Jay Asack (MA)
David Bigler (MN)
Barry Dull (OH)
Jeffrey Kuper (IL)
John Mieyr (MT)
Harold Seaton (KY)

In accordance with 49 U.S.C. 31315(b), each exemption will be valid for 2 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(b).

Larry W. Minor,

Associate Administrator for Policy.

[FR Doc. 2020–11845 Filed 6–1–20; 8:45 am]

BILLING CODE 4910–EX–P

www.gpo.gov/fdsys/pkg/CFR-2015-title49-vol5/pdf/CFR-2015-title49-vol5-part391-appA.pdf.

DEPARTMENT OF TRANSPORTATION

Federal Motor Carrier Safety Administration

[Docket No. FMCSA–2020–0006]

Qualification of Drivers; Exemption Applications; Vision

AGENCY: Federal Motor Carrier Safety Administration (FMCSA), DOT.

ACTION: Notice of final disposition.

SUMMARY: FMCSA announces its decision to exempt eight individuals from the vision requirement in the Federal Motor Carrier Safety Regulations (FMCSRs) to operate a commercial motor vehicle (CMV) in interstate commerce. They are unable to meet the vision requirement in one eye for various reasons. The exemptions enable these individuals to operate CMVs in interstate commerce without meeting the vision requirement in one eye.

DATES: The exemptions were applicable on May 7, 2020. The exemptions expire on May 7, 2022.

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 Operations, (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/docket?D=FMCSA-2020-0006* 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 Operations 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. To be sure someone is there to help you, please call (202) 366–9317 or (202) 366–9826 before visiting Docket Operations.

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.transportation.gov/privacy.*

II. Background

On April 6, 2020, FMCSA published a notice announcing receipt of applications from eight individuals requesting an exemption from vision requirement in 49 CFR 391.41(b)(10) and requested comments from the public (85 FR 19924). The public comment period ended on May 6, 2020, and no comments were 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 § 391.41(b)(10).

The physical qualification standard for drivers regarding vision found in § 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.

III. Discussion of Comments

FMCSA received no comments in this proceeding.

IV. Basis for Exemption Determination

Under 49 U.S.C. 31136(e) and 31315(b), FMCSA may grant an exemption from the FMCSRs for no longer than a 5-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 5-year period. FMCSA grants medical exemptions from the FMCSRs for a 2-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 medical reports about the applicants' vision, as well as their driving records and experience driving with the vision deficiency. The qualifications, experience, and medical condition of each applicant were stated and discussed in detail in the April 6, 2020, **Federal Register** notice (85 FR 19924) and will not be repeated here.

FMCSA recognizes that some drivers do not meet the vision requirement but have adapted their driving to accommodate their limitation and demonstrated their ability to drive safely. The eight exemption applicants listed in this notice are in this category. They are unable to meet the vision requirement in one eye for various reasons, including amblyopia, macular scar, optic nerve atrophy, prosthesis, retinal detachment, and retinal dysplasia. In most cases, their eye conditions did not develop recently. Seven of the applicants were either born with their vision impairments or have had them since childhood. The individual who developed his vision condition as an adult has had it for 6 years. Although each applicant has one eye that does not meet the vision requirement in § 391.41(b)(10), each has at least 20/40 corrected vision in the other eye, and, in a doctor's opinion, has sufficient vision to perform all the tasks necessary to operate a CMV.

Doctors' opinions are supported by the applicants' possession of a valid license to operate a CMV. By meeting State licensing requirements, the applicants demonstrated their ability to operate a CMV with their limited vision in intrastate commerce, even though their vision disqualified them from driving in interstate commerce. We believe that the applicants' intrastate driving experience and history provide an adequate basis for predicting their ability to drive safely in interstate commerce. Intrastate driving, like interstate operations, involves substantial driving on highways on the interstate system and on other roads built to interstate standards. Moreover, driving in congested urban areas exposes the driver to more pedestrian and vehicular traffic than exists on interstate highways. Faster reaction to traffic and traffic signals is generally required because distances between them are more compact. These conditions tax visual capacity and driver response just as intensely as interstate driving conditions.

The applicants in this notice have driven CMVs with their limited vision in careers ranging for 3 to 47 years. In the past 3 years, no drivers were involved in crashes, and one driver was convicted of a moving violation in a CMV. All the applicants achieved a record of safety while driving with their vision impairment that demonstrates the likelihood that they have adapted their driving skills to accommodate their condition. As the applicants' ample driving histories with their vision deficiencies are good predictors of future performance, FMCSA concludes their ability to drive safely can be projected into the future.

Consequently, FMCSA finds that in each case exempting these applicants from the vision requirement in § 391.41(b)(10) 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 be physically examined every year (a) by an ophthalmologist or optometrist who attests that the vision in the better eye continues to meet the standard in § 391.41(b)(10) and (b) by a certified medical examiner (ME) who attests that the individual is otherwise physically qualified under § 391.41; (2) each driver must provide a copy of the ophthalmologist's or optometrist's report to the ME 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 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.

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 eight exemption applications, FMCSA exempts the following drivers from the

vision requirement, § 391.41(b)(10), subject to the requirements cited above:

Terry M. Baldwin (PA)
Samuel L. Eakman (PA)
Raymond C. King (OH)
Robert G. Lanning (VA)
Gary D. Larson (NE)
Larry Owen (TX)
John C. Perrone (PA)
Ronald D. Wilson (KY)

In accordance with 49 U.S.C. 31136(e) and 31315(b), each exemption will be valid for 2 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(b).

Larry W. Minor,

Associate Administrator for Policy.

[FR Doc. 2020–11844 Filed 6–1–20; 8:45 am]

BILLING CODE 4910–EX–P

DEPARTMENT OF TRANSPORTATION

Federal Transit Administration

Solicitation of Proposals for the National Aging and Disability Transportation Center

AGENCY: Federal Transit Administration (FTA), DOT.

ACTION: Notice of funding opportunity.

SUMMARY: The Federal Transit Administration (FTA) is soliciting proposals under FTA's Technical Assistance and Workforce Development Program, to select an entity to administer the National Aging and Disability Transportation Center (NADTC). The NADTC will carry out activities to promote the availability and accessibility of transportation options that serve the needs of people with disabilities, seniors, and their caregivers, with a focus on effectively leveraging the program funds of the Enhanced Mobility of Seniors and Individuals with Disabilities Formula grants and other transit investments. The NADTC provides effective solutions that improve mobility for seniors and individuals with disabilities throughout the country by helping systems remove barriers to transportation services and expanding community transportation mobility options. The FTA intends to fund the NADTC up to $1,900,000, for the first year, subject to availability of funds. The FTA may extend funding for this center for up to five (5) years; however, subsequent funding will depend upon: (1) Future authorizations and appropriations; (2) decisions and program priorities established by the Secretary of Transportation related to the implementation of provisions set forth in 49 U.S.C. 5314; and (3) annual performance reviews.

DATES: Complete proposals for funding opportunity FTA–2020–009–NADTC must be submitted electronically through *GRANTS.GOV.* All applications must be received by 11:59 p.m. Eastern time on July 2, 2020.

FOR FURTHER INFORMATION CONTACT: Elan Flippin, FTA Office of Program Management, (202) 366–3800 or *Elan.flippin@dot.gov.*

SUPPLEMENTARY INFORMATION:

Table of Contents

A. Program Description

The FTA is soliciting proposals to administer the National Aging and Disability Transportation Center (NADTC). The mission of the NADTC is to promote the availability and accessibility of transportation options for older adults, people with disabilities, caregivers and communities. The need for accessible transportation that supports independent community living is growing in the United States. The U.S. Census Bureau American Community Survey in 2018 estimated that 12.6 percent of the U.S. population (40.6 million) living in the community has a disability. The population age 65 and over was 52 million in 2018, 16 percent of the population. Employment and poverty rates disproportionately negatively affect people with disabilities and older adults. Investment in accessible public transportation, including the over $280 million in funding provided annually through the Enhanced Mobility of Seniors and People with Disabilities Program (Section 5310), is an important enabler of the American dream for many people. The NADTC makes a significant difference in helping communities enhance the benefits of public transportation, including high impact Section 5310 projects that improve mobility for people with disabilities and older adults.

The work of the NADTC builds upon the work of the Coordinating Council on Access and Mobility (CCAM), promoting coordination to ensure older adults, people with disabilities, people of low income, and disadvantaged communities benefit from coordinated planning activities and the resulting projects. The NADTC carries out activities that demonstrate impact and achieve the following goals:

- Promoting the essential role of accessible transportation in furthering the economic inclusion, access to healthcare, links to education, connections to recreation/leisure activities, and independent living of people with disabilities and older adults;
- Increasing the effectiveness, efficiency and quality of coordinated human service transportation activities;
- Ensuring that the planning of transportation services for people with disabilities, older adults and caregivers is done in conjunction with broader planning activities at all levels;
- Highlighting and assisting in the development of promising practices, including the use of technology, to solve transportation challenges for people with disabilities and older adults and maximizing the effectiveness of Federal investments in specialized transportation services. For more information on the various programs and services currently provided by the NADTC, visit the NADTC website at: *https://www.nadtc.org/.*

B. Federal Award Information

FTA intends to fund the NADTC through a cooperative agreement at up to $1,900,000 for the first year with the option to extend for up to four (4) additional years. FTA's decision to exercise these options is subject to: (1) Decisions and program priorities established by the Secretary of Transportation related to the implementation of the Technical Assistance and Workforce Development program (49 U.S.C. 5314); (2) future authorizations and appropriations; and (3) annual reviews of the NADTC's performance.

C. Eligibility Information

1. Eligible Applicants

Eligible applicants are non-profit organizations with experience in the delivery of programs and services that seek to serve the targeted population of older adults and people with disabilities; experience in public transportation-related technical assistance; and the organizational capacity to administer a national technical assistance center program.

2. Cost Sharing or Matching

This funding opportunity will be awarded under the terms of a cooperative agreement. The federal share is 100 percent. There is no required local matching share.

D. Application and Submission Information

1. Address To Request Application Package

Applications must be submitted electronically through *GRANTS.GOV*, as described above. General information for registering and submitting applications through *GRANTS.GOV* can be found at *https://www.grants.gov/web/grants/applicants.html* along with specific instructions for the forms and attachments required for submission. Mail and fax submissions will not be accepted. A complete proposal submission will consist of at least two files: (1) The SF–424 Mandatory form (downloaded from *GRANTS.GOV*), and (2) a narrative application document in Microsoft Word, Adobe Acrobat, or compatible file format. The narrative application should be in the format outlined in section 2 below. Once completed, the narrative application must be placed in the attachments section of the SF–424 Mandatory form. Applicants must attach the narrative application file to their submission in *GRANTS.GOV* to successfully complete the proposal process. A proposal submission may contain additional supporting documentation as attachments.

2. Content and Form of Application Submission

Proposals shall be submitted in a Microsoft Word, Adobe Acrobat, or compatible file format, double-spaced using Times New Roman, 12-point font. The proposal must contain the following components and adhere to the specified maximum lengths:

a. Cover sheet (1 page).

The cover sheet must include the name of the entity submitting the proposal, the principal's name, title, and contact information (*e.g.,* address, phone, and email), and the name and contact information for the key point of contact for each function of the agreement referenced under the ''Program Description'' section of this Notice.

b. Abstract (not to exceed 4 pages).

The abstract must include the following sections: Background, purpose, methodology, intended outcomes, and plan for evaluation.

c. Detailed budget proposal and budget narrative (not to exceed 3 pages).

d. Project narrative (not to exceed 25 pages).

The project narrative must include the following information:

i. The methodology for addressing the goals and objectives;

ii. Objectives, activities, deliverables, milestones, timeline and intended outcomes for achieving the goals outlined in the scope for the first year;

iii. The existing and future capacity of the organization to address the issues outlined in the proposal and the organization's ability to implement goals and objectives;

iv. A detailed plan for communication, technical assistance, and outreach at the State and local levels;

v. A plan to work with stakeholders and build partnerships at the national level and;

vi. Staff qualifications, including: (1) Prior experience providing technical assistance, especially related to transportation for people with disabilities and older adults, (2) prior experience implementing the other tasks outlined in this solicitation, (3) staff members' knowledge of issues related to transportation for people with disabilities and older adults, and (4) a one-page biographical sketch for each staff member.

e. Plan for evaluation of NADTC technical assistance center activities and performance measures (not to exceed 5 pages).

f. Supplemental materials, such as bios and letters of support, can be included in an appendices section that is beyond the page limit above but are not to exceed 15 additional pages.

3. Unique Entity Identifier and System for Award Management (SAM)

Each applicant is required to: (1) Register in SAM before applying; (2) provide a valid unique SAM entity identifier in its application; and (3) continue to maintain an active SAM registration with current information, during which the applicant has an active Federal award or an application or plan under consideration by FTA. These requirements do not apply if the applicant: (1) Is excepted from the requirements under 2 CFR 25.110(b) or (c); or (2) has an exception approved by FTA under 2 CFR 25.110(d). The FTA may not make an award until the applicant has complied with all applicable unique entity identifier and SAM requirements. If an applicant has not fully complied with the requirements by the time FTA is ready to make an award, FTA may determine that the applicant is not qualified to receive an award and use that determination as a basis for making a Federal award to another applicant. SAM registration takes approximately 3–5 business days, but FTA recommends allowing ample time, up to several weeks, for completion of all steps. For additional information on obtaining a unique entity identifier, please visit *https://www.sam.gov/SAM/pages/public/index.jsf.*

4. Submission Dates and Times

Project proposals must be submitted electronically through *GRANTS.GOV* and must be received by 11:59 p.m. Eastern time on July 2, 2020. *GRANTS.GOV* attaches a time stamp to each application at the time of submission. Proposals submitted after the deadline will be considered only under extraordinary circumstances not under the applicant's control. Mail and fax submissions will not be accepted.

Within 48 hours after submitting an electronic application, the applicant should receive two email messages from *GRANTS.GOV:* (1) Confirmation of successful transmission to *GRANTS.GOV*, and (2) confirmation of successful validation by *GRANTS.GOV*. If confirmations of successful validation are not received or a notice of failed validation or incomplete materials is received, the applicant must address the reason for the failed validation, as described in the email notice, and resubmit before the submission deadline.

If making a resubmission for any reason, include all original attachments regardless of which attachments were updated and check the box on the supplemental form indicating this is a resubmission.

The FTA urges applicants to submit proposals at least 72 hours prior to the due date to allow time to receive the validation messages and to correct any problems that may have caused a rejection notification. *GRANTS.GOV* scheduled maintenance and outage times are announced on the *GRANTS.GOV* website. Deadlines will not be extended due to scheduled website maintenance.

Applicants are encouraged to begin the process of registration on the *GRANTS.GOV* site well in advance of the submission deadline. Registration is a multi-step process, which may take several weeks to complete before an application can be submitted. Registered applicants may still be required to take steps to keep their registration up to date before submissions can be made successfully: (1) Registration in SAM is renewed annually; and (2) persons making submissions on behalf of the Authorized Organization Representative

(AOR) must be authorized in *GRANTS.GOV* by the AOR to make submissions. To register and for detailed instructions, please see the ''APPLICANTS'' tab in *GRANTS.GOV* (*https://www.grants.gov/web/grants/applicants.html*).

To be eligible to apply for this opportunity, organizations must have a Data Universal Numbering System (DUNS) Number, active System for Award Management (SAM) registration, and an established *GRANTS.GOV* account. DUNS and SAM registrations may take several weeks. Therefore, an organization's registration should be done in sufficient time to ensure it does not impact the entity's ability to meet required application submission deadlines. Complete organization instructions can be found on *GRANTS.GOV: https://www.grants.gov/web/grants/applicants/organization-registration.html.*

5. Funding Restrictions

This award is subject to the governmentwide Uniform Cost Principles for Federal Awards at 2 CFR part 200, subpart E.

6. Other Submission Requirements

Detailed instructions on application and submission requirements are found under ''Section D, Application and Submission Requirements'' of this notice. Project proposals must be submitted electronically through *GRANTS.GOV* by 11:59 p.m. Eastern Daylight Time on July 2, 2020. Late applications will not be accepted. Mail and fax submissions will not be accepted.

E. Application Review Information

1. Criteria

The FTA will evaluate proposals based on each applicant's response to the following criteria: (1) Methodology to Meet the Goals of the NADTC; (2) Qualifications of Key Personnel, Experience, and Knowledge; (3) Communication, Technical Assistance, and Outreach Strategy; (4) Technical, Legal, and Financial Capacity; (5) Ability to Work with Stakeholders and Build Partnerships at the National Level; and (6) Plan to Evaluate the NADTC activities. The criteria are explained below:

a. Methodology To Meet the Goals of the National Aging and Disability Transportation Center

The FTA is seeking innovative and effective approaches and strategies to accomplish the project objectives. Proposals will be evaluated based on the proposed methodology for addressing the goals and objectives of the NADTC, as well as the capacity of the organization to address the issues outlined in the proposal. The proposal should clearly explain the objectives, activities, deliverables, milestones, timelines and intended outcomes for achieving the goals outlined in the scope for the first year, and how the organization intends to implement them.

b. Qualifications of Key Personnel, Experience, and Knowledge

The proposal should demonstrate that key personnel have the appropriate skills and experience to carry out the activities. The FTA will evaluate the qualifications and experience of the key staff detailed in the proposal for their: (1) Prior experience providing technical assistance, especially related to transportation for people with disabilities and older adults, (2) prior experience implementing the other tasks outlined in this solicitation, and (3) knowledge of issues related to transportation for people with disabilities and older adults.

c. Communication, Technical Assistance, and Outreach Strategy

The proposal should demonstrate the ability to execute a technical assistance program with a national scope, as well as strategies for delivering targeted assistance to State, regional, and local stakeholders. Proposing organizations are encouraged to think innovatively about this technical assistance delivery.

The proposal should also demonstrate the ability to carry out outreach, dissemination, and information management activities. These activities will include capturing and sharing useful and best practices in the delivery of Coordinated Human Services Transportation Services, serving the targeted population of older adults and people with disabilities. The proposal should demonstrate innovative approaches, such as the use of communication that is accessible through social media and other information technologies, to manage, plan, and deliver effective technical assistance strategies to stakeholders. Coordination of services for the targeted population is challenging as resources are limited, services are costly, and the population's needs are unique. The proposal should demonstrate effective strategies for providing technical assistance to overcome challenges and address the uniquely unmet needs of the targeted population.

d. Technical, Legal, and Financial Capacity

The proposal must include an effective project management plan to administer and manage the NADTC and must demonstrate that the applicant has the technical, legal, and financial capacity to carry out the plan. FTA will evaluate the applicant's:

a. Technical capacity to administer and manage the services proposed;

b. Total budget and staffing; and

c. Evidence of understanding of the NADTC mission and comprehensive technical approach to delivering the NADTC.

The proposal should indicate a strong organizational capability to address the issues and activities outlined in the proposal. In addition, the proposal should indicate experience in managing and monitoring sub-recipients and contractors, if any are included in the proposal. The applicant selected must be an eligible recipient for a cooperative agreement with FTA and able to sign the required certifications and assurances. The successful applicant must have no technical, legal or financial issues that would impact its eligibility and authority to apply for and accept FTA funds, or carry out the award's scope of work.

e. Ability To Work With Stakeholders and Build Partnerships at the National Level

The proposal must include a plan for effective and meaningful stakeholder engagement. The proposal will be evaluated based on the quality and effectiveness of the plan for engaging and supporting stakeholder engagement to drive the activities of the NADTC.

f. Plan To Evaluate the NADTC Activities

FTA will evaluate the effectiveness of proposed performance measures and the plan for collecting and reporting on data related to the NADTC's products, activities, and outcomes.

2. Review and Selection Process

A technical evaluation committee made up of FTA staff will evaluate proposals based on the published evaluation criteria outlined in this notice (refer to Section E). The technical evaluation committee will advise the FTA Administrator.

The final award decision will be made by the FTA Administrator. In making this decision, the Administrator will take into consideration:

a. Recommendations of the review panel;

b. past performance of the applicant regarding programmatic and grants management compliance;

c. the reasonableness of the estimated cost to the government considering the available funding and anticipated results; and

d. the likelihood that the proposed project will result in the technical assistance outcomes expected.

3. Responsibility Review

FTA is required to review and consider any information about the applicant that is in the designated integrity and performance system accessible through SAM (currently FAPIIS) (see 41 U.S.C. 2313). An applicant, at its option, may review information in the designated integrity and performance systems accessible through SAM and comment on any information about itself that a Federal awarding agency previously entered and is currently in the designated integrity and performance system accessible through SAM. FTA will consider any comments by the applicant, in addition to the other information in the designated integrity and performance system, in making a judgment about the applicant's integrity, business ethics, and record of performance under Federal awards when completing the review of risk posed by applicants as described in 2 CFR 200.205 Federal awarding agency review of risk posed by applicants.

F. Federal Award Administration Information

1. Federal Award Notices

The FTA will notify the successful organization and may announce the selection on its website *https://www.transit.dot.gov.* Following notification, the successful entity will be required to submit its application through the FTA Transit Award Management System (TrAMS). The FTA will work with the successful applicant to develop a detailed Statement of Work and may require modifications to the proposal before a cooperative agreement is awarded. The FTA will award and manage the cooperative agreement through TrAMS.

2. Administrative and National Policy Requirements

(a) Grant Requirements.

Award will be made under FTA's Section 5314 program, and the successful applicant will adhere to the customary FTA cooperative agreement requirements of the Section 5314 Program. Assistance regarding these requirements is available from FTA.

(b) The selection of a cooperative agreement recipient under this NOFO will go through the Congressional notification and release process.

(c) Standard Assurances.

The applicant assures that it will comply with all applicable Federal statutes, regulations, executive orders, FTA circulars, and other Federal administrative requirements in carrying out any project supported by the FTA cooperative agreement. The applicant acknowledges that it is under a continuing obligation to comply with the terms and conditions of the cooperative agreement issued for its project with FTA. The applicant understands that Federal laws, regulations, policies, and administrative practices might be modified from time to time and that modifications may affect the implementation of the project. The applicant agrees that the most recent Federal requirements will apply to the project, unless FTA issues a written determination otherwise. The applicant must submit the Certifications and Assurances before receiving a cooperative agreement if it does not have current certifications on file.

3. Reporting

Post-award reporting requirements include submission of Federal Financial Reports and Milestone Progress Reports in TrAMS on a quarterly basis. Additional reporting may be required specific to functions outlined in the Statement of Work for NADTC. The recipient may be expected to participate in events or peer networks related to the Section 5310 Program and targeted populations. The Federal Financial Accountability and Transparency Act (FFATA) requires data entry at the FFATA Sub Award Reporting System (*http://www.FSRS.gov*) for all sub-awards and sub-contracts issued for $25,000 or more, as well as addressing executive compensation for both grantee and sub-award organizations.

Additionally, FTA may evaluate and report on the success of the program. Applicants may be required to provide information for this purpose indicating the need, problem, or opportunity addressed by activities of the program. The national significance and relevance to the public transportation industry must also be clearly demonstrated.

G. Federal Awarding Agency Contact(s)

For further information concerning this notice, please contact the Technical Assistance Center program manager, Elan Flippin, by phone at 202–366–3800, or by email at *elan.flippin@dot.gov.* A TDD is available for individuals who are deaf or hard of hearing at 800–877–8339.

K. Jane Williams,

Acting Administrator.

[FR Doc. 2020–11846 Filed 6–1–20; 8:45 am]

BILLING CODE P

DEPARTMENT OF TRANSPORTATION

Pipeline and Hazardous Materials Safety Administration

[Docket No. PHMSA–2020–0044]

Pipeline Safety: Request for Special Permit; Florida Gas Transmission Company

AGENCY: Pipeline and Hazardous Materials Safety Administration (PHMSA); DOT.

ACTION: Notice.

SUMMARY: PHMSA is publishing this notice to solicit public comments on a request for a special permit received from Florida Gas Transmission Company (FGT). The special permit request is seeking relief from compliance with certain requirements in the Federal pipeline safety regulations. At the conclusion of the 30-day comment period, PHMSA will review the comments received from this notice as part of its evaluation to grant or deny the special permit request.

DATES: Submit any comments regarding this special permit request by July 2, 2020.

ADDRESSES: Comments should reference the docket number for the specific special permit request and may be submitted in the following ways:

- *E-Gov website: http://www.Regulations.gov.* This site allows the public to enter comments on any **Federal Register** notice issued by any agency.
- *Fax:* 1–202–493–2251.
- *Mail:* Docket Management System: U.S. Department of Transportation, Docket Operations, M–30, West Building Ground Floor, Room W12–140, 1200 New Jersey Avenue SE, Washington, DC 20590.
- *Hand Delivery:* Docket Management System: U.S. Department of Transportation, Docket Operations, M–30, West Building Ground Floor, Room W12–140, 1200 New Jersey Avenue SE, Washington, DC 20590, between 9:00 a.m. and 5:00 p.m., Monday through Friday, except Federal holidays.

Instructions: You should identify the docket number for the special permit request you are commenting on at the beginning of your comments. If you submit your comments by mail, please

submit two (2) copies. To receive confirmation that PHMSA has received your comments, please include a self-addressed stamped postcard. Internet users may submit comments at *http://www.Regulations.gov*.

Note: There is a privacy statement published on *http://www.Regulations.gov*. Comments, including any personal information provided, are posted without changes or edits to *http://www.Regulations.gov*.

Confidential Business Information: Confidential Business Information (CBI) is commercial or financial information that is both customarily and actually treated as private by its owner. Under the Freedom of Information Act (FOIA) (5 U.S.C. 552), CBI is exempt from public disclosure. If your comments responsive to this notice contain commercial or financial information that is customarily treated as private, that you actually treat as private, and that is relevant or responsive to this notice, it is important that you clearly designate the submitted comments as CBI. Pursuant to 49 Code of Federal Regulations (CFR) § 190.343, you may ask PHMSA to give confidential treatment to information you give to the agency by taking the following steps: (1) Mark each page of the original document submission containing CBI as ''Confidential''; (2) send PHMSA, along with the original document, a second copy of the original document with the CBI deleted; and (3) explain why the information you are submitting is CBI. Unless you are notified otherwise, PHMSA will treat such marked submissions as confidential under the FOIA, and they will not be placed in the public docket of this notice. Submissions containing CBI should be sent to Kay McIver, DOT, PHMSA–PHP–80, 1200 New Jersey Avenue SE, Washington, DC 20590–0001. Any commentary PHMSA receives that is not specifically designated as CBI will be placed in the public docket for this matter.

FOR FURTHER INFORMATION CONTACT:

General: Ms. Kay McIver by telephone at 202–366–0113, or by email at *kay.mciver@dot.gov.*

Technical: Mr. Steve Nanney by telephone at 713–272–2855, or by email at *steve.nanney@dot.gov.*

SUPPLEMENTARY INFORMATION: PHMSA received a special permit request from FGT seeking a waiver from the requirements of 49 CFR 192.611(a)(3): Change in class location: Confirmation or revision of maximum allowable operating pressure. This special permit is being requested for class location changes in lieu of pipe replacement, pressure testing, or pressure reduction for 13 special permit segments totaling 1.34 miles of the FGT pipeline system. The proposed special permit segments are located in four (4) counties (Citrus, Hernando, Hillsborough, and Pasco) in Florida. The pipeline class locations in the special permit segments have changed from either a Class 1 to Class 3 location or from a Class 2 to Class 3 location. The FGT pipeline has not been pressure tested to a high enough pressure to meet the requirements in 49 CFR 192.611(a)(3). The special permit segments are not contiguous and are comprised of either 18-inch, 30-inch, or 36-inch diameter pipe with existing maximum allowable operating pressures (MAOP) of either 1,322 pounds per square inch gauge (psig) or 1,333 psig. The installation dates of the special permit segments range from 1992 to 2007. The special permit segments are included in an existing Alternative MAOP special permit (PHMSA–2008–0077) that allows the special permit segments to operate at class location stress levels that meet 49 CFR 192.620(a)(1).

The special permit request, proposed special permit with conditions, and Draft Environmental Assessment (DEA) for the FGT pipeline are available for review and public comment in Docket No. PHMSA–2020–0044. We invite interested persons to review and submit comments on the special permit request, proposed special permit with conditions, and DEA in the docket. Please include any comments on potential safety and environmental impacts that may result if the special permit is granted. Comments may include relevant data.

Before issuing a decision on the special permit request, PHMSA will evaluate all comments received on or before the comment closing date. Comments received after the closing date will be evaluated, if it is possible to do so without incurring additional expense or delay. PHMSA will consider each relevant comment it receives in making a decision to grant or deny this request.

Issued in Washington, DC, under authority delegated in 49 CFR 1.97.

Alan K. Mayberry,

Associate Administrator for Pipeline Safety.

[FR Doc. 2020–11823 Filed 6–1–20; 8:45 am]

BILLING CODE 4910–60–P

DEPARTMENT OF TRANSPORTATION

Pipeline and Hazardous Materials Safety Administration

[Docket No. PHMSA–2020–0040]

Pipeline Safety: Request for Special Permit; Gulf South Pipeline Company, LLC

AGENCY: Pipeline and Hazardous Materials Safety Administration (PHMSA); DOT.

ACTION: Notice.

SUMMARY: PHMSA is publishing this notice to solicit public comments on a request for special permit received from Gulf South Pipeline Company, LLC (GSPC). The special permit request is seeking relief from compliance with certain requirements in the Federal pipeline safety regulations. At the conclusion of the 30-day comment period, PHMSA will review the comments received from this notice as part of its evaluation to grant or deny the special permit request.

DATES: Submit any comments regarding this special permit request by July 2, 2020.

ADDRESSES: Comments should reference the docket number for this special permit request and may be submitted in the following ways:

- *E-Gov website: http://www.Regulations.gov*. This site allows the public to enter comments on any **Federal Register** notice issued by any agency.
- *Fax:* 1–202–493–2251.
- *Mail:* Docket Management System: U.S. Department of Transportation, Docket Operations, M–30, West Building Ground Floor, Room W12–140, 1200 New Jersey Avenue SE, Washington, DC 20590.
- *Hand Delivery:* Docket Management System: U.S. Department of Transportation, Docket Operations, M–30, West Building Ground Floor, Room W12–140, 1200 New Jersey Avenue SE, Washington, DC 20590, between 9:00 a.m. and 5:00 p.m., Monday through Friday, except Federal holidays.

Instructions: You should identify the docket number for the special permit request you are commenting on at the beginning of your comments. If you submit your comments by mail, please submit two (2) copies. To receive confirmation that PHMSA has received your comments, please include a self-addressed stamped postcard. Internet users may submit comments at *http://www.Regulations.gov*.

Note: There is a privacy statement published on *http://www.Regulations.gov*.

Comments, including any personal information provided, are posted without changes or edits to *http://www.Regulations.gov.*

Confidential Business Information: Confidential Business Information (CBI) is commercial or financial information that is both customarily and actually treated as private by its owner. Under the Freedom of Information Act (FOIA) (5 U.S.C. 552), CBI is exempt from public disclosure. If your comments responsive to this notice contain commercial or financial information that is customarily treated as private, that you actually treat as private, and that is relevant or responsive to this notice, it is important that you clearly designate the submitted comments as CBI. Pursuant to 49 Code of Federal Regulations (CFR) 190.343, you may ask PHMSA to give confidential treatment to information you give to the agency by taking the following steps: (1) Mark each page of the original document submission containing CBI as ''Confidential''; (2) send PHMSA, along with the original document, a second copy of the original document with the CBI deleted; and (3) explain why the information you are submitting is CBI. Unless you are notified otherwise, PHMSA will treat such marked submissions as confidential under the FOIA, and they will not be placed in the public docket of this notice. Submissions containing CBI should be sent to Kay McIver, DOT, PHMSA–PHP–80, 1200 New Jersey Avenue SE, Washington, DC 20590–0001. Any commentary PHMSA receives that is not specifically designated as CBI will be placed in the public docket for this matter.

FOR FURTHER INFORMATION CONTACT:

General: Ms. Kay McIver by telephone at 202–366–0113, or by email at *kay.mciver@dot.gov.*

Technical: Mr. Joshua Johnson by telephone at 816–329–3825, or by email at *joshua.johnson@dot.gov.*

SUPPLEMENTARY INFORMATION: PHMSA received a special permit request from GSPC on March 16, 2020. The request is for GSPC's Index 818–9 Pipeline which is currently in carbon dioxide (CO_2) service under 49 CFR part 195 regulations. GSPC proposes to convert the line to natural gas service. Pipeline operators converting pipelines to natural gas service must follow 49 CFR 192.14: Conversion to service subject to this part.

GSPC is seeking a waiver from the requirements of 49 CFR 192.14(a)(4), which requires a pressure test to substantiate the maximum allowable operating pressure of the pipeline (MAOP) in accordance with 49 CFR part 192, subpart J. In lieu of a pressure test, GSPC seeks a special permit to perform alternative risk control activities, based on 49 CFR part 192, subpart O, integrity management program principles, requirements, and assessments, as specified in the proposed special permit conditions. The 16-inch diameter Index 818–9 Pipeline has a maximum operating pressure of 2,875 pounds per square inch gauge (psig) while in CO_2 service as a 49 CFR part 195 regulated pipeline. GSPC proposes to lower the Index 818–9 Pipeline MAOP to 1,480 psig for operation as a 49 CFR part 192 regulated natural gas transmission pipeline.

The 16-inch diameter Index 818–9 Pipeline is 61-miles in length and begins at a point southeast of Heidelberg, Mississippi, and runs northeast to the Kemper County Power Plant in Kemper County, Mississippi. The Index 818–9 Pipeline is located in Jasper, Clarke, Lauderdale, and Kemper Counties in Mississippi.

The special permit request for the Index 818–9 Pipeline is available for review and public comment in the Docket No. PHMSA–2020–0040. We invite interested persons to review and submit comments on the special permit request in the docket. Please include any comments on potential safety and environmental impacts that may result if the special permit is granted. Comments may include relevant data.

Before issuing a decision on the special permit request, PHMSA will evaluate all comments received on or before the comment closing date. Comments received after the closing date will be evaluated, if it is possible to do so without incurring additional expense or delay. PHMSA will consider each relevant comment it receives in making a decision to grant or deny this special permit request.

Issued in Washington, DC, under authority delegated in 49 CFR 1.97.

Alan K. Mayberry,

Associate Administrator for Pipeline Safety.

[FR Doc. 2020–11820 Filed 6–1–20; 8:45 am]

BILLING CODE 4910–60–P

DEPARTMENT OF THE TREASURY

Internal Revenue Service

Proposed Collection; Comment Request for Cognitive and Psychological Research Coordinated by Statistics of Income on Behalf of All IRS Operations Functions

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 Cognitive and Psychological Research Coordinated by Statistics of Income on Behalf of All IRS Operations Functions.

DATES: Written comments should be received on or before August 3, 2020 to be assured of consideration.

ADDRESSES: Direct all written comments to Kinna Brewington, Internal Revenue Service, Room 6526, 1111 Constitution Avenue NW, Washington, DC 20224.

FOR FURTHER INFORMATION CONTACT: Requests for additional information or copies of the form and instructions 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: Cognitive and Psychological Research Coordinated by Statistics of Income on Behalf of All IRS Operations Functions.

OMB Number: 1545–1349.

Abstract: The proposed research will improve the quality of data collection by examining the psychological and cognitive aspects of methods and procedures such as: Interviewing processes, forms redesign, survey and tax collection technology and operating procedures (internal and external in nature).

Current Actions: We will be conducting different opinion surveys, focus group sessions, think-aloud interviews, and usability studies regarding cognitive research surrounding forms submission or IRS system/product development.

Type of Review: Revision of a currently approved collection.

Affected Public: Individuals and businesses or other for-profit organizations.

Estimated Number of Respondents: 6,000.

Estimated Time per Respondent: 1 hour, 30 minutes.

Estimated Total Annual Burden Hours: 9,000.

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: May 21, 2020.

Martha Brinson,

Tax Analyst.

[FR Doc. 2020–11787 Filed 6–1–20; 8:45 am]

BILLING CODE 4830–01–P

DEPARTMENT OF THE TREASURY

Internal Revenue Service

Proposed Collection; Comment Request for Form 1116

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 Foreign Tax Credit (Individual, Estate, or Trust).

DATES: Written comments should be received on or before August 3, 2020 to be assured of consideration.

ADDRESSES: Direct all written comments to Kinna Brewington, Internal Revenue Service, Room 6526, 1111 Constitution Avenue NW, Washington, DC 20224.

FOR FURTHER INFORMATION CONTACT: Requests for additional information or copies of the form and instructions should be directed to LaNita Van Dyke, (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: Foreign Tax Credit (Individual, Estate, or Trust).

OMB Number: 1545–0121.

Form Number: 1116.

Abstract: Form 1116 is used by individuals (including nonresident aliens), estates, or trusts who paid foreign income taxes on U.S. taxable income, to compute the foreign tax credit. This information is used by the IRS to determine if the foreign tax credit is properly computed.

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.

Estimated Number of Responses: 4,143,255.

Estimated Time per Respondent: 6.05 hours.

Estimated Total Annual Burden Hours: 25,066,693.

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: May 21, 2020.

Martha Brinson,

Tax Analyst.

[FR Doc. 2020–11788 Filed 6–1–20; 8:45 am]

BILLING CODE 4830–01–P

DEPARTMENT OF THE TREASURY

Internal Revenue Service

Proposed Collection; Comment Request for Revenue Procedure 2004–47

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 Relief From Ruling Process For Making Late Reverse QTIP Election.

DATES: Written comments should be received on or before August 3, 2020 to be assured of consideration.

ADDRESSES: Direct all written comments to Kinna Brewington, Internal Revenue Service, Room 6526, 1111 Constitution Avenue NW, Washington, DC 20224.

FOR FURTHER INFORMATION CONTACT: Requests for copies of the revenue procedure 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: Relief From Ruling Process For Making Late Reverse QTIP Election.

OMB Number: 1545–1898.

Revenue Procedure Number: Revenue Procedure 2004–47.

Abstract: Revenue Procedure 2004–47 provides alternative relief for taxpayers

who failed to make a reverse QTIP election on an estate tax return. Instead of requesting a private letter ruling and paying the accompanying user fee the taxpayer may file certain documents with the Cincinnati Service Center directly to request relief.

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: Individuals or households.

Estimated Number of Respondents: 6.

Estimated Annual Average Time per Respondent: 9 hours.

Estimated Total Annual Hours: 54.

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: May 21, 2020.

Martha Brinson,

Tax Analyst.

[FR Doc. 2020–11789 Filed 6–1–20; 8:45 am]

BILLING CODE 4830–01–P

DEPARTMENT OF VETERANS AFFAIRS

[OMB Control No. 2900–0696]

Agency Information Collection Activity Under OMB Review: Availability of Educational, Licensing, and Certification Records

AGENCY: Veterans Benefits Administration, Department of Veterans Affairs.

ACTION: Notice.

SUMMARY: In compliance with the Paperwork Reduction Act (PRA) of 1995 this notice announces that the Veterans Benefits Administration (VBA), 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.

DATES: Written comments and recommendations for the proposed information collection should be sent within 30 days of publication of this notice to *www.reginfo.gov/public/do/PRAMain.* Find this particular information collection by selecting ''Currently under 30-day Review—Open for Public Comments'' or by using the search function. Refer to ''OMB Control No. 2900–0696.

SUPPLEMENTARY INFORMATION:

Authority: 10 U.S.C. 16136; 38 U.S.C. 3034, 3241, 3323, 3689, 3690.

Title: Availability of Educational, Licensing, and Certification Records.

OMB Control Number: 2900–0696.

Type of Review: Revision of a currently approved collection.

Abstract: VA uses this information to decide whether beneficiaries of educational assistance have been properly paid, and whether educational institutions and organizations or entities offering approved licensing and certification tests are following the applicable sections of the U.S. Code.

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 85 FR 48 on March 11, 2020, pages 14291 & 14292.

Affected Public: Educational Institutions and Organizations.

Estimated Annual Burden: 9,858 hours.

Estimated Average Burden Per Respondent: 5 hours (300 minutes).

Frequency of Response: On Occasion.

Actual Number of Respondents: 4,929.

By direction of the Secretary.

Danny S. Green,

VA Clearance Officer, Office of Quality, Performance and Risk, Department of Veterans Affairs.

[FR Doc. 2020–11817 Filed 6–1–20; 8:45 am]

BILLING CODE 8320–01–P

FEDERAL REGISTER

Vol. 85 Tuesday,
No. 106 June 2, 2020

Part II

Department of Health and Human Services

Centers for Medicare & Medicaid Services

42 CFR Parts 417, 422, and 423
Medicare Program; Contract Year 2021 Policy and Technical Changes to the Medicare Advantage Program; Final Rule

DEPARTMENT OF HEALTH AND HUMAN SERVICES

Centers for Medicare & Medicaid Services

42 CFR Parts 417, 422, and 423

[CMS–4190–F]

RIN 0938–AT97

Medicare Program; Contract Year 2021 Policy and Technical Changes to the Medicare Advantage Program, Medicare Prescription Drug Benefit Program, and Medicare Cost Plan Program

AGENCY: Centers for Medicare & Medicaid Services (CMS), Department of Health and Human Services (HHS).

ACTION: Final rule.

SUMMARY: This final rule will revise regulations for the Medicare Advantage (MA or Part C) program, Medicare Prescription Drug Benefit (Part D) program, and Medicare Cost Plan program to implement certain sections of the Bipartisan Budget Act of 2018 and the 21st Century Cures Act. In addition, it will enhance the Part C and D programs, codify several existing CMS policies, and implement other technical changes.

DATES: *Effective Date:* These regulations are effective August 3, 2020.

Applicability Dates: Except for §§ 422.166(a)(2)(i), 423.186(a)(2)(i), and 422.514(d)(1) and (2), the provisions in this rule are applicable beginning January 1, 2021. The changes to §§ 422.166(a)(2)(i) and 423.186(a)(2)(i) are applicable beginning January 1, 2022. The provisions of § 422.514(d)(1), are applicable beginning January 1, 2022. The provisions of § 422.514(d)(2) are applicable beginning January 1, 2023.

FOR FURTHER INFORMATION CONTACT: Theresa Wachter, (410) 786–1157, or Cali Diehl, (410) 786–4053—General Questions.

Kimberlee Levin, (410) 786–2549—Part C Issues.

Lucia Patrone, (410) 786–8621—Part D Issues.

Kristy Nishimoto, (206) 615–2367—Beneficiary Enrollment and Appeals Issues.

Stacy Davis, (410) 786–7813—Part C and D Payment Issues.

Melissa Seeley, (212) 616–2329—D–SNP Issues.

SUPPLEMENTARY INFORMATION: CMS intends to address all of the remaining proposals from the February 2020 proposed rule in subsequent rulemaking. Therefore, CMS plans to make any provisions adopted in the subsequent, second final rule, although effective on or before January 1, 2021, applicable no earlier than January 1, 2022. Notwithstanding the foregoing, for proposals from the February 2020 proposed rule that would codify statutory requirements that are already in effect, CMS reminds readers and plan sponsors that the statutory provisions apply and will continue to be enforced. Similarly, for the proposals from the February 2020 proposed rule that would implement the statutory requirements in sections 2007 and 2008 of the Substance Use-Disorder Prevention that Promotes Opioid Recovery and Treatment (SUPPORT) for Patients and Communities Act (hereinafter referred to as the SUPPORT Act), CMS intends to implement these statutes consistent with their effective provisions.

I. Executive Summary and Background

A. Executive Summary

1. Purpose

The primary purpose of this final rule is to implement certain sections of the following federal laws related to the Medicare Advantage (MA or Part C) and Prescription Drug Benefit (Part D) programs before the contract year 2021 MA plan bids (due by statute on the first Monday in June):

- The Bipartisan Budget Act of 2018 (hereinafter referred to as the BBA of 2018)
- The 21st Century Cures Act (hereinafter referred to as the Cures Act)

The rule also includes a number of changes to strengthen and improve the Part C and D programs, codifies in regulation several CMS interpretive policies previously adopted through the annual Call Letter and other guidance documents, and implements other technical changes. We took a measured approach to review each provision proposed and focused finalizing in this first final rule those most helpful for bidding, those that address the Coronavirus Disease (COVID–19) pandemic and public health emergency, as well as those topics on which issuing a final rule now would advance the MA program.

While we intend to address the remaining proposals from the February 18, 2020, proposed rule (85 FR 9002) not included in this final rule in subsequent rulemaking, we are focusing in this final rule on more immediate regulatory actions. CMS plans to make any provisions adopted in the subsequent, second final rule, although effective on or before January 1, 2021, applicable no earlier than January 1, 2022. Notwithstanding the foregoing, for proposals from the February 2020 proposed rule that would codify statutory requirements that are already in effect,[1] CMS reminds readers and plan sponsors that the statutory provisions apply and will continue to be enforced. Similarly, for the proposals from the February 2020 proposed rule that would implement the statutory requirements in sections 2007 and 2008 of the SUPPORT Act, CMS intends to implement the statute consistent with its effective provisions.

2. Summary of the Major Provisions

a. Medicare Advantage (MA) Plan Options for End-Stage Renal Disease (ESRD) Beneficiaries (§§ 422.50, 422.52, and 422.110)

The Cures Act (Pub. L. 114–255) amended sections 1851, 1852, and 1853 of the Act to expand enrollment options for individuals with end stage renal disease (ESRD) and make associated payment and coverage changes to the MA and original Medicare programs. Specifically, since the beginning of the MA program, individuals with ESRD have not been able to enroll in MA plans subject to limited exceptions. Section 17006(a) of the Cures Act removed this prohibition effective for plan years beginning on or after January 1, 2021. We are codifying this change with revisions to §§ 422.50(a)(2), 422.52, and 422.110.

b. Medicare Fee-for-Service (FFS) Coverage of Costs for Kidney Acquisitions for Medicare Advantage (MA) Beneficiaries (§ 422.322)

With this new enrollment option, the Cures Act also made several payment changes in the MA and original Medicare FFS programs. Section 17006(c) of the Cures Act amended section 1852(a)(1)(B)(i) of the Act to exclude coverage for organ acquisitions for kidney transplants from the Medicare benefits an MA plan is required to cover for an MA enrollee, including as covered under section 1881(d) of the Act. Effective January 1, 2021, these costs will be covered under the original Medicare FFS program. Section 17006(c)(2) of the Cures Act also amended section 1851(i) of the Act, providing that CMS may pay an entity other than the MA organization that offers the plan in which the individual is enrolled for expenses for organ

[1] These include the following BBA of 2018 provisions: Improvements to Care Management Requirements for Special Needs Plans (SNPs); Coverage Gap Discount Program Updates; and Part D Income Related Monthly Adjustment Amount (IRMAA) Calculation Update for Part D Premium Amounts.

acquisitions for kidney transplants described in section 1852(a)(1)(B)(i) of the Act. We are finalizing changes to our regulation at § 422.322 in accordance with these new statutory requirements.

c. Exclusion of Kidney Acquisition Costs From Medicare Advantage (MA) Benchmarks (§§ 422.258 and 422.306)

Consistent with how the original Medicare FFS program will cover costs of organ acquisitions for kidney transplants for individuals in an MA plan, section 17006(b) of the Cures Act also amended section 1853 of the Act to exclude these costs from the MA benchmarks used in determining payment to MA plans. Specifically, the Secretary, effective January 1, 2021, is required to exclude the estimate of standardized costs for payments for organ acquisitions for kidney transplants from MA benchmarks and capitation rates. We are finalizing changes to our regulations at §§ 422.258(d) and 422.306 in accordance with these new statutory requirements.

d. Medicare Advantage (MA) and Part D Prescription Drug Program Quality Rating System (§§ 422.162, 422.166, 423.182, and 423.186)

In the Medicare Program; Contract Year 2019 Policy and Technical Changes to the Medicare Advantage, Medicare Cost Plan, Medicare Fee-for-Service, the Medicare Prescription Drug Benefit Programs, and the PACE Program Final Rule (CMS–4182–F) (hereinafter referred to as the April 2018 final rule), we codified the methodology for the Star Ratings system for the MA and Part D programs, respectively, at §§ 422.160 through 422.166 and §§ 423.180 through 423.186. We have stated we will propose through rulemaking any changes to the methodology for calculating the ratings, the addition of new measures, and substantive measure changes.

At this time, we are finalizing the increased weight of patient experience/complaints and access measures from 2 to 4. We are also finalizing our proposal to directly remove outliers prior to calculating the cut points to further increase the predictability and stability of the Star Ratings system, but we are delaying the application of outlier deletion until the 2022 measurement year which coincides with the 2024 Star Ratings produced in October 2023. We are also finalizing removal of the Rheumatoid Arthritis Management measure. Finally, we are finalizing the update to the Part D Statin Use in Persons with Diabetes measure weighting category. Unless otherwise stated, data will be collected and performance measured using these rules and regulations for the 2021 measurement period and the 2023 Star Ratings. The remaining Star Ratings provisions of the proposed rule will be addressed later and, therefore, are not being finalized in this rule. Those provisions include codifying additional existing rules for calculating MA Quality Bonus Payments ratings, implementing updates to the Health Outcomes Survey measures, adding new Part C measures, clarifying the rules around consolidations when data are missing due to data integrity concerns, modifying the extreme and uncontrollable circumstance policy for multiple year-affected contracts and to clarify rules when data are missing due to data integrity concerns, and additional technical clarifications.

e. Medical Loss Ratio (MLR) (§§ 422.2420, 422.2440, and 423.2440)

We are finalizing our proposal to amend the MA medical loss ratio (MLR) regulation at § 422.2420 so that the incurred claims portion of the MLR numerator includes all amounts that an MA organization pays (including under capitation contracts) for covered services. Currently, incurred claims in the MLR numerator include direct claims paid to providers (including under capitation contracts with physicians) for covered services furnished to all enrollees under an MA contract. This amendment will also include in the incurred claims portion of the MLR numerator amounts paid for covered services to individuals or entities that do not meet the definition of ''provider'' as defined at § 422.2.

We are finalizing our proposal to codify in our regulations at §§ 422.2440 and 423.2440 the definitions of partial, full, and non-credibility and the credibility factors that CMS published in the May 2013 Medicare Program; Medical Loss Ratio Requirements for the Medicare Advantage and the Medicare Prescription Drug Benefit Programs Final Rule (78 FR 31284) (hereinafter referred to as the May 2013 Medicare MLR final rule). It is more consistent with the policy and principles articulated in Executive Order 13892 on Promoting the Rule of Law Through Transparency and Fairness in Civil Administrative Enforcement and Adjudication (October 9, 2019) that we codify these definitions and factors in the applicable regulations.

Additionally, we are finalizing our proposal to amend § 422.2440 to provide for the application of a deductible factor to the MLR calculation for MA medical savings account (MSA) contracts that receive a credibility adjustment. The deductible factor serves as a multiplier on the applicable credibility adjustment. This additional adjustment for MA MSAs is appropriate because the variability of claims experience is greater under health insurance policies with higher deductibles than under policies with lower deductibles, with high cost or outlier claims representing a larger portion of the overall claims experience of plans with high deductibles. This is the case because high-deductible health plan enrollees' medical expenses must exceed a higher threshold before the plan begins to incur claims costs that can be included in the MLR numerator. The deductible factor reduces the risk that an MSA contract will fail to meet the MLR requirement as a result of random variations in claims experience. We are finalizing our proposal to adopt the same deductible factors that apply under the commercial MLR regulations at 45 CFR part 158.

f. Medicare Advantage (MA) and Cost Plan Network Adequacy (§§ 417.416 and 422.116)

We are strengthening network adequacy rules for MA plans by codifying our existing network adequacy methodology and finalizing policies that address maximum time and distance standards in rural areas, telehealth, and Certificate of Need (CON) laws. The authorization of additional telehealth benefits pursuant to the BBA of 2018 incentivizes new ways for MA plans to cover beneficiary access to health care beginning in 2020. As a result, CMS has been examining its network adequacy standards overall to determine how contracted telehealth providers should be considered when evaluating the adequacy of an MA plan network. In order to expand access to MA plans where network development can be challenging, we are reducing the percentage of beneficiaries that must reside within the maximum time and distance standards in non-urban counties (Micro, Rural, and Counties with Extreme Access Considerations (CEAC) county type designations) from 90 percent to 85 percent in order for an MA plan to comply with network adequacy standards. Also, MA plans will be eligible to receive a 10-percentage point credit towards the percentage of beneficiaries residing within published time and distance standards when they contract with telehealth providers in the following provider specialty types: Dermatology, Psychiatry, Cardiology, Otolaryngology, Neurology, Ophthalmology, Allergy and Immunology, Nephrology, Primary Care,

Gynecology/OB/GYN, Endocrinology, and Infectious Diseases. Additionally, MA organizations may also receive a 10-percentage point credit towards the percentage of beneficiaries residing within published time and distance standards for affected provider and facility types in states that have CON laws, or other state imposed anti-competitive restrictions, that limit the number of providers or facilities in a county or state. We solicited comments from stakeholders on various aspects of our proposal, which informed the network adequacy methodology adopted in this final rule.

g. Special Election Periods (SEPs) for Exceptional Conditions (§§ 422.62, 422.68, 423.38, and 423.40)

Sections 1851(e)(4) and 1860D–1(b)(3) of the Act establish special election periods (SEPs) during which, if certain circumstances exist, an individual may request enrollment in, or disenrollment from, MA and Part D plans. The Secretary also has the authority to create SEPs for individuals who meet other exceptional conditions. We are codifying a number of SEPs that we have adopted and implemented through subregulatory guidance as exceptional circumstances SEPs. Codifying our current policy for these SEPs provides transparency and stability to the MA and Part D programs by ensuring that these SEPs are known and changed only through additional rulemaking. Among the finalized SEPs are the SEP for Government Entity-Declared Disaster or Other Emergency, the SEP for Employer/Union Group Health Plan (EGHP) elections, and the SEP for Individuals Who Disenroll in Connection with a CMS Sanction. We are also establishing two additional SEPs for exceptional circumstances: The SEP for Individuals Enrolled in a Plan Placed in Receivership and the SEP for Individuals Enrolled in a Plan that has been identified by CMS as a Consistent Poor Performer.

3. Summary of Costs and Benefits

Provision	Description	Impact
Medicare Advantage (MA) Plan Options for End-Stage Renal Disease (ESRD) Beneficiaries (§§ 422.50, 422.52, and 422.110).	CMS is codifying requirements under section 17006 of the Cures Act. Effective for the plan year beginning January 1, 2021, CMS is removing the prohibition on beneficiaries with ESRD enrolling in an MA plan.	To estimate the impact, we used a pre-statute baseline. The analysis shows that removing the prohibition for ESRD beneficiaries to enroll in MA plans results in net costs to the Medicare Trust Funds ranging from $23 million in 2021 to $440 million in 2030.
Medicare Fee-for-Service (FFS) Coverage of Costs for Kidney Acquisitions for Medicare Advantage (MA) Beneficiaries (§ 422.322).	CMS is codifying requirements under section 17006 of the Cures Act. Effective for the plan year beginning January 1, 2021, CMS is finalizing that MA organizations will no longer be responsible for costs for organ acquisitions for kidney transplants for their beneficiaries. Instead, Medicare FFS will cover the kidney acquisition costs for MA beneficiaries, effective 2021.	To estimate the impact, we used a pre-statute baseline. This analysis shows that FFS coverage of kidney acquisition costs for MA beneficiaries results in net costs to the Medicare Trust Funds ranging from $212 million in 2021 to $981 million in 2030.
Exclusion of Kidney Acquisition Costs from Medicare Advantage (MA) Benchmarks (§§ 422.258 and 422.306).	CMS is codifying requirements under section 17006 of the Cures Act. Effective for the plan year beginning January 1, 2021, CMS is removing costs for organ acquisitions for kidney transplants from the calculation of MA benchmarks and annual capitation rates.	To estimate the impact, we used a pre-statute baseline. This analysis shows that excluding kidney acquisition costs from MA benchmarks results in net savings estimated to range from $594 million in 2021 to $1,346 million in 2030.
Medicare Advantage (MA) and Part D Prescription Drug Program Quality Rating System (§§ 422.162, 422.166, 423.182, and 423.186).	CMS is finalizing an increase in the weight of patient experience/complaints and access measures. CMS is also finalizing the use of Tukey outlier deletion, which is a standard statistical methodology for removing outliers, to increase the stability and predictability of the star measure cut points. However, the application of Tukey outlier deletion will be delayed until the 2024 Star Ratings.	Updating the patient experience/complaints and access measures weight creates a cost which is offset after the first year by using the Tukey outlier deletion. The net cost to the Medicare Trust Fund from the increased weight is $345.1 million in 2024; the net savings from both the increased weight and Tukey outlier deletion will grow over time reaching $999.4 million by 2030. The net reduction in spending to the Medicare Trust Fund through and including 2030 is $4.1 billion.

Provision	Description	Impact
Medical Loss Ratio (MLR) (§§ 422.2420, 422.2440, and 423.2440).	CMS is finalizing our three proposed amendments to the Medicare MLR regulations. (1) We will allow MA organizations to include in the MLR numerator as ''incurred claims'' all amounts paid for covered services, including amounts paid to individuals or entities that do not meet the definition of ''provider'' at § 422.2. (2) We also are codifying our definitions of partial, full, and non-credibility and credibility factors that CMS published in the May 2013 Medicare MLR final rule (78 FR 31296) for MA and Part D MLRs. (3) We are finalizing our proposal to apply a deductible factor to the MLR calculation for MA MSA contracts receiving a credibility adjustment. The deductible factor, which functions as a multiplier on the credibility adjustment factor, is calibrated so that the probability that a contract will fail to meet the MLR requirement is the same for all contracts that receive a credibility adjustment, regardless of the deductible level.	(1) Our change to the type of expenditures that can be included in ''incurred claims'' will have neutral dollar impact on the Medicare Trust Fund. These provisions will result in a transfer of funds from the Treasury, through the Medicare Trust Fund, to MA organizations. This transfer will take the form of a reduction in the remittance amounts withheld from MA capitated payments. The amount of this transfer is $35 to $55 million a year, resulting in plans obtaining $455 million over 10 years. (2) Codifying the definitions of partial, full, and non-credibility and the credibility factors is unlikely to have any impact on the Medicare Trust Fund. (3) The deductible factor to the MLR calculation for MA MSA contracts is estimated to result in a gradually increasing cost to the Medicare Trust Fund of $1 to $6 million per year, arising from the Trust Fund paying for benefits due to expected increased enrollment, and will result in a $40 million cost through, and including, 2030.
Medicare Advantage (MA) and Cost Plan Network Adequacy (§§ 417.416 and 422.116).	CMS is—(1) strengthening network adequacy rules for MA and cost plans and to make them more transparent to plans by codifying our existing network adequacy methodology and standards, with some modifications; (2) allowing MA plans to receive a 10-percentage point credit towards the percentage of beneficiaries residing within published time and distance standards when they contract with certain telehealth providers; (3) allowing MA organizations to receive a 10-percentage point credit towards the percentage of beneficiaries residing within published time and distance standards for affected provider and facility types in states that have CON laws, or other state imposed anti-competitive restrictions, that limit the number of providers or facilities in a county or state where CMS has not already customized the standards for that area; and (4) reducing the required percentage of beneficiaries residing within maximum time and distance standards in certain county types (Micro, Rural, and CEAC).	Changes to network standards are unlikely to have any impact on the Medicare Trust Fund.
Special Election Periods (SEPs) for Exceptional Conditions (§§ 422.62, 422.68, 423.38, and 423.40).	CMS is codifying a number of SEPs adopted and implemented through subregulatory guidance as exceptional circumstances SEPs. CMS is also establishing two new SEPs for exceptional circumstances: The SEP for Individuals Enrolled in a Plan Placed in Receivership and the SEP for Individuals Enrolled in a Plan that has been identified by CMS as a Consistent Poor Performer.	This provision codifies existing practice since MA organizations and Part D plan sponsors are currently assessing applicants' eligibility for election periods as part of existing enrollment processes. Consequently, the provision will not have added impact.

B. Background

We received approximately 490 timely pieces of correspondence containing multiple comments on the provisions implemented within this final rule from the proposed rule titled ''Medicare and Medicaid Programs; Contract Year 2021 and 2022 Policy and Technical Changes to the Medicare Advantage Program, Medicare Prescription Drug Benefit Program, Medicaid Program, Medicare Cost Plan Program, and Programs of All-Inclusive Care for the Elderly'' which published February 18, 2020, in the **Federal Register** (85 FR 9002). Comments were submitted by MA health plans, Part D sponsors, MA and beneficiary advocacy groups, trade associations, providers, pharmacies and drug companies, states, telehealth and health technology organizations, policy research organizations, actuarial and law firms, MACPAC, MedPAC, and other vendor and professional associations.

The proposals we are finalizing in this final rule range from minor clarifications to more significant modifications based the comments received. As noted previously, we intend to address the proposals from the February 2020 proposed rule that are not included in this final rule in subsequent rulemaking. Summaries of the public comments received and our responses to those public comments are set forth in the various sections of this final rule under the appropriate headings. We also note that some of the public comments received for the provisions implemented in this final rule were outside of the scope of the proposed rule. For example, we received comments about how much MA organizations pay network providers, and comments that recommend CMS adopt completely new Star Ratings measures or change HEDIS

measures during the COVID–19 pandemic. CMS did not make any proposals in the February 2020 proposed rule on these topics, and as such, those out-of-scope public comments are not addressed in this final rule. However, we note that in this final rule we are not addressing comments received with respect to the other provisions of the February 2020 proposed rule that we are not finalizing at this time. Rather, we will address these comments in subsequent rulemaking, as appropriate.

II. Implementation of Certain Provisions of the Bipartisan Budget Act of 2018

A. Special Supplemental Benefits for the Chronically Ill (SSBCI) (§ 422.102)

The BBA of 2018 (Pub. L. 115–123) was signed into law on February 9, 2018. The law included new authorities concerning supplemental benefits that may be offered to chronically ill enrollees in Medicare Advantage (MA) plans, specifically amending section 1852(a)(3) of the Act to add a new subparagraph (D) authorizing a new category of supplemental benefits that may be offered by MA plans. We discussed this new authority in the April 2018 final rule (83 FR 16481 through 16483).[2] We proposed to codify the existing guidance (April 2019 Health Plan Management System (HPMS) Memo [3] and the 2020 Call Letter [4]) and parameters for these special supplemental benefits for chronically ill enrollees at § 422.102(f) to implement section 1852(a)(3)(D) of the Act.

Specifically, the BBA of 2018 amended section 1852(a)(3) of the Act to: (1) Authorize MA plans to provide additional supplemental benefits that have a reasonable expectation of improving or maintaining the health or overall function of the chronically ill enrollee to chronically ill enrollees; (2) permit those additional supplemental benefits to be not primarily health related; (3) define ''chronically ill enrollee'' to limit eligibility for these additional supplemental benefits; and (4) authorize CMS to waive uniformity requirements in connection with providing these benefits to eligible chronically ill enrollees. We refer to these benefits hereafter as Special Supplemental Benefits for the Chronically Ill (SSBCI). The heading for new subparagraph (D) of section 1852(a)(3) of the Act, as added by the BBA, states, ''Expanding supplemental benefits to meet the needs of chronically ill enrollees.'' Consistent with this text, we interpret the intent of this new category of supplemental benefits as enabling MA plans to better tailor benefit offerings, address gaps in care, and improve health outcomes for the chronically ill enrollee population.

Section 1852(a)(3)(D)(ii) of the Act, as amended, defines a chronically ill enrollee as an individual who—

- Has one or more comorbid and medically complex chronic conditions that is life threatening or significantly limits the overall health or function of the enrollee;
- Has a high risk of hospitalization or other adverse health outcomes; and
- Requires intensive care coordination.

Thus, with respect to SSBCI benefits, at § 422.102(f)(1)(i), we proposed to codify this definition of a chronically ill enrollee. Section 1859(f)(9) of the Act requires us to convene a panel of clinical advisors to establish and update a list of conditions that meet the definition of a severe or disabling chronic condition under section 1859(b)(6)(B)(iii) of the Act, which provides how having such a condition is an eligibility criterion for enrollment in a chronic care special needs plan. The standard for severe or disabling chronic condition under section 1859(b)(6)(B)(iii) of the Act is substantially similar to the criterion used in defining ''chronically ill enrollee'' for purposes of SSBCI eligibility. We proposed that MA plans may consider any enrollee with a condition identified on this list to meet the statutory criterion of having one or more comorbid and medically complex chronic conditions that is life threatening or significantly limits the overall health or function of the enrollee. Further, an MA plan may consider any chronic condition not identified on this list if that condition is life threatening or significantly limits the overall health or function of the enrollee. We explained that our proposal was based on our policy goal of allowing MA plans the flexibility to continue to innovate around providing care for their specific plan populations. This includes targeted chronic conditions. We stated that we recognize that there may be some conditions or a subset of conditions in a plan population that may meet the statutory definition of a chronic condition (for purposes of the statutory definition of a chronically ill enrollee), but may not be present on the list. To encourage plans to identify needs within their unique plan population and to avoid preventing a plan from addressing a condition or need in their population that may not be on the list, we proposed regulation text permitting us to publish a non-exhaustive list of medically complex chronic conditions as determined by the panel as described in section 1859(b)(6)(B)(iii) to be life threatening or significantly limit the overall health or function of an individual. This was proposed at § 422.102(f)(1)(i)(B).

As we explained in the proposed rule, we did not propose that MA plans be required to submit to CMS the processes used to identify chronically ill enrollees that meet the three pronged definition of chronically ill enrollee.

However, plans should describe the chronic conditions for which they will offer SSBCI in the notes field in the plan benefit package submitted to CMS. We emphasized that all three criteria must be met for an enrollee to be eligible for the SSBCI authorized under section 1852(a)(3)(D) of the Act. In subregulatory guidance (April 2019 HPMS Memo and the 2020 Call Letter), CMS noted that we expect MA plans to document their determinations about an enrollee's eligibility for SSBCI based on the statutory definition. We proposed to codify this as a requirement at § 422.102(f)(3)(ii). In addition, we also proposed at § 422.102(f)(3)(ii) to require plans to make information and documentation (for example, copies of the internal policies used to make the determinations, etc.) related to determining enrollee eligibility as a chronically ill enrollee available to CMS upon request.

We proposed a definition of SSBCI at paragraph (f)(1)(ii). In addition to limiting the class of enrollees who may be eligible to receive the new SSBCI benefits to the chronically ill, section 1852(a)(3)(D) of the Act requires that the specific supplemental benefit provided under this authority have a reasonable expectation of improving or maintaining the health or overall function of the enrollee. We proposed to codify this statutory requirement as part of the definition of SSBCI. Because SSBCI are supplemental benefits, they must also comply with the criteria for supplemental benefits that we proposed to codify at § 422.100(c)(2)(ii), which was discussed in detail in section VI.F. of the proposed rule. We are not addressing that proposal in this final rule and intend to address it in a future final rule. We considered whether the regulation for SSBCI should explicitly reference those requirements for supplemental benefits (proposed in § 422.100(c)(2)(ii)) to make this clear

[2] *https://www.govinfo.gov/content/pkg/FR-2018-04-16/pdf/2018-07179.pdf.*

[3] *https://www.cms.gov/Medicare/Health-Plans/HealthPlansGenInfo/Downloads/Supplemental_Benefits_Chronically_Ill_HPMS_042419.pdf.*

[4] *https://www.cms.gov/Medicare/Health-Plans/MedicareAdvtgSpecRateStats/Downloads/Announcement2020.pdf.*

and solicited comment on this point. Traditionally, CMS has required supplemental benefits to be benefits that: (1) Are primarily health related; (2) require the MA plan to incur a non-zero medical cost; and (3) are not covered under Medicare Parts A, B or D. In light of the authority in section 1852(a)(3)(D) of the Act for SSBCI, we modified some aspects of this longstanding policy to address SSBCI. First, as the statute provides that SSBCI may be not primarily health related, we proposed specific text on this point in both §§ 422.100(c)(2)(ii) and 422.102(f)(1)(ii). Second, we proposed regulation text at § 422.100(c)(2)(ii)(B) that the requirement that the MA organization incur a non-zero direct medical cost for all supplemental benefits would mean, in the context of SSBCI that are not primarily health related, the MA organization must incur a non-zero direct non-administrative cost for the SSBCI. In all other respects not specifically addressed as part of our proposal, SSBCI would be treated like and subject to the same standards as other supplemental benefits. Although we are not finalizing the requirements for supplemental benefits proposed to be codified at § 422.100(c)(2) in this final rule, we are clarifying that our final rule for SSBCI at § 422.102(f) incorporates these concepts.

Under section 1852(a)(3)(D)(ii)(I) of the Act, SSBCI benefits may include items or services that are not primarily health related. As discussed in detail in section VI.F. of the proposed rule, a primarily health related benefit is an item or service that is used to diagnose, compensate for physical impairments, acts to ameliorate the functional/psychological impact of injuries or health conditions, or reduces avoidable emergency and healthcare utilization. Therefore, at § 422.102(f)(1)(ii), we proposed to codify, as part of the definition, that SSBCI benefits may be non-primarily health related SSBCI benefits. Our proposed regulation text included a cross-reference to the regulation text we proposed at § 422.100(c)(2)(ii) to codify the definition of primarily health related. In the proposed rule, we made clear that in all cases, an SSBCI must have, with respect to a chronically ill enrollee, a reasonable expectation of improving or maintaining the health or overall function of the enrollee. By including it in the definition, we proposed to implement the statutory authority for MA plans to offer both primarily health and non-primarily health related SSBCI. We summarized in the proposed rule how the 2019 HPMS memo provided examples of what could be non-primarily health related SSBCI benefits, depending on the needs and health or overall function of the chronically ill enrollee. Those examples included: Meals (beyond a limited basis), food and produce, transportation for non-medical needs, pest control, indoor air quality and equipment and services, access to community or plan-sponsored programs and events to address enrollee social needs (such as non-fitness club memberships, community or social clubs, park passes, etc.), complementary therapies (offered alongside traditional medical treatment), services supporting self-direction, structural home modifications, and general supports for living (for example, plan-sponsored housing consultations and/or subsidies for rent or assisted living communities or subsidies for utilities such as gas, electric, and water). We stated in the proposed rule that the 2019 HPMS memo this guidance was equally applicable to our proposed regulation and part of how we intended our proposed regulation to be implemented and enforced.

We explained in the proposed rule another way that the statutory authority for SSBCI to be not primarily health related would be part of our proposed regulation. Unlike with traditional supplemental benefits, MA plans might not incur direct medical costs in furnishing or covering SSBCI. In the CY 2020 Call Letter, we issued guidance that so long as an MA plan incurs a non-zero non-administrative cost in connection with SSBCI, the benefits would be considered to meet this standard. As supplemental benefits, SSBCI may also take the same form as traditional supplemental benefits. For example, reductions in cost sharing for benefits under the original Medicare fee-for-service program are an allowable supplemental benefit, as reflected in the definitions of mandatory supplemental benefit in § 422.2. Thus, we stated in the proposed rule that SSBCI can be in the form of—

- Reduced cost sharing for Medicare covered benefits (such as to improve utilization of high-value services that meet the definition of SSBCI);
- Reduced cost sharing for primarily health related supplemental benefits;
- Additional primarily health related supplemental benefits; or
- Additional non-primarily health related supplemental benefits.

Eligibility for SSBCI must be determined based on identifying the enrollee as a chronically ill enrollee, using the statutory definition, and if the item or service has a reasonable expectation of improving or maintaining the health or overall function of the enrollee. In the April 2019 HPMS memo CMS clarified that MA plans can provide non-primarily health related supplemental benefits that address chronically ill enrollees' social determinants of health so long as the benefits maintain or improve the health or function of that chronically ill enrollee. MA plans may consider social determinants when determining eligibility for an SSBCI of health as a factor to help identify chronically ill enrollees whose health could be improved or maintained with SSBCI. However, MA plans may not use social determinants of health as the sole basis for determining eligibility for SSBCI. We proposed to codify (at § 422.102(f)(2)(iii)) the ability of an MA plan to consider social determinants (for example, food and housing insecurity) when determining whether an SSBCI benefit is likely to improve or maintain the health of a chronically ill enrollee,

We also explained how our proposal addressed the statutory authority to waive uniformity for an MA plan to offer SSBCI. Generally, § 422.100(d) and other regulations require all MA plan benefits to be offered uniformly to all enrollees residing in the service area of the plan. As explained in the April 2018 final rule (83 FR 16480 through 16485), MA plans may also provide access to services (or specific cost sharing or deductibles for specific benefits) that are tied to a disease state in a manner that ensures that similarly situated individuals are treated uniformly. Section 1852(a)(3)(D)(ii)(II) of the Act authorizes CMS to waive the uniformity requirements generally applicable to benefits covered by MA plans with respect to SSBCI, effective in CY 2020. As discussed in the April 2018 final rule (83 FR 16481 and 16482), this gives CMS the authority to allow MA plans to offer chronically ill enrollees supplemental benefits that are not uniform across the entire population of chronically ill enrollees in the MA plan and may vary SSBCI offered to the chronically ill as a specific SSBCI relates to the individual enrollee's specific medical condition and needs. We proposed to codify the authority for this waiver at § 422.102(f)(2)(ii) such that upon approval by CMS, an MA plan may offer non-uniform SSBCI.

In both the CY 2020 Call Letter and the April 2019 HPMS memo, we explained how we expect MA plans to: (i) Have written policies based on objective criteria (for example, health risk assessments, review of claims data, etc.) for determining SSBCI eligibility to receive a particular SSBCI benefit; (ii) document these criteria; and (iii) make

this information available to CMS upon request. We also proposed to codify requirements at § 422.102(f)(3)(iii) and (iv) for MA plans that offer SSBCI to have written policies based on objective criteria, document those criteria, to document each determination that an enrollee is eligible to receive an SSBCI, and to make this information available to CMS upon request. We explained in the proposed rule that objective criteria are necessary to address potential beneficiary appeals, complaints, and/or general oversight activities performed by CMS. We also proposed, at § 422.102(f)(3)(i), to require plans to have written policies for determining enrollee eligibility and to document its determination that an enrollee is a chronically ill enrollee based on the statutory definition codified in paragraph (f)(1)(i) of this section. We proposed to require plans to make information and documentation related to determining enrollee eligibility available to CMS upon request at § 422.102(f)(3)(ii). We explained in the proposed rule that the determination on the benefits an enrollee is entitled to receive under an MA plan's SSBCI is an organization determination that is subject to the requirements of part 422, subpart M, including the issuance of denial notices to enrollees.

We also explained how the proposal on SSBCI would codify already existing guidance and practices and therefore was not expected to have additional impact above current operating expenses. We also stated our belief that our proposal would not impose any collection of information requirements.

We thank commenters for helping inform CMS' SSBCI policy. We received approximately 62 comments on this proposal; we summarize these comments and our responses as follows:

Comment: A number of commenters supported CMS' proposal to allow MA plans to consider any chronic condition not identified on chronic condition list if that condition is life threatening or significantly limits the overall health or function of the enrollee. A commenter encouraged CMS to continue requiring MA plans to consider any enrollee with a condition identified on list to meet the statutory criterion of having one or more comorbid and medically complex chronic conditions that is life threatening or significantly limits the overall health or function of the enrollee.

Response: We thank commenters for their feedback. In the April 24, 2019 HPMS memo and 2020 Call Letter, CMS indicated that it would consider any enrollee with a condition identified as a chronic condition in section 20.1.2 of Chapter 16b of the Medicare Managed Care Manual to meet the statutory criterion of having one or more comorbid and medically complex chronic conditions that is life threatening or significantly limits the overall health or function of the enrollee. This was done in an effort to maintain a consistent standard in CMS policy for what is a chronic condition (for purposes of eligibility for SSBCI and for special needs plans for individuals with a severe or disabling chronic condition).

In this rule, we proposed that MA plans may consider any enrollee with a condition identified on the list of chronic conditions as determined by the panel as described in section 1859(b)(6)(B)(iii) to meet the statutory criterion of having one or more comorbid and medically complex chronic conditions that is life threatening or significantly limits the overall health or function of the enrollee in an effort to also maintain this consistency. However, we recognize that there may be some conditions and/or a subset of conditions in a plan population that may meet the statutory definition of a chronic condition, but the chronic condition may not be present on the list of medically complex chronic conditions. Therefore, we also proposed that a plan may identify an enrollee as meeting this first criterion of the definition of chronically ill enrollee—that the enrollee have one or more comorbid and medically complex chronic conditions that is life threatening or significantly limits the overall health or function of the enrollee—using a condition that is not on that list so long as the statutory (and proposed regulatory) standards are met. As stated in the proposed rule, we want to allow plans the flexibility to identify needs within their unique plan population and do not want to inadvertently prevent a plan from addressing a condition or need in their population that may not be on the list. We wish to allow plans the flexibility to continue to innovate around providing care for their specific plan populations. Thus, we are finalizing this aspect of our proposal, which is reflected in how § 422.102(f)(1)(i)(B) provides that the list published by CMS is a non-exhaustive list. We reiterate that, as we proposed, we intend this list to be the list of severe or disabling chronic conditions developed by the panel of technical advisors convened in accordance with section 1859(f)(9)(A)(i) of the Act. In addition to having one or more comorbid and medically complex conditions that is life threatening or significantly limits overall health and function, an enrollee must also have a high risk of hospitalization and require intensive care coordination to be considered chronically ill. Additionally, the covered item or service must have a reasonable expectation of improving or maintaining the health or overall function of the chronically ill enrollee.

Comment: Some commenters requested CMS provide additional guidance concerning the definition of the phrase ''intensive care coordination'' as it is used in the regulation.

Response: We expect MA plans to develop objective criteria (for example, health risk assessments, review of claims data, etc.) in determining SSBCI eligibility. We are not adopting a specific definition or standard for the statutory requirement that the chronically ill enrollee require intensive care coordination as the phrase is sufficiently clear for MA organizations to develop reasonable approaches in determining when it is met. We believe that objective criteria for determining what constitutes intensive care coordination are present in the medical community and readily accessible to the plan, such as the expertise of the plan medical director and plan physicians. We believe MA plans should have flexibility to determine what objective criteria to use when determining what meets the intensive care coordination criterion in their plan populations. However, we will keep this recommendation under advisement as we gain experience with SSBCI offerings.

Comment: A few commenters requested CMS allow plans to use functional status, rather than medical diagnoses, to determine whether an enrollee is eligible for SSBCI. A commenter stated that individuals with the same diagnosis may have different functional limitations and therefore different needs.

Response: We thank commenters for their feedback. We note that for the purposes of SSBCI, the statute requires the enrollee to have a chronic condition(s) that is life threatening or limits the overall health and function of an enrollee; this is in addition to the requirements that the enrollee have a high risk of hospitalization or other adverse health outcomes and require intensive care coordination to be eligible for SSBCI. Two of the required criteria refer to the function of the enrollee, so we believe it is sufficiently clear that this is something that can be considered when determining if an enrollee is a chronically ill enrollee.

Once meeting the criteria to be a chronically ill enrollee, and therefore eligible for SSBCI, the statute and our implementing regulation permit SSBCI that are designed to address the functional status of the enrollee. As discussed in the proposed rule, SSBCI must have a reasonable expectation of improving or maintaining the health or overall function of the enrollee. Thus, a plan may choose to provide an SSBCI that improves or maintains overall function of an enrollee who is eligible for SSBCI per the three-pronged definition.

Comment: Some commenters expressed concern that the new SSBCI policies could potentially undermine the role of SNPs in the Medicare Advantage program.

Response: SNPs are specifically designed to provide targeted care to special needs individuals. SNPs offer a wider array of specific interventions regarding their targeted population. Additionally, SNPs are required to develop and implement an evidence based model of care that provides structure for care management processes and systems that enables the plan to provide coordinated care for special needs individuals. We do not believe that the availability of SSBCI as permissible supplemental benefits undermines the specialized care model that SNPs provide. We believe that the MA program and the diverse needs of Medicare population have room for MA plans that are designed, as a whole, to address special needs populations and for specific benefits designed to improve or maintain the health or overall function of a specific chronically ill enrollee.

Comment: Some commenters expressed concern that the new benefit flexibilities, including the different eligibility requirements, could confuse enrollees.

Response: MA plans are required to provide enrollees with information on covered benefits, including SSBCI if the MA plan offers them, each year through the Annual Notice of Change (ANOC) and Evidence of Coverage (EOC) documents. In addition, MA organizations must comply with the marketing and communications regulations in part 422, subpart V, when issuing any information regarding SSBCI to enrollees; these include prohibitions on MA organizations misleading beneficiaries, providing information that inaccurate, or engaging in activities that confuse beneficiaries. Consistent with MCMG requirements, it is our expectation that plans communicate information on SSBCI to enrollees in a clear manner about the scope of SSBCI that the MA plan covers and who is eligible for those benefits.

Comment: Several commenters requested that CMS ensure that these new benefit flexibilities for the chronically ill do not lead to discrimination against high-need beneficiaries.

Response: We thank commenters for sharing their concerns. We note that section 1852(b)(1)(A) of the Act prohibits an MA plan from denying, limiting, or conditioning the coverage or provision of a service or benefit based on health-status related factors. MA regulations (for example, §§ 422.100(f)(2) and 422.110(a)) reiterate and implement this non-discrimination requirement. In interpreting these obligations to protect against discrimination, we have historically indicated that the purpose of the requirements is to protect high-acuity enrollees from adverse treatment on the basis of their higher cost health conditions (79 FR 29843; 76 FR 21432; and 74 FR 54634). As MA plans implement these benefit flexibilities for SSBCI, they must be mindful of ensuring compliance with non-discrimination responsibilities and obligations.[5] Additionally, CMS reviews benefit designs to make sure that the overall impact is non-discriminatory and that higher acuity, higher cost enrollees are not being excluded in favor of healthier populations. Additionally, we believe it is important to note that in order to be eligible for SSBCI an enrollee must as stated above (1) have one or more comorbid and medically complex chronic conditions that is life threatening or significantly limits the overall health or function of the enrollee; (2) have a high risk of hospitalization or other adverse health outcomes; and (3) require intensive care coordination. It is only enrollees with chronic conditions, as described by the three pronged definition above, that are eligible for these benefits. Thus, it is these individuals who are intended to receive these special benefits.

Comment: Commenters also requested CMS provide additional subregulatory guidance on SSBCI and supplemental benefits in general, including updating Managed Care Manuals. Although characterized as being in response to the proposal to change the costs that may be included in the definition of ''incurred costs'' for MLR purposes (addressed in section V.I. of the proposed rule and section IV.D of this final rule), other commenters noted how SSBCI are not always delivered by medical providers.

Response: We believe that our discussion in the proposed rule explaining the proposal we are finalizing provides extensive guidance for MA organizations on this topic. The April 2019 HPMS Memo and CY 2020 Call Letter address SSBCI and that guidance is still applicable as § 422.102(f), as proposed and as finalized, codifies significant portions of that guidance. CMS will consider additional subregulatory guidance, including manual updates, as the program develops. Additionally, as discussed in the 2020 Call Letter, we note that MA plans may contract with community-based organizations such as those providing other home and community-based services (HCBS) to provide supplemental benefits, including SSBCI, that are compliant with the statutory and regulatory requirements. For example, an MA plan could elect to offer, as a SSBCI, the provision of meals or food/produce and pay a community-based organization for furnishing the covered benefit. Community-based organizations can also help determine whether an individual meets the eligibility requirements for SSBCI. These organizations may already be providing services in the community and, in some cases, have contractual arrangements with Medicaid managed care or MA plans. We note that some community services programs are funded by the HHS Administration for Community Living (ACL) and utilizing ACL programs would also be permissible in delivering these supplemental benefits. This is consistent with the amendment to § 422.2420, discussed in section III.D.1 of this final rule, to include amounts paid for SSBCI to providers that are not necessarily healthcare professionals as incurred claims in the calculation of the MLR.

Comment: Some commenters requested CMS provide greater detail on allowable SSBCI including meals, transportation, and durable medical equipment (DME).

Response: A non-exhaustive list of examples of non-primarily health related, which includes meals (beyond a limited basis) and non-medical transportation SSBCI can be found in the April 2019 HPMS Memo and this preamble. However, we note the requirements around the SSBCI, which include the statutory authority for the Secretary to waive uniformity requirements and the statutory requirement that SSBCI have a reasonable expectation of improving or

[5] Among these responsibilities and obligations are compliance with Title VI of the Civil Rights Act, section 504 of the Rehabilitation Act, the Age Discrimination Act, section 1557 of the Affordable Care Act, and conscience and religious freedom laws.

maintaining the health or overall function of the chronically ill enrollee, allow significant of flexibility for MA plans to consider the needs of enrollees who meet the high standards in the definition of chronically ill enrollee and to design benefits to assist enrollees at an individualized level. We encourage MA plans to continue to consider the unique needs of their plan populations when proposing items or services that meet SSBCI conditions in their bid and submitted plan benefit package. As explained in the referenced April 2019 HPMS memo, MA plans have broad discretion in developing items and services they may offer as SSBCI provided that the item or service has a *reasonable* expectation of improving or maintaining the health or overall function of the chronically ill enrollee. Under our current guidance and this final rule, MA plans also have broad discretion in determining what may be considered 'a reasonable expectation' when choosing to offer specific items and services as SSBCI so long as the statutory standard is met.

Concerning DME, MA plans are required to ''provide coverage of, by furnishing, arranging for, or making payment for, all services that are covered by Medicare Part A and Part B'' (see 42 CFR 422.101(a)), which includes coverage of durable medical equipment, prosthetics and supplies. As discussed in the referenced HPMS memo, non-Medicare-covered safety devices to prevent injuries in the home or bathroom are considered primarily health related and may be offered as a supplemental benefit to all enrollees for whom the item is medically necessary. We remind MA organizations of our long-standing guidance in Chapter 4 of the Medicare Managed Care Manual about medical necessity in the context of supplemental benefits and how MA plans may develop their own medical necessity policies and procedures, so long as access to and coverage of Part A and Part B benefits is not more restrictive than Original Medicare. Other equipment that is not primarily health related may be considered as an SSBCI if it has a reasonable expectation of improving or maintaining the health or overall function of the chronically ill enrollee.

Comment: A few commenters suggested CMS allow plans to target some services to address social risk factors. A commenter suggested CMS test ways to provide more flexibility in targeting supplemental benefits to address social risk factors like homelessness.

Response: The statute does not authorize MA plans to offer and cover supplemental benefits, even SSBCI, based solely on social risk factors; the statute explicitly provides that eligibility for SSBCI is based on whether an enrollee meets the definition to be a chronically ill enrollee, which does not include a reference to social risk factors. As discussed in this preamble, MA plans can provide non-primarily health related supplemental benefits that address chronically ill enrollees' social determinants of health so long as the benefits have a reasonable expectation of maintaining or improving the health or function of that chronically ill enrollee. MA plans may consider social determinants of health as a factor to help identify chronically ill enrollees whose health could be improved or maintained with SSBCI. However, they may not use social risk factors as the sole basis for determining eligibility for SSBCI. Please note that the current CMS Innovation Center Medicare Advantage Value-Based Insurance Design (VBID) model allows participants to vary supplemental benefits based on chronic condition or socioeconomic status or a combination of the two. MA organizations have the option of participating in this model if they choose.

Comment: Some commenters suggested that information and documentation concerning SSBCI eligibility determinations should be reported more broadly, rather than only made available upon request. A commenter stated that this information would be necessary to better understand the efficacy of offered benefits.

Response: We thank commenters for their suggestions. At this time, we do not wish to place additional reporting burden on plans. However, we will take this comment under advisement as we continue to develop and refine SSBCI policy. Concerning the written policy requirements at § 422.102(f)(3)(i) and (iii), we clarify that these requirements concern the existence of such policies and that we do not intend to regularly review the content for compliance with the substantive standards of the regulation. We are implementing the statutory authority for SSBCI in a way to provide discretion and flexibility for MA plans, consistent with our approach to supplemental benefits design, within the statutory and regulatory limits. Per § 422.102(f)(3)(i), plans are required to have written policies for determining enrollee eligibility. As we explained in the CY 2020 Call Letter, maintaining detailed internal documentation is, at a minimum, necessary to address potential beneficiary appeals and complaints. However, MA organizations will have discretion in developing these policies. Additionally, per § 422.102(f)(3)(iii), plans are required have written policies based on objective criteria for determining a chronically ill enrollee's eligibility to receive a particular SSBCI and must document the criteria. We do not intend to closely monitor or regularly request these documentation and reiterate that MA plans will have discretion in designing which items and services to offer as SSBCI and for which chronically ill enrollees to cover them, so long as the statutory and regulatory standards are met.

Comment: Some commenters expressed concern that SSBCI are not available to individuals enrolled in Original Medicare. Other commenters suggested CMS test a model that includes original Medicare enrollees.

Response: The Balanced Budget Act of 1997 (BBA) authorized CMS to contract with public or private organizations to offer a variety of health plan options for beneficiaries. Under section 1852(a)(3)(D), MA plans are authorized to offer supplemental benefits, including SSBCI. The MA program has historically authorized MA plans to offer some form of additional or supplemental benefits to MA enrollees. Medicare beneficiaries choose to elect either original Medicare or an MA health plan that may have supplemental benefits. Concerning additional models, CMS appreciates this suggestion and will take it under consideration as we consider new Innovation Center models.

Comment: Several commenters suggested CMS study how many beneficiaries actually receive these benefits and not just how many are eligible for them in order to understand the actual impact of these new benefits.

Response: We appreciate this comment and will take this comment under consideration as we monitor how MA plans offer these benefits and continue to develop these policies.

We thank commenters for their feedback.

As discussed in this preamble, because SSBCI are supplemental benefits, they must also comply with our longstanding interpretation of the criteria for supplemental benefits; we also proposed to codify those criteria at § 422.100(c)(2)(ii), which was discussed in detail in section VI.F. of the proposed rule. We considered whether the regulation for SSBCI should explicitly reference the requirements in § 422.100(c)(2)(ii) to make this clear and solicited comment on this point. We received no comments on this specific subject.

After consideration of the comments received and for the reasons outlined in

the proposed rule and our responses to comments, we are finalizing § 422.102(f) largely as proposed. We are finalizing slight revisions to the regulation text, to eliminate a reference to § 422.100(c)(2)(i) in paragraph (f)(1)(ii) which was tied to the proposal regarding § 422.100(c)(2) that is not being addressed in this final rule. We are also correcting a typographical error in paragraph (f)(2)(iii).

B. Contracting Standards for Dual Eligible Special Needs Plan (D–SNP) Look-Alikes (§ 422.514)

Special needs plans (SNPs) are MA plans created by the MMA that are specifically designed to provide targeted care and limit enrollment to individuals with special needs. Under section 1859 of the Act, SNPs are able to restrict enrollment to: (1) Institutionalized individuals, who are currently defined in § 422.2 as those residing or expecting to reside for 90 days or longer in a long term care facility; (2) individuals entitled to medical assistance under a State Plan under Title XIX; or (3) other individuals with certain severe or disabling chronic conditions who would benefit from enrollment in a SNP. As of July 2019, there are 321 SNP contracts with 734 SNP plans that have at least 11 members, including all of the following:

- 480 dual eligible SNPs (D–SNPs).
- 125 institutional SNPs (I–SNPs).
- 129 chronic or disabling condition SNPs (C–SNPs).[6]

Beneficiaries who are dually eligible for both Medicare and Medicaid can face significant challenges in navigating the two programs, which include separate or overlapping benefits and administrative processes. Fragmentation between the two programs can result in a lack of coordination for care delivery, potentially resulting in—(1) missed opportunities to provide appropriate, high-quality care and improve health outcomes; and (2) undesirable outcomes, such as avoidable hospitalizations and poor beneficiary experiences. Advancing policies and programs that integrate care for dually eligible individuals is one way in which we seek to address such fragmentation. Under plans that offer integrated care, dually eligible individuals receive the full array of Medicaid and Medicare benefits through a single delivery system, thereby improving care coordination, quality of care, and beneficiary satisfaction, and reducing administrative burden. Some studies have shown that highly integrated managed care programs perform well on quality of care indicators and enrollee satisfaction.[7]

D–SNPs are intended to integrate or coordinate care for this population more effectively than standard MA plans or the original Medicare fee-for-service program by focusing enrollment and care management on dually eligible individuals. As of July 2019, approximately 2.6 million dually eligible individuals (1 of every 5 dually eligible individuals) were enrolled in 480 D–SNPs.

As summarized in our proposed rule, federal statute and implementing regulations have established several requirements for D–SNPs in addition to those that apply to all MA plans to promote coordination of care, including health risk assessment (HRA) requirements as described in section 1859(f)(5)(A)(ii)(I) of the Act and at § 422.101(f)(1)(i), evidence-based models of care (MOCs) as described in section 1859(f)(5)(A)(i) of the Act and at § 422.101(f), and state Medicaid agency contracts as described in section 1859(f)(3)(D) of the Act and at § 422.107. The state Medicaid agency contracting requirement allows states to require greater integration of Medicare and Medicaid benefits from the D–SNPs in their markets.

More recently, section 50311(b) of the BBA of 2018 amended section 1859 of the Act to add new requirements for D–SNPs, beginning in 2021, including minimum integration standards, coordination of the delivery of Medicare and Medicaid benefits, and unified appeals and grievance procedures for integrated D–SNPs, the last of which we implemented through regulation to apply to D–SNPs with exclusively aligned enrollment, termed ''applicable integrated plans.'' These requirements, along with clarifications to existing regulations, were codified in the April 2019 final rule (84 FR 15680 through 15844).

We discussed in the proposed rule and reiterate here the pattern of federal legislation, CMS rulemaking, and state use of D–SNP contracting requirements has incrementally created new requirements for D–SNPs that have generally promoted additional beneficiary protections, coordination of care, and integration of Medicare and Medicaid coverage for dually eligible individuals. While many of these requirements impose additional burdens for D–SNPs, they have not impeded enrollment growth in these plans. Total D–SNP enrollment has more than doubled from one million in 2010 to 2.6 million in 2019.[8] Participation of MA organizations is robust, and most markets are stable and competitive.

In this final rule, we address the emergence of ''D–SNP look-alike'' plans that are a hindrance to meaningful implementation of statutory requirements for D–SNPs, particularly those connected with the BBA of 2018. As the Medicare Payment Advisory Commission (MedPAC) described in its June 2018 and 2019 reports to Congress and as summarized in the proposed rule, D–SNP look-alikes have levels of dual eligible enrollment that are virtually indistinguishable from those of D–SNPs and far above those of the typical MA plan.

As discussed in the proposed rule, we believe the low enrollment of non-dually eligible individuals in D–SNP look-alikes results from benefits and cost-sharing that, like the benefits and cost-sharing offered by D–SNPs, are designed to attract only dually eligible individuals. In contrast to non-SNP MA plans, both D–SNPs and D–SNP look-alikes allocate a lower percentage of MA rebate dollars received under the bidding process at § 422.266 to reducing Medicare cost-sharing and a higher percentage of rebate dollars to supplemental medical benefits such as dental, hearing, and vision services. With such a benefit design, many D–SNP look-alikes technically require members to pay higher cost sharing for Parts A and B services than most MA plans require, which we believe dissuades most non-dually eligible

[6] Centers for Medicare & Medicaid Services. *SNP Comprehensive Report.* (July 2019) Retrieved from *https://www.cms.gov/Research-Statistics-Data-and-Systems/Statistics-Trends-and-Reports/MCRAdvPartDEnrolData/Special-Needs-Plan-SNP-Data.html.*

[7] See Kim, H., Charlesworth, C.J., McConnell, K.J., Valentine, J.B., and Grabowski, D.C. ''Comparing Care for Dual-Eligibles Across Coverage Models: Empirical Evidence From Oregon'', *Medical Care Research and Review,* (November 15, 2017) 1–17. Retrieved from *http://journals.sagepub.com/doi/abs/10.1177/1077558717740206*;

Anderson, W.L., Feng, Z., & Long, S.K. *Minnesota Managed Care Longitudinal Data Analysis,* prepared for the U.S. Department of Health and Human Services Assistant Secretary for Planning and Evaluation (ASPE) (March 31, 2016). Retrieved from *https://aspe.hhs.gov/report/minnesota-managed-care-longitudinal-data-analysis*;

Health Management Associates. *Value Assessment of the Senior Care Options (SCO) Program* (July 21, 2015). Retrieved from *http://www.mahp.com/wp-content/uploads/2017/04/SCO-White-Paper-HMA-2015_07_20-Final.pdf*; and

Medicare Payment Advisory Committee. ''Chapter 2, Care coordination programs for dual-eligible beneficiaries.'' In *June 2012 Report to Congress: Medicare and Health Care Delivery System* (June 16, 2012). Retrieved from *http://www.medpac.gov/docs/default-source/reports/jun12_entirereport.pdf?sfvrsn=0.*

[8] Centers for Medicare & Medicaid Services. *SNP Comprehensive Report* (July 2010 & July 2019). Retrieved from *https://www.cms.gov/Research-Statistics-Data-and-Systems/Statistics-Trends-and-Reports/MCRAdvPartDEnrolData/Special-Needs-Plan-SNP-Data.html.*

Medicare beneficiaries from enrolling. However, because most dually eligible individuals are Qualified Medicare Beneficiaries (QMBs) who are not required to pay Medicare cost sharing under sections 1848(g)(3) and 1866(a)(1)(A) of the Act, we believe they are not dissuaded from enrolling in these non-D–SNPs by the relatively higher cost sharing. A similar dynamic exists for Part D premiums and high deductibles, both of which are covered by the Part D low-income subsidy that dually eligible individuals receive. We believe that such benefit designs are unattractive for Medicare beneficiaries who are not dually eligible individuals because they would need to cover these costs out-of-pocket. Despite the similarities with D–SNPs in terms of levels of dual eligible enrollment and benefits and cost-sharing design, D–SNP look-alikes are regulated as non-SNP MA plans and are not subject to the federal regulatory and state contracting requirements applicable to D–SNPs.

As summarized in the proposed rule, the proliferation and growth of D–SNP look-alikes raises concerns related to effective implementation of the BBA of 2018 requirements; meaningful integration of Medicare-and Medicaid programs via state Medicaid agency contracting; care coordination through HRAs; evidence-based MOCs; and beneficiary confusion stemming from misleading marketing practices by brokers and agents that misrepresent to dually eligible individuals the characteristics of D–SNP look-alikes. We direct readers to the proposed rule, 85 FR 9018 through 9021, for a more detailed discussion of D–SNP look-alikes and their impact on implementation of D–SNP Medicare and Medicaid integration.

Under our authority to adopt standards implementing the Part C statute and to add contract terms in sections 1856(b) and 1857(e)(1) of the Act, we proposed establishing contracting standards at § 422.514 for MA organizations based on their projected dually eligible enrollment in plan bids or on the proportion of dually eligible enrollees actually enrolled in the MA plan. As discussed in the proposed rule, a high rate of enrollment by dually eligible individuals in a non-D–SNP would allow us to identify non-SNP MA plans that are intended to predominantly enroll dually eligible individuals (that is, D–SNP look-alikes). To prevent the undermining of the statutory and regulatory framework for D–SNPs, we proposed a new regulation precluding CMS from entering into or renewing a contract for an MA plan that an MA organization offers, or proposes to offer, with enrollment of dually eligible individuals that exceeds specific enrollment thresholds (85 FR 9021–9025). We also proposed that the regulation apply in any state where there is a D–SNP or any other plan authorized by CMS to exclusively enroll dually eligible individuals.

As described in our proposal, we would not enter into or renew MA contracts for an MA plan for an upcoming plan year if that MA plan exceeds specific enrollment thresholds for dually eligible individuals. However, MA organizations with plans exceeding the enrollment threshold that also have approved D–SNPs for the following plan year would be permitted to transition dually eligible enrollees from D–SNP look-alikes to D–SNPs for which the individuals are eligible. We proposed this transition process to minimize disruptions to beneficiary coverage and allow enrollees in these D–SNP look-alikes to benefit from the statutory and regulatory care coordination and Medicaid integration requirements. We describe the specific proposed changes to § 422.514 as follows.

We proposed changing the title of § 422.514 by removing the word ''minimum'' because the changes we proposed to § 422.514 reflect an additional type of enrollment requirement beyond the minimum enrollment requirements currently articulated in § 422.514. We also proposed changing the title of paragraph (a) from ''Basic rule'' to ''Minimum enrollment rules'' for clarity due to the proposed change to the scope of § 422.514.

We proposed adding a new paragraph (d) to establish new contract requirements related to dual eligible enrollment. The proposed requirement at paragraph (d) would apply for an MA plan that is not a special needs plan for special needs individuals as defined in § 422.2. We explained our rationale in depth for this approach in the proposed rule.

We proposed to limit the requirement at paragraph (d) to states where there is a D–SNP or any other plan authorized by CMS to exclusively enroll dually eligible individuals, such as Medicare-Medicaid Plans (MMPs). We proposed this limitation because it is only in such states that the implementation of D–SNP requirements necessitates our proposed new contracting requirements. That is, in a state with no D–SNPs or comparable managed care plans like MMPs, the D–SNP requirements have not had any relevance historically, as there are no plans contracted with the state to implement the D–SNP requirements or otherwise integrate Medicare and Medicaid services. Therefore, the operation of a D–SNP look-alike would not have any material impact on the full implementation of federal D–SNP requirements. In such states, the existence of D–SNP look-alikes is not impeding state or federal implementation of any requirements for enhanced care coordination and Medicaid integration by providing a vehicle for MA organizations to avoid compliance with those requirements that are imposed on D–SNPs or comparable managed care plans like MMPs. We also noted the limited number of states—eight, as of July 2019—with no D–SNPs. Therefore, we expressed our belief that it is not critical for our proposed requirements in paragraph (d) to apply in such states. We solicited comment on whether the absence of these data sharing and care coordination requirements for D–SNP look-alikes in states where they could continue to operate under our final rule disadvantages the dually eligible individuals in D–SNP look-alikes and whether we should extend the proposed requirement at paragraph (d) to all states.

We proposed new paragraphs (d)(1) and (2) that would require that CMS not enter into or renew a contract, for plan year 2022 or subsequent years, for an MA plan that is a non-SNP plan that either:

- Projects in its bid submitted under § 422.254 that 80 percent or more of the plan's total enrollment are enrollees entitled to medical assistance under a state plan under Title XIX, or
- Has actual enrollment, as determined by CMS using the January enrollment of the current year, consisting of 80 percent or more of enrollees who are entitled to medical assistance under a state plan under Title XIX, unless the MA plan has been active for less than one year and has enrollment of 200 or fewer individuals at the time of such determination.

We explained that using each enrollment scenario is necessary to ensure that both new D–SNP look-alikes are not offered and that current, or existing, D–SNP look-alikes are not continued. We proposed a threshold for dually eligible enrollment at 80 percent of a non-SNP MA plan's enrollment because it far exceeds the share of dually eligible individuals in any given market and, therefore, would not be the result for any plan that had not intended to achieve high dually eligible enrollment. As detailed in the proposed rule, MedPAC data show that our proposed threshold would have minimal impact on total dually eligible enrollment in non-SNP MA plans.

As discussed in the proposed rule, we considered an alternative discussed by MedPAC in its June 2019 report to Congress for identifying traditional MA plans with predominantly dually eligible enrollment: Setting the bar at the higher of 50 percent dually eligible enrollment or the proportion of dually eligible MA-eligible individuals in the plan service area plus 15 percentage points. We also considered setting a lower threshold for dually eligible enrollment at a point between 50 percent and our 80 percent threshold. However, as explained in the proposed rule, we proposed an enrollment threshold of 80 percent or higher as an indicator that the plan is designed to attract disproportionate dually eligible enrollment because it aligns with MedPAC's 2019 research findings, provides a threshold that would be easier for MA organizations to determine prospectively, and would be operationally easier for CMS to implement. We solicited comment on these alternative enrollment thresholds.

Under our proposal for paragraph (d)(2), we proposed making the annual determination whether an MA organization has a non-SNP MA plan with actual enrollment exceeding the established threshold using the plan's enrollment in January of the current year in order to make such evaluations and issue the necessary information to affected MA organizations sufficiently early in the year for MA organizations to have time to take the necessary steps to adjust other plan offerings before the point at which CMS would decline to renew the contract for an MA plan—which effectively (and as described later in this section) would result in the non-renewal (that is, termination) of the D–SNP look-alike plan benefit package. Proposed paragraph (d)(2) would also limit the prohibition to MA plans that have been active for one or more years and with enrollment greater than 200 individuals at the time of CMS' determination under proposed paragraph (d)(2).

In paragraph (e), we proposed processes and procedures for transitioning individuals who are enrolled in a D–SNP look-alike to another MA–PD plan (or plans) offered by the MA organization to minimize disruption as a result of the prohibition on contract renewal for existing D–SNP look-alikes. Under our proposal, an MA organization with a non-SNP MA plan determined to meet the enrollment threshold in proposed paragraph (d)(2) could transition enrollees into another MA–PD plan (or plans) offered by the same MA organization, as long as any such MA–PD plan meets certain proposed criteria. This proposed transition process would allow MA enrollees to be transitioned from one MA plan offered by an MA organization to another MA–PD plan (or plans) without having to fill out an election form or otherwise indicate their enrollment choice as typically required, but it would also permit the enrollee to make an affirmative choice for another MA plan of his or her choosing.

In proposed paragraph (e)(1), we specified that, for coverage effective January 1 of the next year, the MA organization could only transition individuals from the D–SNP look-alike that is not being renewed into one or more MA plans (including a D–SNP) if such individuals are eligible to enroll in the receiving plan(s) in accordance with §§ 422.50 through 422.53. Thus, the individual would have to reside in the service area of the new plan and otherwise meet eligibility requirements for it. The proposed transition process would allow, but not require, the MA organization to transition dually eligible enrollees from a D–SNP look-alike into one or more D–SNPs offered under the MA organization, or another MA organization that shares the same parent organization as the MA organization, and therefore allow enrollees to benefit not only from continued coverage under the same parent organization but also from the care coordination and Medicaid benefit integration offered by a D–SNP.

We also proposed at paragraphs (e)(1)(i) through (iii) specific criteria for any MA plan to receive enrollment through this transition process to ensure that enrollees receive coverage under their new MA plan that is similarly affordable as the plan that would not be permitted for the next year:

- Under proposed paragraph (e)(1)(i), we would allow a non-renewing D–SNP look-alike to transition enrollment to another non-SNP plan (or plans) only if the resulting total enrollment in each of the MA plans receiving enrollment consists of less than 80 percent dually eligible individuals. SNPs receiving transitioned enrollment would not be subject to this proposed limit on dual eligible enrollment. As described in the proposed rule, the percent of dually eligible individuals in the resulting total enrollment would have to be determined prospectively in order for us to make a timely decision on whether to allow for an MA organization to transition enrollment into a non-SNP MA plan or plans. Under proposed paragraph (e)(3), we would make such determination by adding the cohort of enrollees that the MA organization proposes to enroll into a different non-SNP plan to the April enrollment of the receiving plan and calculating the resulting percent of dually eligible enrollment. As discussed in the proposed rule, we would make this calculation for each non-SNP plan into which the MA organization proposes to transition enrollment in order to ensure that the enrollment transitions do not result in another non-SNP MA plan being treated as a D–SNP look-alike.
- Under proposed paragraph (e)(1)(ii), we would require that any plan receiving transitioned enrollment be an MA–PD plan as defined in § 422.2.
- Under proposed paragraph (e)(1)(iii), any MA plan receiving transitioned enrollment from a D–SNP look-alike would be required to have a combined Part C and D beneficiary premium of $0 after application of the premium subsidy for full subsidy eligible individuals described at § 423.780(a).

As proposed in paragraph (e)(2)(ii), the MA organization would be required to describe changes to MA–PD benefits and provide information about the MA–PD plan into which the individual is enrolled in the Annual Notice of Change (ANOC) that the MA organization must send, consistent with § 422.111(a), (d), and (e) and proposed § 422.2267(e)(3). Consistent with § 422.111(d)(2), enrollees would receive this ANOC describing the change in plan enrollment and any differences in plan enrollment at least 15 days prior to the first day of the annual election period (AEP).

As proposed in paragraph (e)(4), in cases where an MA organization does not transition some or all current enrollees from a D–SNP look-alike plan to one or more of the MA organization's other plans as provided in proposed paragraph (e)(1), it would be required to send affected enrollees a written notice consistent with the non-renewal notice requirements at § 422.506(a)(2).

As discussed in more detail in the proposed rule preamble, this proposed transition process is conceptually similar to ''crosswalk exception'' procedures historically allowed by CMS and proposed at § 422.530 in the notice of proposed rulemaking. However, in contrast to the proposed crosswalk exceptions, our proposal would allow the transition process to apply across legal entities offered by MA organizations under the same parent organization, as well as between non-SNP plans and SNPs. Because this transition process is not the same as the crosswalk process, we proposed to codify it as part of § 422.514.

In the proposed rule, we explained how we also considered an alternative

that would require transitioning any dually eligible individuals into a D–SNP for which they were eligible if such a plan is offered by the MA organization. In addition, we solicited comment on whether additional criteria for the receiving plan are necessary to protect beneficiaries who are affected by this proposed prohibition on renewing MA plans that meet the criteria in proposed § 422.514(d).

We described in the proposed rule our intent for the transition process to take effect in time for D–SNP look-alikes operating in 2020 to utilize the transition process for enrollments to be effective January 1, 2021. This will allow current MA–PD plans that expect to meet the enrollment threshold in proposed paragraph (d)(2) to retain some or all of their current enrollment by transitioning these individuals to other MA–PD plans offered by the same MA organization a year before CMS implements any contracting limitations under this proposal.

Overall, our proposed rule focused on dually eligible individuals as a percentage of an MA plan's total enrollment. We considered using alternative criteria instead of, or in addition to, the percentage of projected or actual dually eligible enrollment, to identify non-SNP MA plans designed to exclusively or predominantly enroll dually eligible individuals. In particular, we considered identifying D–SNP look-alikes by the benefit design these plans typically offer—relatively high Parts A and B cost sharing and a high Part D deductible that make the plans unattractive to Medicare-only beneficiaries, supplemental benefits like dental and hearing services and over-the-counter drugs that mimic typical D–SNP offerings, and a premium for Part D coverage that is fully covered by the Part D low-income subsidy. We also considered using the percentage of MA rebate dollars allocated to buy down Parts A and B cost sharing compared to other supplemental benefits—D–SNP look-alikes typically allocate a greater percentage to the latter—as a way to identify D–SNP look-alikes. We explained in the proposed rule why we did not propose those alternatives but solicited comment on whether these alternative criteria should be used instead of, or in addition to, the criteria for identifying D–SNP look-alikes and applying contracting prohibition.

We received the following comments on these proposed contract requirements and respond to them below:

Comment: Many commenters expressed strong support for our proposal to preclude CMS from entering into or renewing a contract for an MA plan that an MA organization offers, or proposes to offer, with enrollment of dually eligible individuals that exceeds a specific threshold. Several commenters agreed with CMS that D–SNP look-alikes are an impediment to Medicare-Medicaid integration and meaningful implementation of federal and state requirements, including the new statutory requirements for D–SNPs under the BBA of 2018. A commenter appreciated that the proposal would, in most states, ensure that any entity whose enrollment consists mainly of dually eligible individuals follows the standards Congress established for MA plans serving dually eligible individuals. Several commenters agreed with MedPAC's 2018 and 2019 analyses, cited by CMS in the proposed rule preamble, that the proliferation of D–SNP look-alikes negatively impacts integrated care programs for dually eligible individuals. Some commenters believed the proposal would ultimately improve access to integrated care for dually eligible individuals. Several commenters also believed that D–SNPs were in the best position to serve the dually eligible population because of the D–SNP MOC, including care coordination and case management, which is not required of D–SNP look-alikes.

Several commenters also supported the proposed regulation because of their concern about how D–SNP look-alikes operate. A number of commenters expressed concern about D–SNP look-alikes marketing to dually eligible individuals in ways that misrepresent the plans' ability to integrate Medicare and Medicaid services. Several commenters noted that while D–SNP look-alikes advertise that they integrate care, they are not designed to serve the needs of dually eligible individuals nor required to do so. For these reasons, many commenters believed look-alikes confuse dually eligible individuals about their coverage options and lead to beneficiary harm.

Response: We appreciate the widespread support we received for our proposal. Many of the commenters' concerns about D–SNP look-alikes mirror the comments discussed in the 2020 Final Call Letter [9] and summarized in the proposed rule preamble. We believe that the contracting requirement we are finalizing in this rule will address these concerns and ensure the meaningful implementation of the new Medicare-Medicaid integration requirements under the BBA of 2018, along with other state and federal requirements. As discussed in the proposed rule and our responses to other comments, the prohibition will not apply to D–SNP look-alikes in states where there is a D–SNP or plan authorized by CMS to exclusively enroll dually eligible individuals.

Comment: A few commenters expressed support for CMS' efforts to integrate care but had concerns about the proposed contracting standard. Some commenters noted that the proposed rule may disrupt services and benefits for beneficiaries enrolled in D–SNP look-alikes. These commenters cautioned CMS to attend to continuity of care, the nuances of state requirements, and market dynamics as this final rule is implemented.

Response: We thank these commenters for their comments. We believe that the requirements we are finalizing in this rule, described in more detail later in this section, strike a balance between allowing for continuity of care for beneficiaries and promoting integrated care. In particular, as discussed later in this section, we are delaying implementation of D–SNP look-alike contract limitations for one additional year to provide sufficient time for MA organizations to develop and seek approval for new plans, coordinate with state integrated care efforts, and facilitate a transparent and smooth transition of beneficiaries. With a technical clarification described later in this section, we are finalizing our proposed transition approach for D–SNP look-alikes to transition enrollees into an MA plan or plans meeting certain criteria within the same parent organization to promote continuity of care.

Comment: Several commenters opposed our proposal to limit enrollment of dually eligible individuals in non-SNP MA plans. Some commenters noted that D–SNP look-alikes were created in response to states' contracting policies like those of California that restricted D–SNPs. A commenter questioned the need to regulate D–SNP look-alikes, citing the June 2019 MedPAC finding that only a small portion of traditional MA plans have dual eligible enrollment that comprises 80 percent or more of total plan membership.[10]

Some commenters believed that our proposal limited competition between MA plans that could lead to higher

[9] Available at *https://www.cms.gov/Medicare/Health-Plans/MedicareAdvtgSpecRateStats/Announcements-and-Documents.html.*

[10] See *June 2019 MedPAC Report to Congress, Chapter 12* at *http://www.medpac.gov/docs/default-source/reports/jun19_ch12_medpac_reporttocongress_sec.pdf?sfvrsn=0.*

quality, innovative care, additional supplemental benefits, and improved provider network access for dually eligible individuals. A commenter stated that competition from D–SNP look-alikes targeted by our proposal has not hurt D–SNPs, noting that total D–SNP enrollment has more than doubled from one million in 2010 to 2.6 million in 2019.

A few commenters believed that D–SNP look-alikes fill critical gaps in markets where D–SNPs and MMPs are not available. Some commenters also believed that D–SNP look-alikes provide access to supplemental benefits and increased levels of care management, particularly for partial-benefit dually eligible individuals. These commenters were concerned that if the proposed contracting standard was implemented, D–SNP look-alike enrollees would lose access to these benefits and may return to the original Medicare fee-for-service program, which does not coordinate with Medicaid. A few commenters requested that, prior to finalizing any rule on D–SNP look-alikes, CMS perform a more detailed analysis of available options and impacts of the proposal on enrollees, both full- and partial-benefit dually eligible individuals, such as loss of benefits.

Several commenters expressed concern that CMS' proposed contracting standard would unnecessarily limit beneficiary choice. A few commenters requested that CMS explain how the value of choice was taken into account for this proposal. Other commenters encouraged CMS to continue to promote consumer choice and provide dually eligible beneficiaries with an array of plan options that allow individuals to choose how to best meet their health care needs. A commenter noted that the need for beneficiary choice was supported by the June 2018 MedPAC finding that 64 percent of partial-benefit dually eligible MA enrollees were enrolled in traditional MA plans in 2016,[11] and that a large percentage of full-benefit dually eligible individuals passively enrolled in MMPs also have indicated a preference for choice by opting out of MMP enrollment.

Response: We thank the commenters for the feedback on our proposal. We maintain that MA plans with enrollment exclusively, or predominantly, consisting of dually eligible individuals—the principal criterion that distinguishes D–SNPs from other MA plans in statute—should be subject to the federal regulatory and state contracting requirements that are applicable to D–SNPs. We note that, despite D–SNP regulations promulgated since 2006, MA organization participation in the D–SNP program is robust. Most D–SNP enrollment is in markets that feature numerous other plan choices for beneficiaries, and enrollment in D–SNPs has continued to increase. We also note that while state contracting policies may have been the impetus for some sponsors to create D–SNP look-alikes, states are authorized to play a role in coordinating Medicaid benefits with MA plans that exclusively enroll dually eligible individuals, as described in section 164 of MIPPA, which amended section 1859(f) of the Act. Therefore, if our proposal leads to any change in the degree of beneficiary choice, such impact would be marginal, and we believe the benefits from our proposal—described here and in the proposed rule—outweigh any such impact.

We agree with the commenter that D–SNP look-alikes are currently a small number of all MA plans; however, D–SNP look-alikes' growth—both in terms of the number of plans offered and their total enrollment—is concerning, especially given Congress' requirements in the BBA of 2018 to further integrate Medicare and Medicaid benefits through D–SNPs. As noted in our proposed rule preamble, MedPAC found that D–SNP look-alike enrollment in California markets grew from around 5,000 in 2013 to over 95,000 in 2017.[12] MedPAC also explored enrollment trends more broadly, identifying 31 non-SNP plans [13] operating in 2017 in which dually eligible individuals comprised 80 percent or more of total plan enrollment. These 31 plans, which operated in 10 states, included approximately 151,000 enrollees. MedPAC estimated that in 2019 enrollment would increase to 193,000 beneficiaries in 54 D–SNP look-alikes across 13 states.[14]

We acknowledge the commenters' concerns about reducing access to supplemental benefits for D–SNP look-alike members and beneficiary choice, particularly for partial-benefit dually eligible individuals. However, as we stated in the proposed rule, we chose not to propose regulating benefit design to avoid inadvertently diminishing benefit flexibility that genuinely improves competition and beneficiary choice. We also note that most D–SNP look-alike enrollment is in markets that feature numerous other plan choices for beneficiaries, including D–SNPs that offer similar benefits; therefore, D–SNP look-alikes are not generally filling gaps in most of their markets nor significantly contributing to beneficiary choice. The majority of D–SNP look-alikes will be able to transition enrollees into another MA plan under the process described at § 422.514(e) of this final rule; therefore, we project that few D–SNP look-alike enrollees will be enrolled by default in the original Medicare fee-for-service program when this regulation limits the continued offering of a D–SNP look-alike.

We also note the contracting standard that we proposed and are finalizing does not apply to MA plans in states without D–SNPs or other plans authorized by CMS to exclusively enroll dually eligible individuals, further limiting the impact of this provision on access to supplemental benefits or beneficiary choice. Of the seven states that do not contract with D–SNPs or other plans authorized to exclusively enroll dually eligible individuals, only two have D–SNP look-alikes. As discussed in response to other comments on this topic, we will continue to engage with stakeholders to identify issues related to choice and access to supplemental benefits.

Comment: A commenter suggested that CMS work with states to provide multiple integrated care options for dually eligible individuals as an alternative to limiting D–SNP look-alikes. Another commenter requested that if CMS decides to implement the proposal, we should also require states to contract with D–SNPs.

Response: We note that section 164(c)(4) of MIPPA does not in any way obligate states to contract with a D–SNP; therefore, CMS does not have the authority to mandate states to contract with D–SNPs, and states have significant control over the availability of D–SNPs. We generally agree that increasing the number of integrated care options for dually eligible individuals is desirable, and CMS will continue to work with states to identify ways to integrate Medicare and Medicaid benefits in a way that best serves the states' dually eligible population. We also provide technical assistance to states on integration issues, including

[11] See *June 2018 MedPAC Report to Congress, Chapter 9* at *http://medpac.gov/docs/default-source/reports/jun18_ch9_medpacreport_sec.pdf?sfvrsn=0.*

[12] See *June 2018 MedPAC Report to Congress, Chapter 9* at *http://medpac.gov/docs/default-source/reports/jun18_ch9_medpacreport_sec.pdf?sfvrsn=0.*

[13] MedPAC also excluded employer group waiver plans (EGWPs) and a select group of medical savings account (MSA) plans.

[14] See *June 2018 MedPAC Report to Congress, Chapter 9* at *http://medpac.gov/docs/default-source/reports/jun18_ch9_medpacreport_sec.pdf?sfvrsn=0* and *June 2019 MedPAC Report to Congress, Chapter 12* at *http://www.medpac.gov/docs/default-source/reports/jun19_ch12_medpac_reporttocongress_sec.pdf?sfvrsn=0.*

through the Integrated Care Resource Center (see *https://www.integratedcareresourcecenter.com/*).

Comment: Several commenters supported our proposed approach in paragraph (d) to limit the availability of D–SNP look-alikes only in those states where there is a D–SNP or any other plan authorized by CMS to exclusively enroll dually eligible individuals. These commenters stated that look-alikes provide valuable supplemental benefits to dually eligible individuals that would not be available in a traditional MA benefit design in those states without D–SNP or MMP options. Some commenters further agreed with our rationale in the proposed rule that, in states without D–SNPs or comparable managed care plans (like MMPs), the existence of D–SNP look-alikes is not impeding full implementation of D–SNP integration requirements. A number of commenters recommended that our proposal to limit availability of D–SNP look-alikes apply only in counties where there are no D–SNPs or other plans authorized to exclusively enroll dually eligible individuals. A commenter agreed with CMS' observation that operating MA plans in rural areas presents a challenge to MA plan operations, including for D–SNPs. This commenter stated that, in those rural areas without D–SNPs or other plans authorized by CMS to exclusively enroll dually eligible individuals, eliminating MA plan options can harm rather than benefit dually eligible individuals, and in the absence of integrated plan options, access to D–SNP look-alikes should be preserved.

Response: We appreciate these commenters' support of the proposed limit on this policy to states where there is a D–SNP or any other plan authorized by CMS to exclusively enroll dually eligible individuals, such as an MMP. In our proposed rule we noted that, as of July 2019, seven states did not have D–SNPs or other plans authorized by CMS to exclusively enroll dually eligible individuals. In these states, there are no plans contracted with the state to implement the D–SNP requirements or otherwise integrate Medicare and Medicaid services, and therefore the operation of a D–SNP look-alike would not have any immediate material impact on the full implementation of federal D–SNP requirements. In such states, the existence of D–SNP look-alikes is not impeding federal or state implementation of any requirements for enhanced care coordination and Medicaid integration by providing a vehicle for MA organizations to avoid compliance with those requirements that are imposed on D–SNPs or comparable managed care plans like MMPs.

We disagree with the recommendation to further limit the proposed D–SNP look-alike policy to those counties where a D–SNP or comparable managed care plan like an MMP currently exists. From our work with states on Medicare-Medicaid integration, we recognize that states often proceed incrementally, contracting first for integrated managed care plans in certain counties before incorporating more areas or going statewide. We believe that allowing D–SNP look-alikes to precede D–SNPs or other more integrated plans in these markets would hinder expansion of state efforts to expand integrated managed care. In addition, we believe it would be more complicated for CMS to administer, MA organizations to comply with, and consumers to understand, if there was a county-by-county limitation on D–SNP look-alike availability.

With respect to the comments about contracting in rural areas, we understand that operating MA plans, including D–SNPs, can be a challenge in areas where the Medicare population is sparse and establishing networks is difficult. As discussed in section V.A. of this preamble, we are taking steps to improve access to managed care in rural areas through changes in network adequacy assessments. We will continue to monitor the volume of MA plans, including D–SNPs, offered in rural areas.

Comment: A commenter requested that CMS exempt from our proposed dual eligible enrollment rules in paragraph (d) D–SNP look-alikes in states that require the parent organization of the D–SNP to have a Medicaid contract with the state. The commenter expressed concern that implementing the rule as proposed would have an anticompetitive effect of locking out new plan entrants in such states.

Response: We disagree with the commenter that implementing paragraph (d) as proposed would reduce competition by not allowing new plan entrants in those states that limit D–SNP approval to parent organizations that have existing Medicaid contracts. As discussed in our April 2019 final rule in implementing the BBA of 2018, we sought to maintain existing state flexibility to promote integrated care for dually eligible individuals. As discussed earlier in this section, section 164 of MIPPA, which amended section 1859(f)(3)(D) of the Act, does not mandate that states contract with D–SNPs. The ability of states to determine the entities with which they enter into D–SNP contracts has been a core tenet for coordinating care between Medicare and Medicaid. We support efforts by states to further the integration of care coordination continuum and believe that the benefit from such coordination, in fact, increases competition to develop and win integrated products (that is, Medicaid contracts).

Comment: Many commenters stated that the dual eligible enrollment requirement should apply in all states to discourage the proliferation of plans that are not truly integrated and that offer limited or no care coordination. Several commenters noted that D–SNP look-alikes may detract from state efforts to coordinate care for dually eligible individuals, such as managed fee-for-service models. These commenters believed that states that do not contract with D–SNPs or MMPs should be able to exercise oversight and have freedom to set a broader strategy to coordinate care for their dually eligible population without worrying about the proliferation of D–SNP look-alike products. A commenter stated that proliferation of D–SNP look-alikes may discourage states from future contracting with D–SNPs and gives plans no incentive to introduce D–SNPs. This commenter noted that CMS and states need to work together to improve the way they serve dually eligible individuals because such individuals include the highest need, highest cost Medicare and Medicaid beneficiaries, and limiting D–SNP look-alike regulation to only some states impedes progress toward that end.

Response: We appreciate the commenters' perspective on this issue. We believe that our proposal as finalized strikes a balance between prohibiting look-alikes and allowing them to continue in states without D–SNPs or any other plan authorized by CMS to exclusively enroll individuals entitled to medical assistance under a state plan under Title XIX. We do not believe that in such states, the existence of look-alikes is materially impeding state or federal implementation of any requirements for enhanced care coordination and Medicaid integration or providing a vehicle for MA organizations to avoid compliance with those requirements that are imposed on D–SNPs or comparable managed care plans like MMPs. We recognize that substantial enrollment in D–SNP look-alikes in these states can alter the landscape if any of these states decides to begin contracting with D–SNPs. However, we believe state policy can accommodate these changes, for example, by contracting with MA organizations offering look-alikes to offer D–SNPs, enabling the transition of

look-alike enrollees into more integrated plans. We continue to collaborate and work with all states to strengthen integrated care, and we will monitor the penetration of MA plans as we continue to promote integrated care. As discussed in our proposed rule, we believe the limitation on the states where the dual eligible enrollment requirement applies will continue to protect states' ability to contract with plans—including for Medicaid behavioral health services and long-term supports and services (LTSS)—in a manner that promotes integration and coordination of benefits and a more seamless experience for dually eligible individuals in such plans. Therefore, in this final rule, we decline to expand our dual eligible enrollment requirements to plans operating in such states. However, we will continue to monitor D–SNP look-alikes in these states and consult with state officials about their impact on dually eligible individuals and state policy objectives.

Comment: Many commenters requested that CMS clarify whether the proposed 80 percent threshold for dual eligible enrollment in a non-SNP plan included both individuals entitled to full Medicaid benefits and individuals entitled to partial Medicaid benefits, such as state payment of Medicare Part B premiums or payment of Medicare premiums and cost sharing.

Response: Our proposed regulatory language in paragraph (d) regarding ''enrollees who are entitled to medical assistance under a state plan under title XIX'' is the same language used in section 1859(b)(6)(B)(ii) of the Act and in § 422.2 to define the population of special needs individuals D–SNPs may exclusively enroll. This language includes both full- and partial-benefit dually eligible individuals. Therefore, we clarify here that our proposed threshold for dual eligible enrollment—which we are finalizing in this rule—included both full- and partial-benefit dually eligible individuals.

Comment: A commenter recommended that our regulatory language in paragraph (d) be modified to refer to individuals who are ''entitled to and enrolled in medical assistance,'' since plans only know which enrollees actually receive Medicaid benefits, not those whose income levels might qualify them for such benefits.

Response: While we appreciate the commenter's concern, we believe that the language in § 422.514(d)(1) (individuals ''entitled to medical assistance'' under a state plan under Title XIX) sufficiently refers to individuals who have been determined to be entitled to medical assistance by virtue of having been enrolled in medical assistance under a state plan under Title XIX. That is our intent and interpretation of this language in § 422.514(d).

Comment: Some commenters recommended that the final rule not count any partial-benefit dually eligible individuals toward the threshold, while maintaining the threshold at 80 percent, in order to minimize the potential disruption caused by the non-renewal of D–SNP look-alikes, including D–SNP look-alikes in contracts with high Star Ratings. Other commenters supported setting the threshold at 80 percent if it applied only to full-benefit dually eligible individuals. Some commenters recommended that the threshold consist only of the categories of dually eligible individuals who were allowed to enroll in a D–SNP in any given market, defined at either the state or county level.

In contrast, other commenters supported counting enrollment of partial-benefit dually eligible individuals toward the 80 percent threshold. A commenter wrote that exclusion of partial-benefit dually eligible individuals while maintaining the threshold at 80 percent would drastically reduce the number of D–SNP look-alikes captured by the proposed regulation and potentially render the entire proposal ''meaningless.''

Response: We disagree with the recommendation to exclude partial-benefit dually eligible individuals from the enrollment threshold and agree with those commenters who believed such an exclusion would render the proposal less effective. Such an exclusion would allow 32 of the 64 non-SNP MA plans with more than 80 percent enrollment by both full- and partial-benefit dually eligible individuals to continue to operate. These include nine D–SNP look-alikes in states that have D–SNPs or MMPs that only enroll full-benefit dual eligible individuals. Those nine plans would continue to operate if, as suggested by a commenter, we did not count partial-benefit dually eligible individuals towards the threshold only in states that exclude these individuals from D–SNPs and other integrated plans. While partial-benefit dually eligible individuals are not currently eligible to enroll in D–SNPs or MMPs in those states, they have access to other MA plans that are not D–SNP look-alikes. As discussed in the proposed rule, over 98 percent of dually eligible individuals who are enrolled in non-SNP MA plans are in plans that are not D–SNP look-alikes.

The data show that the exclusion of partial-benefit dually eligible individuals would render the proposed regulation ineffective in achieving its primary goal: Preserving the ability of CMS and states to meaningfully implement the BBA of 2018 requirements and to use D–SNPs and other integrated care plans to integrate Medicare and Medicaid for dually eligible individuals.

In addition, exclusion of partial-benefit dually eligible individuals from the threshold would allow any MA organization to design a benefit package and target enrollment for an MA plan that exclusively enrolled partial-benefit dually eligible individuals. Section 1859(b)(6)(B)(ii) of the Act, however, only allows D–SNPs to exclusively enroll dually eligible individuals.

Comment: Some commenters recommended excluding partial-benefit dually eligible individuals from the threshold and put forward a number of rationales for their recommendation. Some commenters stated that partial-benefit dually eligible individuals did not benefit from the coordination of Medicaid benefits provided by D–SNPs or other integrated plans because they were not entitled to receive such benefits. A few commenters also noted that many states exclude partial-benefit dually eligible individuals from D–SNPs or other integrated plans, and therefore excluding partial-benefit dually eligible individuals from the enrollment threshold would ensure the availability of another meaningful plan option to such individuals. A few commenters noted that partial-benefit dually eligible individuals have greater social, functional, and health needs than the broader Medicare population and could benefit from the enhanced care coordination provided by MA plans, including the D–SNP look-alike in which they enrolled. Another commenter requested that CMS provide an analysis of how the proposed regulation would impact areas where partial-benefit dually eligible individuals are not allowed to enroll in D–SNPs or other integrated care options. A commenter that supported inclusion of partial-benefit dually eligible individuals in the 80 percent threshold stated that any CMS decision to exclude such individuals should be accompanied by a reduction in the threshold to capture roughly the same number of D–SNP look-alikes.

Response: We do not find these commenters' arguments persuasive. First, partial-benefit dually eligible individuals benefit from the requirements that SNPs, including D–SNPs, have a MOC that addresses enrollees' needs and perform periodic HRAs precisely because these

individuals have greater social, functional, and health needs. States, through their contracts with D–SNPs, can enhance these care coordination requirements, including for partial-benefit dually eligible individuals. Second, QMBs without full Medicaid benefits, who constitute roughly half of partial-benefit dually eligible individuals nationally, can benefit when D–SNPs, or the Medicaid managed care plans offered under the same parent company in which these individuals are enrolled, pay providers for Medicare cost sharing under a capitation agreement with the state. Such direct and seamless payment of cost sharing can result in an improved experience for providers serving these individuals, which itself may improve access to care for beneficiaries.

Of course, partial-benefit dually eligible individuals cannot benefit from these features of the D–SNP program if the state D–SNP contract excludes these individuals from enrollment, and we recognize that some states using managed care as a platform for integration exclude partial-benefit dually eligible individuals from D–SNPs and other managed care plans. While some states that are using the D–SNP platform for integration only allow full-benefit dually eligible individuals to enroll in D–SNPs, others allow partial-benefit dually eligible individuals to enroll in separate D–SNP plan benefit packages, facilitating integrated care and seamless provision of benefits for both categories of dually eligible individuals. We think that allowing D–SNP look-alikes to continue to enroll partial-benefit dually eligible individuals with no limit would discourage states from taking this approach.

Comment: A number of commenters recommended that we set a lower threshold for the percentage of dually eligible enrollees a non-SNP MA plan could have, either in actual or projected enrollment. These commenters expressed concern that a threshold of 80 percent could be ''gamed'' by MA organizations to keep their dual eligible enrollment just under the ceiling. Some commenters recommended that CMS set the ceiling for dual eligible enrollment at 50 percent, with a commenter citing MACPAC analysis showing faster growth in projected enrollment among MA plans with dual eligible enrollment greater than 50 percent than among those greater than 80 percent. Another commenter recommended a threshold of 60 percent.

Response: We appreciate the concern that CMS establish a threshold that is effective at curtailing D–SNP look-alikes, which we believe threaten to undermine our ability and that of our state partners to implement the higher integration standards under the BBA of 2018. However, as described in the proposed rule, we believe our proposed 80 percent threshold is reasonable because it far exceeds the share of dually eligible individuals in any given market—no market has more than 50 percent dually eligible beneficiaries [15]—and, therefore, would not be the result for any plan that had not intended to achieve high dually eligible enrollment. The 80 percent threshold also captures almost three-quarters of enrollment in non-SNP plans with more than 50 percent dually eligible enrollees. We will monitor for potential gaming after implementation of this final rule by reviewing plan enrollment data, including the Monthly Membership Report, and consider future rulemaking as needed.

Comment: A range of commenters, including MACPAC and MedPAC, supported the proposed 80 percent threshold for projected and actual enrollment. Along with several other commenters, MACPAC and MedPAC urged CMS to monitor levels of MA dual eligible enrollment after implementation to verify that the final rule's requirements remain effective against the proliferation of D–SNP look-alikes.

Response: We thank the commenters for their support and agree that post-implementation monitoring will be important to determine the effectiveness of the rule. We are finalizing the proposed regulatory language regarding the dual eligible enrollment threshold at paragraphs (d)(1)(ii) and (d)(2)(ii) of this final rule and reiterating here that the threshold includes enrollment of all categories of dually eligible individuals, including partial-benefit and full-benefit dually eligible individuals who are actually enrolled in medical assistance under a state plan under Title XIX.

Comment: A commenter requested that we clarify that the 80 percent threshold applies at the plan level (that is, the PBP level) and not at the contract, or ''H number,'' level.

Response: We reiterate here that the 80 percent threshold in paragraphs (d)(1)(ii) and (d)(2)(ii) applies at the plan level and not at the contract, or ''H number,'' level.

Comment: A commenter requested that we specify the data source used to determine the percentage of dually eligible enrollees in a plan subject to the proposed regulation.

Response: We intend to use data and reports on January enrollment and dual eligible status, such as the January Monthly Membership Report, generated by the MARx system (or a similar or successor report) to determine the percentage of dually eligible enrollees.

Comment: Several commenters stated that our proposed regulatory language at § 422.514(d), ''CMS does not enter into or renew a contract under this subpart for an MA plan,'' was confusing since the language references both contracts and plans. These commenters suggested that CMS clarify that it will not approve or renew a specific plan benefit package (PBP), rather than the entire contract, when D–SNP look-alike MA plans meet the 80 percent threshold.

Response: We appreciate the commenters' request for clarification. When an MA organization enters into a contract with CMS to offer MA products, the MA organization can establish multiple PBPs within that one contract, so long as those products are the same type (for example, all HMO or all PPO). We proposed the language at paragraph (d) to accommodate this reality. When an MA organization has multiple plans under one contract, § 422.514(d), read in combination with contract severability rules at § 422.503(e), allows CMS to sever the D–SNP look-alike from the rest of the contract, in effect allowing CMS to renew only the portion of the contract that does not include the D–SNP look-alike. We believe the language at paragraph (d) accurately describes our intent. Therefore, we are finalizing this regulatory language as proposed. In addition, for those circumstances where the D–SNP look-alike is the only PBP offered in the contract, we are finalizing a new paragraph (f) to clarify that we would consider actions taken consistent with paragraph (d) to warrant special consideration to exempt affected MA organizations from the denial of an application for a new contract or service area expansion pursuant to §§ 422.502(b)(3) and (4), 422.503(b)(6) and (7), 422.506(a)(3) and (4), 422.508(c) and (d), and 422.512(e)(1) and (2). In other words, when CMS declines to enter into or renew a contract consistent with paragraph (d), that action does not preclude the impacted MA organizations from applying for a new MA contract or a service area expansion or its board members or trustees from serving another MA organization.

Comment: A commenter recommended that CMS consider defining D–SNP look-alikes as MA organizations that offer a D–SNP and an MA–PD plan under the same contract, with the majority (that is, 50 percent or

[15] *June 2019 MedPAC Report to Congress, Chapter 12* at *http://www.medpac.gov/docs/default-source/reports/jun19_ch12_medpac_reporttocongress_sec.pdf?sfvrsn=0.*

more) of dually eligible beneficiaries enrolled in the MA–PD plan rather than the D–SNP.

Response: While we appreciate the comment, we do not understand the rationale for defining D–SNP look-alikes as MA organizations that have a majority of dually eligible individuals enrolled in an MA–PD plan as compared to a D–SNP offered by the same MA organization. We would be concerned that any such policy would undermine our proposal in two ways. First, it would permit certain organizations to maintain D–SNP look-alikes whenever such plans were coupled with D–SNPs with a larger number of dually eligible individuals, even if the D–SNP is in a different geographic area. Second, it would allow D–SNP look-alikes to continue operating as long as the MA organization did not also offer a D–SNP under the same contract. Therefore, we decline to accept this recommendation.

Comment: A commenter supported CMS' proposal at § 422.514(d)(2) to exempt from the prohibition on D–SNP look-alikes those MA plans that are active for less than one year and with enrollment less than or equal to 200 enrollees at the time of CMS' determination. A few commenters suggested that CMS consider alternative criteria for which new MA plans are exempted from our proposed requirements. A commenter recommended that CMS expand the exemption to plans that had been active three or more years. The commenter believed this change would allow plans to appropriately respond to any unexpected enrollment patterns. Another commenter encouraged CMS to raise the enrollment minimum from 200 enrollees to 500 enrollees to better align with enrollment levels already required for plan viability for Medicare Part D Prescription Drug Plans (PDPs) and reduce administrative burden.

Response: We appreciate the comments, but we do not find the recommended changes to be persuasive. While the minimum enrollment threshold for low enrollment PDPs is higher at 1,000 beneficiaries, we do not believe PDPs are an apt comparison. We believe a better comparison for D–SNP look-alikes is the minimum enrollment threshold for low enrollment SNPs, which is 100 enrollees for plans in existence for three or more years, as outlined in the 2020 Final Call Letter.[16] We proposed a minimum enrollment standard of 200 to allow some additional flexibility for initial enrollment patterns that may not be representative of the longer term enrollment pattern for the plan. Once the initial enrollment period has passed or the number of enrollees during that first year of operation exceeds 200 enrollees, we believe the enrollment profile accurately reflects whether or not the plan was designed to exclusively enroll dually eligible individuals. Therefore, we are finalizing the D–SNP look-alike exemption criteria in this final rule at paragraph (d)(2)(ii) to exempt those D–SNP look-alikes active for less than one year and with enrollment less than or equal to 200 enrollees at the time of CMS' determination using January enrollment of the current year.

Comment: A commenter noted that certain C–SNPs, including ESRD C–SNPs, may enroll a large number of dually eligible individuals and appreciated that we were clear in the proposed preamble that the proposed enrollment threshold for D–SNP look-alikes only applies to non-SNP MA plans.

Response: We welcome the comment's perspective. As we stated in the proposed rule preamble, we proposed applying this requirement only to non-SNP plans to allow for the predominant dually eligible enrollment that characterizes D–SNPs, I–SNPs, and some C–SNPs by virtue of the populations that the statute expressly permits each type of SNP to exclusively enroll. We are finalizing as proposed at paragraph (d) that the prohibition on D–SNP look-alike contracting does not apply to any specialized MA plan for special needs individuals as defined in § 422.2.

Comment: A commenter supported our proposed implementation timing at paragraphs (d)(1) and (2) to allow D–SNP look-alikes operating in 2020 to transition enrollees to other MA plans offered by the D–SNP look-alikes' parent organizations for an effective date of January 1, 2021, and to no longer enter into or renew contracts with D–SNP look-alikes for plan year 2022 and subsequent years. A few commenters suggested that CMS finalize any policy on D–SNP look-alikes in time for plan year 2021 bid preparation, preferably by April 2020, and to ensure a smooth transition for enrollees. Some commenters requested that CMS delay implementation of the proposed changes by requesting a one-year delay, a two-year delay, or by specifically requesting that D–SNP look-alikes be permitted to operate until 2023 or later. A commenter recommended CMS employ an incremental phased-in approach so that plans above the 80 percent enrollment threshold are permitted to continue operating for a longer period of time. Another commenter suggested that, if CMS will not allow at least an additional year for implementation, CMS allow for continuation of certain plans for the 2022 plan year where the MA organization can demonstrate a good faith effort to apply for and implement a compliant D–SNP product. Commenters cited various reasons for delaying implementation, including allowing MA organizations additional time to file applications, gain approval of compliant D–SNP products, facilitate a smooth transition of enrollees, and consider continuity of care, nuances of state requirements, and market dynamics that might conflict with the proposed rule.

A commenter noted that the need for a delay is particularly important in states where plans' ability to create D–SNPs is limited, and several commenters emphasized the need for sufficient time to develop new products, especially to meet state requirements for integrated plans. A few commenters indicated that CMS' proposed timeline did not align with the California Advancing and Innovating Medi-Cal (CalAIM) initiative to integrate Medicare and Medicaid through D–SNPs and Medicaid MLTSS plans. These commenters expressed concern that, under the proposed timeline, D–SNP look-alike enrollees in California could face multiple Medicare plan transitions in a short period of time, which would potentially disrupt care and confuse beneficiaries. These commenters believed that a later implementation timeframe would allow D–SNP look-alikes extra time to implement a transparent process by which beneficiaries can select plans and transition with minimal disruption.

A commenter noted the additional time necessary for approval of new D–SNPs and a coordinated transition process is especially important given the COVID–19 pandemic. Another commenter requested that CMS allow at least two years for dually eligible individuals, MA plans, states, and other stakeholders to review policy options and devise and implement viable alternatives to CMS' proposal to achieve compliance.

Response: We appreciate the comments supporting the proposed implementation timeline, and we agree with many of the comments recommending that we consider delaying the contract limitation for existing D–SNP look-alikes by one year. While we believe the proposed

[16] *https://www.cms.gov/Medicare/Health-Plans/MedicareAdvtgSpecRateStats/Downloads/Announcement2020.pdf.*

implementation timeframe remains feasible, we understand that providing an additional year before CMS declines to renew existing D–SNP look-alike plans would give all states and MA organizations more time to consider and collaborate on a more integrated approach and an appropriate transition for enrollees. However, we disagree with the request to delay the proposed dual eligible enrollment thresholds for at least two years. We believe that delaying our implementation of D–SNP non-renewals for one additional year prior will provide sufficient time for MA organizations to develop and seek approval for new plans, coordinate with state integrated care efforts, and facilitate a transparent and smooth transition of beneficiaries.

Therefore, we are finalizing paragraph (d)(2) to provide that CMS will not renew a contract for a D–SNP look-alike starting for plan year 2023 (rather than plan year 2022 as proposed). For plan year 2023, our determination that plans meet the criteria in paragraph (d)(2) would be based on our assessment of the plan's enrollment in January 2022. This will extend by one year the timeline for CMS to non-renew a contract for any non-SNP plan with actual enrollment consisting of 80 percent or more dually eligible enrollees (with the exception of an MA plan active less than one year and with enrollment of 200 or fewer individuals at the time of the determination). Additionally, we are finalizing paragraph (d)(2) with a slight restructuring of using new paragraphs (d)(2)(i) and (ii) for better organization and clarity.

Comments recommending a delay in implementation were based on MA organizations seeking more time to establish new D–SNPs, ensure smooth beneficiary transitions for existing D–SNP look-alike enrollees, and coordinate transitions with state integrated care approaches. Since these expressed reasons for an implementation delay apply to existing D–SNP look-alikes but not to potential new D–SNP look-alikes that are either in contract application or annual bidding stages, we do not believe there is a need to delay the effective date for the prohibition on CMS not entering into contracts for new D–SNP look-alikes. Implementing the timeline for the prohibition on new D–SNP look-alikes as proposed also avoids the need for additional beneficiary transitions.

We are therefore finalizing our proposal in paragraph (d)(1) that CMS does not enter into a contract—beginning with plan year 2022—for a new MA plan that projects in its bid submitted under § 422.254 that 80 percent or more of its total enrollment are enrollees entitled to medical assistance under a state plan under Title XIX. We are finalizing paragraph (d)(1) with a slight restructuring of using new paragraphs (d)(1)(i) and (ii) for better organization and clarity. We are retaining the proposed date in paragraph (d)(1), despite changing the date in paragraph (d)(2), to prevent the creation of new D–SNP look-alikes in 2022 that CMS would subsequently non-renew one year later. We are also finalizing as proposed the timeline on which MA organizations will be authorized to transition enrollees from a D–SNP look-alike to another plan, proposed at paragraph (e).

The changes to our proposed policy give MA organizations with existing D–SNP look-alikes more time to coordinate with state integrated care approaches and transition enrollees in a thoughtful, transparent manner that minimizes the number of beneficiary transitions. This finalized approach also allows D–SNP look-alikes that are ready to transition their enrollees the ability to do so as soon as 2021 and eliminates the proliferation of new D–SNP look-alikes, beginning in 2022. We are available to provide guidance to any MA organization regarding transition to a new or existing D–SNP and encourage MA organizations to monitor their Monthly Membership Reports to determine if they are approaching or above the allowable threshold for dually eligible enrollees in a non-SNP plan in any state where the contracting limitations under this regulation will apply.

Comment: A commenter noted that if an MA organization has not submitted an application for a D–SNP for contract year 2021, it would not be able to transition D–SNP look-alike enrollees in 2021, as the commenter believed was required under CMS' proposal. This commenter added that some states have not yet clarified which plans will be allowed to offer D–SNPs in specific markets for 2021.

Response: We agree with the commenter that the D–SNPs that will operate in specific markets in plan year 2021 are not yet known and will not be public information until fall 2020. However, we believe this commenter may have misunderstood the timing of our proposal. We proposed to allow, but not require, D–SNP look-alikes operating in 2020 to transition enrollees for an effective date of January 1, 2021, and we proposed that CMS not enter into or renew contracts with D–SNP look-alikes beginning January 1, 2022. As explained earlier in this section, we are finalizing paragraph (d)(2) to allow an additional year—until plan year 2023—before CMS will decline to renew a contract for an existing MA plan that meets our dual eligible enrollment threshold. Under our original proposal, existing D–SNP look-alikes could, but were not required to, transition their enrollees for a January 1, 2021, or a January 1, 2022 effective date before the contract limitation in paragraph (d)(2) requires action by CMS. With our revisions for the final rule, we are also permitting an option for existing D–SNP look-alikes to transition enrollees for a January 1, 2023 effective date. Under the final provisions of § 422.514(d), CMS will permit any new D–SNP look-alike that begins to operate on January 1, 2021 to continue operating until December 31, 2022. However, an MA organization offering such a new D–SNP look-alike could choose to transition its enrollees as early as January 1, 2022. Further, the transition is not required to be only to a D–SNP, so the MA organization operating an existing D–SNP look-alike does not need to apply to offer a D–SNP.

Comment: A number of commenters preferred an alternative discussed in the proposed rule that would require an MA organization to transition any dually eligible individuals enrolled in a non-renewing D–SNP look-alike into a D–SNP for which they were eligible if such a plan is offered by the MA organization. Some of these commenters believed D–SNP look-alikes should not be able to transition dually eligible individuals into other MA plans when a more integrated option exists. A commenter supported this alternative since it viewed a requirement to transition dually eligible individuals into D–SNPs as continuing federal efforts to strengthen integration of care for dually eligible individuals. A commenter specifically suggested that CMS prioritize transition of full-benefit dually eligible individuals to D–SNP products and other integrated plans.

Response: We appreciate the commenters' support for the proposed alternative, and we share the commenters' preference for integrated care. Although we considered an alternative in the proposed rule that would require transitioning any dually eligible individuals into a D–SNP for which they were eligible if such a plan is offered by the MA organization, we opted for proposing a less prescriptive set of transition rules, recognizing a potentially wide array of transition scenarios. We believe that transitioning D–SNP look-alike enrollees to D–SNPs or other plans authorized by CMS to exclusively enroll dually eligible individuals, when one is offered by the

same MA organization or another MA organization that shares the same parent organization as the MA organization, furthers federal goals to integrate care for dually eligible individuals. However, we also expect that some MA organizations may be unable to transition all D–SNP look-alike enrollees into the same MA plan, since the D–SNP look-alike enrollees may not all meet the eligibility criteria for a particular special needs plan offered by the MA organization or another MA organization that shares the same parent organization as the MA organization.

Our proposal included language at paragraph (e)(1) to allow MA organizations to transition D–SNP look-alike enrollees into one or more MA plans that meet the criteria proposed at paragraphs (e)(1)(i)–(iii). While we expect and encourage dually eligible enrollee transitions to D–SNPs or other integrated plans to occur in many cases, even in the absence of a specific federal requirement, we believe that the complexities associated with a regulation that prioritizes or restricts transitions to D–SNPs or other integrated plans that way would outweigh the potential benefits. Thus, we are finalizing paragraph (e) that an MA organization with a non-SNP MA plan determined to meet the enrollment threshold finalized at paragraph (d)(2)(ii) may transition enrollees into another MA–PD plan (or plans), including a D–SNP, if offered by the same MA organization, as long as any such MA–PD plan meets certain proposed criteria finalized at paragraph (e) and, if such transition is to a D–SNP, enrollees meet the D–SNP eligibility criteria.

Paragraph (e) allows MA organizations multiple options. First, an MA organization can choose not to participate in any transition process under paragraph (e), in which case the enrollees in a D–SNP look-alike would be enrolled by default in the original Medicare fee-for-service program, unless the enrollee made an active choice otherwise. Second, an MA organization can choose to transition all enrollees from a D–SNP look-alike to a different plan that meets the criteria in paragraph (e)(1). Third, recognizing that D–SNP look-alike enrollees may not all qualify for the same new plan, paragraph (e) allows an MA organization to transition look-alike enrollees to multiple plans. For example, an MA organization could transition from its D–SNP look-alike: (1) Dually eligible enrollees into a D–SNP for which they were eligible and (2) non-dually eligible enrollees into a non-SNP plan, provided both plans meet the criteria in paragraph (e)(1).

MA organizations must abide by the anti-discrimination provision (based on health status) in section 1852 of the Act and § 422.110 and other applicable law (for example, civil rights law) when exercising the transition authority. These provisions are applicable to the enrollment transitions authorized under § 422.514(e) and would be especially important to consider where an MA organization chooses to transition enrollees into more than one MA plan. With the exception of transitioning an individual into a C–SNP, an MA organization must not choose a particular plan for an enrollee to transition into based on health status, if the enrollee were eligible for more than one plan offered by the MA organization or its parent organization to receive transitioned enrollees. For example, it would be a violation of the anti-discrimination provision if an MA organization transitioned most dually eligible members from a D–SNP look-alike to a D–SNP but transitioned dually eligible members with diabetes to a different qualifying non-SNP MA plan. As necessary, we will monitor use of the transition authority under this rule to ensure compliance with the applicable anti-discrimination provisions and may take other action as warranted to protect beneficiaries.

Finally, we note that we intend to inform state Medicaid agencies of transitions of enrollees from D–SNP look-alikes into D–SNPs in their state so the states are aware for purposes of their own integrated care efforts and communications with stakeholders.

Comment: A commenter requested that CMS add language that specifically includes MMPs as a plan type eligible to receive beneficiaries who transition from D–SNP look-alikes. Another commenter requested that states be given the flexibility to transition dually eligible look-alike enrollees into a D–SNP or other plan authorized by CMS to exclusively enroll dually eligible individuals, such as an MMP.

Response: We appreciate these comments. The proposed language did not explicitly name MMPs as a type of MA plan into which D–SNP look-alike enrollees could transition because MMPs are not defined in regulation, and CMS can facilitate enrollments from D–SNP look-alikes into MMPs under separate authority. We clarify that MMPs are a type of plan authorized to exclusively enroll individuals entitled to medical assistance under a state plan under Title XIX. CMS is testing the Financial Alignment Initiative under section 1115A of the Act. Some of the demonstration states in the Financial Alignment Initiative are transitioning individuals from an MA plan, including a D–SNP look-alike, to an MMP through passive enrollment. If an MA organization also sponsors an MMP and desires to transition D–SNP look-alike enrollees to the MMP, we would partner with the state Medicaid agency and use our existing authority and processes to execute the transition. Outside of the context of a demonstration or model test under section 1115A of the Act, however, we do not agree with the commenter's request that states be given the flexibility to transition D–SNP look-alike enrollees. CMS will work directly with D–SNP look-alikes to operationalize the transitions, consistent with other Medicare plan transitions, and ensure states are aware of them.

Comment: A commenter requested that CMS ensure dually eligible individuals who previously received care through a managed care plan do not default into the original Medicare fee-for-service program. The commenter stated that these individuals should have the opportunity and support necessary to choose a plan that meets their needs and does not disrupt their care.

Response: We appreciate the commenter's request and agree with the concern. However, we expect the number of D–SNP look-alike enrollees who enroll in the original Medicare fee-for-service program as a result of this rulemaking to be very small. In our proposed Collection of Information (COI) burden estimates, we estimated that only one percent, or 1,808, D–SNP look-alike enrollees would make a Medicare choice other than the MA plan into which they are transitioned by the MA organization. Our estimate was based on our experience with the rate of dually eligible enrollees opting-out of passive enrollment from an MA plan to an MMP offered by the same parent organization as part of the Medicare-Medicaid Financial Alignment Initiative.

Comment: A commenter requested that CMS clarify whether the proposed transition approach allows transition of D–SNP look-alike enrollees to MA plans of a different plan type, such as from an HMO to a PPO.

Response: We appreciate the commenter's request for clarification. In the proposed rule, we stated that our proposed transition process was conceptually similar to ''crosswalk exception'' procedures historically allowed by CMS and proposed at § 422.530 in the proposed rule. We also clarified that, in contrast to the proposed crosswalk exceptions, our proposal would allow the transition process to apply across legal entities

offered by MA organizations under the same parent organization, as well as between SNPs and non-SNP plans. However, it was not our intent to allow for the transition process to apply across product types—for example, HMO to PPO, and vice versa. We are therefore modifying the regulation text to add a new paragraph (e)(1)(iv) to stipulate that an MA plan or plans receiving enrollees under the transition process we are finalizing in paragraph (e) must be of the same plan type (for example, HMO or PPO) as the D–SNP look-alike. An MA organization will not be permitted to transition an individual from a D–SNP look-alike PPO to an MA–PD plan that is an HMO, or vice versa.

Comment: A commenter appreciated that our proposed transition gives D–SNP look-alikes the ability to transition non-D–SNP members into a D–SNP across legal entities. This commenter requested that CMS allow transitions across legal entities in other situations where it would be in the beneficiary's best interest, such as transitioning a beneficiary with a chronic condition into a C–SNP under a different legal entity.

Response: The commenter's understanding of our proposed transition approach in § 422.514 in connection with transitioning enrollees out of a D–SNP look-alike is accurate. Our approach, which we are finalizing as proposed at paragraph (e), allows MA organizations to transition D–SNP look-alike enrollees into an MA plan or plans which meet the criteria in paragraph (e)(1) and are offered by the same MA organization or another MA organization that shares the same parent organization as the MA organization. Under our approach, D–SNP look-alike enrollees who are eligible for a C–SNP could be transitioned into a C–SNP that meets the criteria in paragraph (e)(1). With regard to crosswalks or enrollment changes in other contexts, the recommendation is outside of the scope of our proposal for § 422.514; we will take the comment under consideration in connection with the crosswalk proposal (proposed to be codified at § 422.530) in section VI.C. of the proposed rule, which we intend to address in a future final rule.

Comment: Some commenters encouraged CMS to finalize the proposed policy on D–SNP look-alikes with sufficient advance timing, preferably in advance of the 2021 bid deadline, to allow for enrollee transitions.

Response: We agree it is important, where possible, to finalize the policy in advance of bid deadlines so that MA organizations can have sufficient time to make decisions for 2021 plan offerings. At paragraph (d), we are finalizing the timing of when we would implement the prohibition on contracting for D–SNP look-alikes with the modifications discussed earlier. D–SNP look-alikes operating in 2020 may choose to transition their enrollees effective January 1, 2021, January 1, 2022, or January 1, 2023, and D–SNP look-alikes operating in 2021 may choose to transition their enrollees effective January 1, 2022 or January 1, 2023. For plan year 2022 and subsequent years, CMS will not enter into a contract with a new MA plan that meets criteria outlined in paragraph (d)(1), and for plan year 2023 and subsequent years, CMS will not renew a contract with a MA plan that meets criteria outlined in paragraph (d)(2). We note that MA organizations will be able, under § 422.514(e) as finalized here, to transition enrollees in D–SNP look-alikes to other plans in advance of CMS non-renewing the D–SNP look-alike PBPs effective January 1, 2023 and January 1 of subsequent plan years.

Comment: A commenter noted that D–SNPs currently must have executed state Medicaid agency contracts with applicable states and requested that CMS also allow plans to meet this requirement with subcontracts through a directly contracted entity in order to ease transitions for beneficiaries into the most integrated plan possible.

Response: Consistent with the revised SMAC requirements and the new definition of a D–SNP codified in the April 2019 final rule, a plan must have a direct contract with the state Medicaid agency to meet the definition of a D–SNP at § 422.2. CMS does not consider subcontracting arrangements with Medicaid managed care plans in lieu of SMACs to approve a plan as a D–SNP.

Comment: A commenter recommended that CMS allow an opt-out process for D–SNP look-alike enrollees being transitioned to a new plan. The commenter indicated that such an opt-out process would preserve beneficiary choice.

Response: We appreciate the comment and agree that the ability of an enrollee to opt out is important to ensure beneficiary choice. As we discussed in the preamble of the proposed rule, an MA organization with a non-SNP MA plan determined to meet the enrollment threshold in proposed paragraph (d)(2) could transition enrollees into another MA–PD plan (or plans) offered by the same MA organization, as long as any such MA–PD plan meets certain criteria described in the proposed rule and finalized here. Under the transition authority we are finalizing, an MA enrollee could be transitioned from one MA plan offered by an MA organization to another MA–PD plan (or plans) without the enrollee having completed an election form or otherwise indicate their enrollment choice as typically required. However, the timing of these transitions permits the enrollee to make an affirmative choice for another MA plan of his or her choosing during the annual election period (AEP) from October 15 through December 7. Section 422.514(e) ensures this right because the description of the MA plan to which the enrollee would be transitioned must be provided in the ANOC that must be sent consistent with requirements in § 422.111(a), (d), and (e). The ANOC must be sent at least 15 days before the beginning of the AEP. Enrollees would still have the opportunity to choose their own plan during this transition process because of how the proposed transition process would overlap with the annual coordinated election period. If a transitioned enrollee elects to enroll in a different plan during the AEP, enrollment in the plan the enrollee selected would take precedence over the plan into which the MA organization transitioned the enrollee. Transitioned enrollees would also have additional opportunities to select another plan through the Medicare Advantage Open Enrollment Period described in § 422.62(a)(3) from January 1 through March 31. Affected individuals may also qualify for a Special Election Period (SEP), such as the SEP for plan non-renewals at § 422.62(b) or the SEP for dually eligible individuals or Part D low-income subsidy eligible beneficiaries at § 423.38(c)(4). For D–SNP look-alike enrollees who are not transitioned by an MA organization per proposed paragraph (e)(1), the MA organization must send a written notice consistent with § 422.506(a)(2). This requirement will ensure that the content of that notice includes the content sent when a plan is non-renewing (including information about other enrollment options) and that the notice is sent by October 2 (90 days before the end of the year). We believe that the transition process we proposed and are finalizing provides sufficient opportunity for affected enrollees to opt out of their new plan and make a different election. Therefore, as described earlier in this section, we are finalizing the transition process at paragraph (e) largely as proposed with some minor modifications and technical changes described elsewhere in this section.

Comment: A few commenters expressed concern about the disruption

of aligned Medicare and Medicaid coverage at the point of transition, especially when an individual is enrolled in a Medicaid plan under the same parent organization as the D–SNP look-alike. These commenters recommended that affected beneficiaries be permitted to stay with the MA plan or MA organization to ensure continued integration of Medicare and Medicaid benefits. The commenters believed that such a disruption in ongoing care plans and care teams at the individual level would likely outweigh any additional benefit from the D–SNP integration requirements at the plan level.

Response: We appreciate the commenters' concerns about potential disruption of aligned coverage. The transition approach proposed and finalized at paragraph (e) permits MA organizations to transition D–SNP look-alike enrollees into another MA plan or plans (including into a D–SNP for enrollees who are eligible for such a plan) offered by that MA organization or by another MA organization that shares the same parent organization. We expect the vast majority of D–SNP look-alike enrollees to be transitioned into a plan offered by the same parent organization as the D–SNP look-alike, which would facilitate the sharing of any enrollee care plans and, in some cases, continued access to the same care teams. Also, as explained earlier in this section, we estimate that only one percent of D–SNP look-alike enrollees will move to the original Medicare fee-for-service program or to another MA plan outside of the same parent organization. To the extent that any enrollees in a D–SNP look-alike are enrolled in a Medicaid managed care plan under the same parent organization as the D–SNP look-alike, the transition authority finalized in paragraph (e) allows similar enrollment in plans offered by the same entity or parent organization.

Comment: Some commenters requested that CMS consider state-specific integrated care initiatives as it finalizes its transition policy. In particular, a few commenters encouraged CMS to coordinate transition of D–SNP look-alikes with states where integrated care plan initiatives are proposed or underway to avoid unintended confusion or enrollment barriers for dually eligible individuals. A commenter suggested that CMS issue guidance to states about enrollee transitions initiated by D–SNP look-alikes so that transitions of dually eligible individuals are coordinated with any changes that states are proposing in Medicaid enrollment, which would help minimize the number of transitions an individual experiences over a short period of time. A few commenters requested that CMS consider the impacts of any state-imposed moratorium on contracting with D–SNPs in counties where MMPs are offered, citing such a policy in California. A commenter stated that any such moratorium could affect the ability of individuals who have opted out of MMPs or do not meet MMP eligibility criteria to enroll in other integrated plan options. Another commenter noted that D–SNPs are best positioned to meet the unique needs of dually eligible individuals, and the California restrictions on D–SNP enrollment are harmful when dually eligible individuals do not have the flexibility to enroll in a D–SNP. This commenter expressed concern that if CMS moved forward with the proposed policy and D–SNPs remained closed to enrollment, beneficiaries in areas like those in certain California counties would likely enroll in non-SNP MA plans that not only would not offer the care coordination required by D–SNPs, but may impose higher premiums and out-of-pocket expenses.

Response: We thank the commenters for sharing these concerns. As we stated in our proposed rule preamble, section 164(c)(4) of MIPPA does not obligate states to contract with D–SNPs, which therefore provides states with significant control over the availability of D–SNPs. As discussed earlier, we are finalizing language to delay CMS non-renewal of D–SNP look-alikes to January 1, 2023 and subsequent years, to allow more time for MA organizations and states to coordinate transitions. This delay will also better align the timing of any enrollee transitions from D–SNP look-alikes in California with the current CalAIM implementation timing of January 1, 2023. We do not expect D–SNP look-alike enrollees to experience higher premiums since the transition approach proposed and finalized at paragraph (e) only permits MA organizations to transition D–SNP look-alike enrollees into MA plans that meet certain criteria, including having a combined Part C and Part D premium of $0 for individuals eligible for the premium subsidy for full subsidy eligible individuals described in § 423.780(a).

Comment: A commenter appreciated CMS giving MA plans the ability to transition enrollees in non-D–SNP look-alikes into D–SNPs across legal entities but expressed concern that there could be disproportionate and unintended impacts to the Members Choosing to Leave the Plan Star Rating measure for contracts with the D–SNP look-alikes where the transition authority is used. This commenter requested that CMS ensure that all proposed D–SNP look-alike transitions are excluded from the Members Choosing to Leave the Plan Star Rating measure because the commenter did not believe this measure, which is representative of enrollee satisfaction, would accurately reflect performance if transitioned members were included in the measure.

Response: We thank the commenter for raising this issue. The specifications for the Members Choosing to Leave the Plan Star Rating measure allow beneficiaries transitioned as a result of a PBP termination to be excluded from the calculation of this Star Rating measure. The vast majority of D–SNP look-alike enrollees transitioned into another MA plan or plans will be identified in MARx as disenrollment reason code 09, termination of a contract (CMS-initiated), or disenrollment reason code 72, disenrollment due to a plan-submitted rollover. Neither disenrollment reason code 72 nor 09 will be counted toward the calculation of the Members Choosing to Leave the Plan Star Rating measure. As discussed earlier, we estimated one percent of, or 1,808, D–SNP look-alike enrollees would make a Medicare choice other than the MA plan into which they are transitioned. MARx will identify these transitions as disenrollment code 13, disenrollment because of enrollment in another plan, and these transactions will be counted toward calculation of the Members Choosing to Leave the Plan Star Rating measure. Since such a small number of transitioning D–SNP look-alike enrollees would be counted, we do not believe a change to the Star Rating measure specifications is needed.

Comment: Some commenters requested that CMS only permit D–SNP look-alikes to transition members into other MA plans for which provider networks have at least a 90 percent overlap with the provider network of the D–SNP look-alike. These commenters requested that, if this standard is not met, enrollees should not be transitioned to another plan and instead default to coverage under the original Medicare fee-for-service program. One of these commenters noted that because any plan receiving D–SNP look-alike enrollees would be part of the same parent organization as the D–SNP look-alike, that parent organization could adjust the MA plan networks to meet this 90 percent standard.

Response: We appreciate the commenters' concern that dually eligible individuals maintain their providers from the network of the D–

SNP look-alike. As we discussed in response to other comments, MA organizations may transition enrollees from a D–SNP look-alike into another MA plan offered by the same parent organization, including a D–SNP. Many provider participation agreements used by MA organizations include provisions that the providers contract for all product types the MA organization offers. In fact, CMS assesses network adequacy at the contract level rather than at the plan level (see section V.A. of this preamble). In similar instances where CMS transitioned enrollees from MMPs to D–SNPs under the same parent organization, there was a high degree of overlap in the provider network, as assessed at the contract level. Based on our understanding of common contracting processes and past experience with MMPs and MA organizations that offer D–SNPs, we believe a high degree of overlap will exist between the contracted provider networks in a D–SNP look-alike and a MA plan offered by the same parent organization, making it unnecessary for CMS to impose a standard that requires a specific percentage of provider overlap. Additionally, and as we noted earlier in this section, in those instances where a dually eligible individual receives notice that they are being transitioned to a MA plan that does not include their providers, they retain the ability to choose a different MA plan or the original Medicare fee-for-service program. Finally, in any instances in which there would be meaningful network differences between the D–SNP look-alike and the MA plan to which a member is transitioned, we strongly encourage plans to communicate with members about the potential impacts of such changes.

Comment: A commenter explained that there were many lessons learned during the implementation of Cal MediConnect, a capitated model demonstration under the Financial Alignment Initiative, that highlighted the importance of consumer protections such as continuity of care and network parity. The commenter noted that during the transition to Cal MediConnect, the Department of Health Care Services, California's state Medicaid agency, implemented continuity of care standards and provided guidance allowing the receiving Cal MediConnect plan, which was an MMP, to use the HRA completed by a D–SNP. To minimize disruptions in care, the commenter requested that CMS consider beneficiary protections similar to those included in the state's proposed CalAIM D–SNP transition plan and establish requirements for transferring a D–SNP look-alike enrollee's HRA and care plan, as well as requirements for continuity of care and network parity, and a prohibition on receiving plans' imposition of additional cost-sharing requirements.

Response: We appreciate the commenter's perspective and support a smooth transition between D–SNP look-alikes and another MA plan, but we do not believe establishing additional requirements as suggested is necessary. As discussed in the preamble of our proposed rule, D–SNP look-alikes are not subject to federal D–SNP requirements, including the requirements to develop HRAs and individualized care plans. Thus, we do not expect D–SNP look-alikes necessarily will have any HRAs or care plans to transfer to another MA plan in connection with the transition of a beneficiary's enrollment. As discussed earlier in this section, to the extent that a D–SNP look-alike has developed HRAs or individualized care plans, we expect the vast majority of D–SNP look-alike enrollees to be transitioned into a plan offered by the same parent organization as the D–SNP look-alike. We believe that transitions under paragraph (e) will facilitate the sharing of any HRAs and care plans and promote continuity of care because the new plan will be operated by an entity with the same parent organization, if not the same MA organization, which likely means overlapping or the same personnel and policies. Additionally, all transitioning beneficiaries will have Medicare's standard Part D continuity of care protections for prescription drugs (including temporary fills of non-formulary drugs during a transition period as provided under § 423.120(b)(3)). Plans receiving transitioned enrollees must also provide other continuity of care requirements for MA plans, including those outlined in § 422.112(b). As we describe earlier in this section, we believe that there will be a high degree of provider network overlap across plans that are offered by the same MA organization or share a parent organization, making it unnecessary for CMS to impose a standard that requires a specific percentage of provider overlap. Finally, we do not expect D–SNP look-alike enrollees to experience higher premiums since the transition approach proposed and finalized at paragraph (e) only permits MA organizations to transition enrollees in a D–SNP look-alike into MA plans that meet certain criteria, including having a combined Part C and Part D premium of $0 for individuals eligible for the premium subsidy for full subsidy eligible individuals described in § 423.780(a). We also note that, pursuant to § 422.504(g)(1), MA organizations cannot impose cost sharing requirements for Medicare Parts A and B services on full-benefit dually eligible individuals that would exceed the amounts permitted under the state Medicaid plan if the individual were not enrolled in the MA plan.

Comment: Several commenters encouraged CMS to require that the ANOC notifying a beneficiary being transitioned to a new plan identify D–SNP look-alike providers known to not be in the receiving plan's network, focusing specifically on primary care providers and specialists who the beneficiary has seen twice or more in the past year. One of these commenters explained that this information would help beneficiaries make informed choice about whether to participate in the transition and prevent surprise access-to-care issues in the early months of enrollment. A commenter expressed a similar view but suggested the ANOC identify any providers seen in last year. Another commenter noted the importance of a plan's provider network to beneficiaries with disabilities. We also received one comment recommending that the ANOC contain information about other plan options.

Response: We appreciate the commenters' perspectives and support transparency on MA provider networks, but we do not agree that the ANOC is an appropriate means of communicating beneficiary-specific provider information since it is not a beneficiary-specific notice. Standardized language in the ANOC model already provides general information about changes to an MA plan's network and directs enrollees to the plan's updated provider network directory to help with decision-making during the AEP. As we discussed earlier in this section, we believe the vast majority of D–SNP look-alike enrollees will be transitioned into an MA plan within the same parent organization as the D–SNP look-alike and there will be a high degree of provider network overlap across plans that are offered by the same MA organization or share a parent organization, lessening the need to provide beneficiary-specific provider information. Additionally, and as we noted earlier in this section, in those instances where a dually eligible individual is transitioned to a MA plan that does not include their providers, they retain the ability to choose a different MA plan or the original Medicare fee-for-service program.

While we support beneficiary education and choice about plan options, we also do not believe the ANOC is the appropriate vehicle for communicating information about other plan options. As described earlier, the transition process of D–SNP look-alike enrollees into another MA plan or plans will overlap with the AEP. Enrollees who are subject to being transitioned under § 422.514(d) have multiple ways of identifying other plan choices, such as through reviewing the Medicare & You Handbook, consulting Medicare Plan Finder, and contacting 1–800-Medicare and the State Health Insurance Assistance Program in their state.

Comment: A commenter requested that CMS provide guidance for providers and beneficiaries explaining why the transition from D–SNP look-alikes to another MA plan or plans is occurring.

Response: We appreciate the comment and the desire for providers and beneficiaries to be informed about the transition. However, we believe it is the responsibility of MA organizations that are transitioning enrollees to other MA plans to educate providers and enrollees about the transition and the benefits of the new (receiving) plans. As discussed earlier in this section, the MA organization receiving D–SNP look-alike enrollees is required to send these enrollees an ANOC consistent with § 422.111(a), (d), and (e) that includes information on benefits and provider network changes. We are, however, finalizing paragraph (e)(2)(ii) with minor modifications to clarify that the responsibility of providing information to transitioned enrollees in the ANOC rests with the MA–PD plan into which individuals are transitioned, and that the ANOC describes changes to the MA–PD plan's benefits and provides information about the MA–PD plan.

Comment: A commenter expressed support for the proposed D–SNP look-alike contracting standards, while noting potential negative impacts, including reduced plan competition and consumer choice. The commenter recommended that states be required to contract with all MA–PD plans that have an approved MOC and suggested three different contracting options: (1) States enter into a care coordination contract with plans; (2) states pay plans to coordinate Medicare and Medicaid services, assuring alignment with the state's strategy to deliver LTSS or managed LTSS (MLTSS); and (3) states pay plans to coordinate Medicare and Medicaid services and deliver LTSS. Another commenter suggested that plans meeting certain CMS criteria for integrated care could earn a ''Standard of Excellence for Dually-Eligible Individuals'' seal of approval that could be used for marketing purposes and posting on Medicare Plan Finder.

Response: We appreciate the commenters' input on strategies that could improve plan competition and support consumer choice. We note that some of the commenters' recommendations, such as requiring states to contract with all MA–PD plans that have an approved MOC, are beyond CMS's existing authority. As we gain experience with implementing the requirements in this final rule, we will take into consideration those recommendations that are within CMS's authority.

Comment: A commenter recommended CMS consider requiring that any entity that meets the 80 percent dual enrollment threshold meet minimum standards of integrated care coordination and data sharing for its full-benefit dually eligible members, including in the eight states that do not currently have any D–SNPs (as of July 2019). This commenter supported requiring that MA organizations in these eight states transition members to an MMP if one exists or, if one does not, submit a MOC, complete HRAs, and provide integrated care coordination and information sharing for all of its full-benefit dually eligible members.

Response: We appreciate the commenter's alternative approach. We clarify that proposed paragraphs (d)(1) and (2) would, in fact, limit new and existing D–SNP look-alikes from operating in states where a D–SNP or any other plan authorized by CMS to exclusively enroll individuals entitled to medical assistance under a state plan under Title XIX, including MMPs, exists. The limit on new D–SNP look-alikes precludes CMS from entering into a new contract for a D–SNP look-alike for 2022 and subsequent years. The limit on existing D–SNP look-alikes precludes CMS from renewing a contract for an existing D–SNP look-alike for 2023 and subsequent years. However, under current law, CMS does not have the authority to require D–SNP look-alikes in the eight states without D–SNPs to submit MOCs, conduct HRAs, or provide integrated care coordination and information for all of its full-benefit dually eligible members. Section 1859(f) of the Act requires that each D–SNP have a contract with the state Medicaid agency; this requirement is in addition to other D–SNP requirements this commenter references. Allowing D–SNP look-alikes to operate without such state contracts would allow such plans to circumvent an important D–SNP requirement.

Comment: A few commenters proposed the application of new federal measures nationwide that would require D–SNP look-alikes to make progress on a pathway toward greater care integration. Rather than not approving or renewing contracts for certain D–SNP look-alikes, a commenter suggested that this alternative approach would assure continued beneficiary choice, as certain integrated care plans receive lower Star Ratings than other plans that do not provide integrated care. Another commenter suggested that D–SNP look-alikes could provide more integrated care if CMS required them to notify the state Medicaid agency or appropriate Medicaid managed care plan when full-benefit dually eligible individuals are admitted to a hospital or skilled nursing facility (that is, the requirement recently codified at § 422.107(d) as one of three integration options available to D–SNPs beginning in 2021).

Response: We appreciate the support for increased opportunities to integrate care for individuals who are dually eligible and the importance of beneficiary choice. Though we intend, through this final rule, to discourage the rapid proliferation of D–SNP look-alikes that undermine the statutory and regulatory framework for D–SNPs, we will continue to consider other ways to further promote integrated care for individuals who are dually eligible.

Comment: A few commenters proposed that CMS conduct additional research on the market dynamics of D–SNP look-alikes, noting factors such as incentives for brokers who steer enrollees toward or away from certain service delivery models. These commenters suggested that, rather than implementing broad restrictions on D–SNP look-alikes, CMS could address those market distortions directly. For example, if D–SNP look-alikes result from inappropriate steering of beneficiaries, these commenters noted that CMS could institute measures reinforcing referrals to products best suited to the beneficiary's needs. A few commenters noted that if misleading marketing practices were found to be a root cause, CMS has regulations and program rules to stop them. Another commenter supported the strong enforcement of existing marketing and broker requirements to prevent the targeting of dually eligible individuals for marketing MA plans that do not offer integrated care. The commenter noted that if CMS believes it lacks the authority required to discontinue this behavior, Congress should grant the agency the authority it needs.

Response: We appreciate the commenters' perspectives on the need

to avoid beneficiary confusion and take steps against misleading marketing practices. Our proposed rule included various proposed provisions codifying previous subregulatory guidance from the Medicare Communications and Marketing Guidelines prohibiting non-D–SNP plans from marketing their plan as if it were a D–SNP; those proposals will be addressed in a future final rule. We note, however, that MA organizations remain responsible for ensuring that their agents and brokers comply with part 422, subpart V. Current requirements (such as § 422.2268(a)(1) and (2)) include prohibitions on misleading or confusing marketing and communications; MA organizations must ensure downstream entities—such as their agents and brokers—that perform marketing or enrollment on behalf of the MA organization also comply with these requirements. We will also continue to monitor plans' compliance with CMS marketing rules prohibiting misleading marketing practices, including activities of agents and brokers, to ensure that dually eligible individuals can make informed choices. This includes review of complaints about inappropriate marketing practices CMS receives through the Complaint Tracking Module described in § 422.504(a)(15). As we gain experience with implementing the requirements in this final rule, we will evaluate whether additional rulemaking on marketing practices is necessary.

Comment: A few commenters suggested improving and increasing education for dually eligible individuals and providers about the benefits of integrated care and the availability of plans that offer such care. A few commenters suggested that brokers should be required to educate dually eligible individuals on the integrated care options within their service area to assure that they can make informed choices. A commenter recommended that CMS require any low-premium MA plan that attracts dually eligible individuals to educate them about the availability of D–SNP options within their service area.

Response: We appreciate recommendations for improved provider and beneficiary education on the availability and benefits of integrated products, and we will take into consideration ways to strengthen agent and broker training requirements and marketing rules within our current authority.

After considering the comments we received and for the reasons outlined in the proposed rule and our responses to comments, we are finalizing our proposed provisions at § 422.514(d) and (e) with the following modifications:

- We are reorganizing the regulation text by adding new paragraphs (d)(1)(i) and (ii) and (d)(2)(i) and (ii) for better organization and clarity of the final requirements, as well as to establish different effective dates for the provisions of paragraphs (d)(1) and (2). Accordingly, we are also updating the reference in paragraph (e)(1)(i) from paragraph (d)(2) to paragraph (d)(2)(ii).
- We are finalizing the provision at paragraph (d)(2) with the date 2023 instead of 2022 to extend by one year the timeline on which the contract limitation will apply to an existing non-SNP plan with actual enrollment consisting of 80 percent or more dually eligible enrollees (with the exception of an MA plan active less than one year and with enrollment of 200 or fewer individuals at the time of the determination).
- We are modifying paragraph (e)(1)(iv) to stipulate that an MA plan (or plans) receiving enrollees under the transition process in paragraph (e) must be of the same plan type (for example, HMO or PPO) as the D–SNP look-alike.
- We are making a minor modification to paragraph (e)(2)(ii) to eliminate the reference to § 422.2267(e)(3), as that proposed provision is not being finalized in this rule. We are also modifying paragraph (e)(2)(ii) to clarify that the responsibility of providing information to transitioned enrollees in the ANOC rests with the MA–PD plan into which individuals are transitioned, and that the ANOC describes changes to the MA–PD plan's benefits and provides information about the MA–PD plan.
- We are finalizing paragraph (e)(4) with a technical change to clarify that the content as well as the mechanism and timing requirements in § 422.506(a)(2) apply to the notice an MA organization must provide to any enrollees in a D–SNP look-alike that the MA organization is not transitioning to a new plan.
- We are adding a new paragraph (f) to clarify that we would consider actions taken consistent with paragraph (d) to warrant special consideration to exempt affected MA organizations from the denial of an application for a new contract or service area expansion pursuant to §§ 422.502(b)(3) and (4), 422.503(b)(6) and (7), 422.506(a)(3) and (4), 422.508(c) and (d), and 422.512(e)(1) and (2).

III. Implementation of Certain Provisions of the 21st Century Cures Act

A. Medicare Advantage (MA) Plan Options for End-Stage Renal Disease (ESRD) Beneficiaries (§§ 422.50, 422.52, and 422.110)

Section 4001 of the Balanced Budget Act of 1997 (hereinafter referred to as the BBA of 1997) added sections 1851 through 1859 to the Act establishing Part C of the Medicare program known originally as ''Medicare + Choice'' and later as ''Medicare Advantage (MA).'' As enacted, section 1851 of the Act provided that every individual entitled to Medicare Part A and enrolled under Part B, except for individuals with end stage renal disease (ESRD), could elect to receive benefits through an MA plan. The statute further permitted that, in the event that an individual developed ESRD while enrolled in an MA plan or in a health plan offered by the MA organization, he or she could remain in that MA plan or could elect to enroll in another health plan offered by that organization. These requirements were codified at § 422.50(a)(2) in the initial implementing regulations for the Part C program published in 1998 (63 FR 35071).

Section 1851 of the Act was subsequently amended several times to expand coverage of ESRD beneficiaries in MA plans.

- Section 620 of the Medicare, Medicaid, and SCHIP Benefits Improvement and Protection Act of 2000 (hereinafter referred to as BIPA), established a one-time opportunity for individuals, medically determined to have ESRD, whose enrollment in an MA plan was terminated or discontinued after December 31, 1998, to enroll in another MA plan.
- Section 231 of the MMA gave the Secretary authority to waive section 1851(a)(3)(B) of the Act, which precludes beneficiaries with ESRD from enrolling in MA plans. Under this authority, CMS undertook rulemaking to allow individuals with ESRD to join an MA special needs plan.

In 2016, paragraph (a) of section 17006 of the Cures Act further amended section 1851 of the Act to remove the prohibition for beneficiaries with ESRD from enrolling in an MA plan. This change is effective for plan years beginning on or after January 1, 2021. (Please see sections III.B. and III.C. of this final rule for further changes established by section 17006 of the Cures Act.) To implement these changes in eligibility for MA plan enrollment made by the Cures Act, we proposed the following amendments:

- Section 422.50(a)(2) would be revised to specify that the prohibition of beneficiaries with ESRD from enrolling in MA plans (and associated exemptions) is only applicable for coverage prior to January 1, 2021.
- Section 422.52(c) would be revised to specify that CMS authority to waive the enrollment prohibition in § 422.50(a)(2) to permit ESRD beneficiaries to enroll in a special needs plan would also only be applicable for plan years prior to 2021.
- Section 422.110(b) would be revised to specify that the exception to the anti-discrimination requirement, which was adopted to account for the prohibition on MA enrollment by beneficiaries who have ESRD, is only applicable for plan years prior to 2021.

As noted earlier, the changes mandated by the Cures Act do not take effect until the 2021 plan year. As such, individuals entitled to Medicare Part A and enrolled under Part B, and medically determined to have ESRD, are not eligible to choose to receive their coverage and benefits through an MA plan prior to plan year 2021, subject to the limited exceptions reflected in the current regulation text.

We received a large number of comments related to this proposal. The discussion below pertains specifically to comments related to eligibility and the removal of the prohibition on beneficiaries with ESRD enrolling in an MA plan as proposed in §§ 422.50(a)(2), 422.52(c), and 422.110(b).

Comment: Generally, all commenters supported the statutory change removing the prohibition for ESRD beneficiaries to enroll in an MA plan. Many commenters noted that allowing these beneficiaries to enroll in MA plans will provide care coordination and, thus, improved clinical outcomes for this vulnerable population. A commenter also noted that MA beneficiaries have a relatively low rate of switching among plans and tend to stay with the selected plan long term, and this could contribute to better outcomes through longer coordination of care. Many commenters stated that this change will provide options for obtaining supplemental benefits and access to health and wellness programs not available in Original Medicare.

Several commenters stated that MA plans provide a maximum out-of-pocket (MOOP) cost sharing for all enrollees, which makes MA an attractive option for these beneficiaries with high annual medical costs. Commenters noted that this MOOP may significantly decrease patients' out-of-pocket costs. A commenter noted that the MOOP is especially important for those ESRD beneficiaries who are under age 65, and may not be eligible to purchase a Medigap policy to supplement their Original Medicare expenses. Several commenters noted that this provision will help improve the lives of, and empower, ESRD beneficiaries consistent with the President's Executive Order on Advancing American Kidney Health.

Response: We agree with the commenters and appreciate their support of the proposal.

Comment: Several commenters requested that CMS clarify if the current optional employer/union group waiver for enrollment of ESRD members will be eliminated and, if so, questioned when guidance would be updated to reflect the change.

Response: Under Section 1857(i) of the Act, CMS has the statutory authority to waive or modify requirements that hinder the design of, the offering of, or the enrollment in, employer/union-sponsored MA plans. As noted in the Medicare Managed Care Manual Chapter 9, section 30.3, CMS used this authority to grant a waiver to allow MA plans offered by MA organizations under contract with an employer or union, or offered directly by an employer or union, to choose to accept enrollees with ESRD under certain circumstances, provided that all otherwise eligible individuals with ESRD are permitted to enroll. With the enactment of the Cures Act, effective plan years on or after January 1, 2021, the prohibition on MA enrollment for ESRD beneficiaries is removed. Therefore, the waiver will no longer be effective and MA plans, including MA EGWPs, must accept enrollments of ESRD beneficiaries. We plan to update guidance as soon as possible.

Comment: A commenter questioned if the 30-month coordination of benefits period for those entitled to Medicare based on ESRD status will be eliminated based on the removal of the prohibition.

Response: The regulation codifies that those individuals with ESRD cannot be restricted from enrolling in an MA plan. However, nothing in the language of the regulation eliminates or is to be construed as eliminating the 30-month coordination of benefits period that section 1862(b)(1) of the Act imposes with regard to Medicare coverage of beneficiaries whose entitlement is based on ESRD. In other words, any Group Health Plan coverage effective at the time a beneficiary with ESRD enrolls in an MA plan will remain the primary payer during the 30-month coordination of benefits period.

Comment: A commenter questioned how removing the prohibition on individuals with ESRD from enrolling in

MA plans will impact the way ESRD information must be obtained and reconciled in order to ensure appropriate payment. The commenter also questioned if CMS is considering increasing resources for the QualityNet helpdesk, as ESRD enrollments in MA plans are likely to increase, which may prompt higher volumes of cases where ESRD statuses and payments need to be reconciled and corrected in the future.

Response: Completion of the CMS–2728–U3 form (*End Stage Renal Disease Medical Disease Evidence Report—Medicare Entitlement and/or Patient Registration,* OMB control number 0938–0046) by a dialysis center, (including physician attestation and patient signature) is required for an individual to be medically determined to have ESRD for purposes of filing for Medicare benefits. However, collection of these data on the CMS–2728–U3 are also used to establish and maintain a nationwide kidney disease registry for dialysis, transplant, and prospective transplant patients, and will store pertinent medical facts on each registrant, regardless of Medicare status. CMS enrollment systems ultimately receive this information resulting in MA plans receiving payment based on ESRD capitation rates and risk adjustment. Further information on this process can be found in section 6.2.2 of the *Plan Communication User Guide for Medicare Advantage Prescription Drug Plans.*

At this time, we have no plans to add additional resources to the QualityNet Help Desk but we will monitor call volumes to see if we need to increase the number of agents fielding ESRD Quality Reporting System calls.

Comment: A commenter requested clarification on whether MA plans will be allowed to include the question regarding ESRD status on the MA enrollment form. The commenter also questioned if this change will impact the required Data Elements to consider an enrollment request complete.

Response: CMS has proposed changes to the standard (''long'') model form used for MA and Prescription Drug Plan (PDP) enrollment (currently approved under OMB control number 0938–0753 CMS–R–267), to reduce data collection and simplify the enrollment process. When adopted, the new, ''shortened'' enrollment form will limit data collection to what is lawfully required to process the enrollment and other limited information that the sponsor is required, or chooses to, provide to the beneficiary. The new ''shortened'' form used for enrollment into MA and PDP plans will not contain the ESRD status question. We expect MA plans to use the new shortened form, (once OMB has approved its use) for the 2020 AEP, which begins on October 15, 2020, for January 1, 2021 effective dates. This timeframe aligns with the effective date of the removal of the prohibition of MA enrollment for ESRD beneficiaries. As the ESRD status question will not be on the form, it is not a data element which will be required to consider the enrollment complete. MA plans do not need to know the ESRD status of an enrollee to process an enrollment in light of the changes made by the Cures Act, and are prohibited from discriminating against potential enrollees on the basis of a health status factor. Data element requirements will be updated in future guidance.

Comment: A commenter questioned how CMS plans to work with state Medicaid agencies regarding implementation of ESRD enrollment in D–SNPs. Specifically, the commenter stated that some states do not permit enrollment into a D–SNP plan when a beneficiary has been diagnosed with ESRD and questioned how CMS plans to address the discrepancy between current state enrollment restrictions prohibiting patients with ESRD from enrolling in a state's D–SNP plans and the removal of the prohibition. The commenter also questioned if CMS will require states to adopt policies or align with CMS' enrollment changes.

Response: States already have the ability in their state Medicaid agency contract with each D–SNP to restrict which dually-eligible individuals may enroll in the D–SNP. If the state's contract with a D–SNP excludes those with ESRD, the D–SNP may retain that exclusion in order to comply with the state contract required under § 422.107.

Comment: A commenter questioned how the enrollment change will affect MMPs. They specifically questioned if CMS and state Medicaid agencies will revise the three-way-contracts and if MMP plan rates would be affected.

Response: We note that currently, most states that are testing a capitated model of integrated care in demonstrations under the Financial Alignment Initiative (FAI) authorized under section 1115A of the Act permit those beneficiaries with ESRD to enroll in MMPs. Only South Carolina and six counties in California exclude those with ESRD from enrolling in an MMP. We are consulting with those two states to determine if, starting CY2021, they want to continue that exclusion under the model of integrated care being tested under the FAI demonstration authority. If they decide they do want to include the ESRD population, CMS would work with those states to update the applicable Medicaid MMP rates, as needed. The MMP Medicare rate structure already includes rates specific for individuals with ESRD and these rates would apply for any MMP enrollees with ESRD; specifically, the ESRD dialysis state rate applies for individuals in the dialysis and transplant status phases, and the Medicare Advantage 3.5 percent bonus county rate applies for individuals in the functioning graft status phase, with all of these rates risk adjusted using the Hierarchical Condition Category -ESRD risk adjustment model for the applicable year.

Comment: A commenter stated that a disproportionate share of beneficiaries with ESRD could be enrolling in D–SNPs and requested that CMS monitor enrollment of beneficiaries with ESRD into D–SNPs and ensure that payments are adequate.

Response: We appreciate the feedback provided by the commenter. We will continue to analyze these issues as additional data emerges. We will consider whether, consistent with the statutory requirements for setting ESRD rates in section 1853(a)(1)(H) of the Act, any refinements to the ESRD rate setting methodology may be warranted in future years.

Comment: A commenter stated that there should be oversight and penalties for companies who use aggressive marketing campaigns to recruit ESRD patients and ''bait and switch'' with services the beneficiary was promised and not delivered.

Response: We appreciate the commenters' concerns. MA plans must comply with the marketing and communications requirements in 42 CFR part 422, subpart V, and specifically, § 422.2268(a)(1) and (2), which include prohibitions on providing information that is inaccurate or misleading, and engaging in activities that could mislead or confuse Medicare beneficiaries. As part of ensuring their compliance with these requirements, MA organizations must monitor and oversee the activities of their subcontractors, downstream entities, and/or delegated entities as well. If CMS finds that MA plans have failed to comply with applicable rules and guidance, CMS may take compliance or enforcement actions, including, but not limited to, intermediate sanctions or civil money penalties.

Comment: Some commenters raised concerns with implementing new rules given the ongoing COVID–19 pandemic and the strain it is putting on the entire United States health care system. A few commenters urged CMS to consider delaying implementation of this change

and continue to prohibit beneficiaries with ESRD from enrolling in MA plans until at least 2022. A commenter requested that CMS consider making all new 2021 requirements voluntary rather than mandatory.

Response: The statutory change provides beneficiaries with the right to make an election for an MA plan if they meet the otherwise applicable requirements beginning January 1, 2021. CMS lacks authority to delay implementation of this statutory change. We are sympathetic to the commenters' concerns that additional changes during the on-going pandemic may increase burdens and make compliance more difficult. However, the pandemic has further indicated that it is important to break down the barrier that has prohibited beneficiaries with ESRD from the enrolling in MA and having access to benefits such as care coordination and limitations to out-of-pocket costs. We also note that these changes are required by law (the Cures Act), effective for plans years on or after 2021. We appreciate that the COVID–19 pandemic has interrupted timing for implementing new requirements, but we are also mindful of the fact that the Cures Act was enacted in 2016 and, as a result, plans have been aware of the change and are likely planning for these enrollments.

Comment: Several commenters suggested that CMS develop educational materials that will provide accurate and objective information about MA plan availability and options, services provided, and potential out-of-pocket costs. A commenter requested that CMS provide clear and easy to understand rules that prohibit discriminatory behavior so that patients that are entitled to Medicare Part A and enrolled in Part B know how they can exercise their right to select an MA plan.

Response: Thank you for the comments. We agree, and as we implement this new and important policy, we will continue to provide educational and outreach materials and other clear guidance to those beneficiaries that are entitled to Medicare Part A and enrolled in Part B. CMS has reviewed, and will continue to review beneficiary publications to identify potential areas for improvement, and update public facing documents as needed so that Medicare beneficiaries are able make an informed coverage choice.

Comment: A commenter stated that it is important for individuals with ESRD to have access to MA plan options through special election periods (SEPs) for exceptional conditions. A commenter stated that an ESRD beneficiary should understand his or her option to change back to Original Medicare. Another commenter noted that if people sign up for MA and they realize it is not the option for them, they should have the ability to modify their enrollment, switch plans, or to cancel and return to Original Medicare.

Response: We agree that beneficiary choice is important and beneficiaries with ESRD—like all other beneficiaries—should carefully consider their enrollment options when they become eligible for Medicare and during subsequent AEPs. All beneficiaries who join an MA plan have opportunities to change plans or return to the original Medicare fee-for-service program during the AEP (October 15 through December 7) or the Medicare Advantage Open Enrollment Period (January 1 through March 31, and during the first three months of Medicare Part A entitlement and Part B enrollment). In some cases, such as when a beneficiary moves out of the service area or is in a plan that does not renew its contract, a SEP is available. Of particular note is the ''SEP65,'' wherein an MA eligible individual who elects an MA plan during his or her initial enrollment period for Part B surrounding his or her 65th birthday may disenroll from this MA plan and elect coverage through the original Medicare fee-for-service program any time during the 12-month period that begins on the effective date of coverage in the MA plan. Beneficiaries may also use SEPs for exceptional conditions newly codified in § 422.62(b)(4) through (25) and described in section 30.4.4 of Chapter 2, Medicare Managed Care Manual, as appropriate, including the SEP for Individuals with ESRD Whose Entitlement Determination Made Retroactively to enroll in an MA plan. Further, to the extent that there is an exceptional situation for an individual that is not addressed by our existing SEPs, codified in this final rule, we will have the ability to respond to the exceptional situation pursuant to § 422.62(b)(26). Finally, there are SEPs available, under § 422.62(b)(3), in situations where the MA plan fails to provide medically necessary services or the plan (or its agents) materially misrepresented the plan's provisions in marketing materials.

Comment: A commenter suggests the establishment of an ESRD ombudsman to address any issues with implementation of this expansion of MA eligibility that may arise for beneficiaries, MA organizations, or their contracted providers.

Response: The Medicare Beneficiary Ombudsman is dedicated to resolving complaints, grievances and requests for information submitted by Medicare-eligible individuals and their advocates concerning any aspect of the Medicare program. Other entities and resources, including the CMS Regional Offices, State Health Insurance Assistance Programs, and 1–800–MEDICARE are also available to assist beneficiaries with issues or questions.

Comment: A commenter proposed that CMS update the enrollment guidance to remove ESRD enrollment restrictions and to release the updated guidance in April. The commenter further states that the technology and process updates necessary for plans to implement the changes and the increase in MA membership has led to an increase in the number of materials that plans need to produce, straining production timelines.

Response: Thank you for the comment. We understand the commenter's concern and plan to issue guidance as soon as possible. We are also mindful of the fact that the Cures Act was enacted in 2016 and, as a result, MA organizations have been aware of this change for some time.

Comment: A commenter suggested that dialysis cost sharing be included in the standard services/items reflected on individual plan searches in the Medicare Plan Finder (MPF) tool, and added that this information is not currently reflected.

Response: We appreciate and agree that this additional data will help Medicare beneficiaries with ESRD find and choose an MA plan. We plan to add this information for plans offering coverage in 2021.

Comment: A couple of commenters agreed with our decision not to amend § 422.66(d)(1) (requiring MA organizations to accept newly eligible Medicare beneficiaries who are seamlessly converting from health plan coverage offered by the MA organization) because the provision already applied to all beneficiaries regardless of their ESRD status. A commenter suggested that CMS slightly modify § 422.66(d)(1) to remove the language, ''(regardless of whether the individual has end-stage renal disease)'' to eliminate any confusion about the prohibition no longer being in effect.

Response: We thank the commenters for their feedback. We believe that the regulation does not require further amendment.

Comment: Commenters also provided a wide range of feedback regarding other downstream issues related to this change in enrollment criteria for the MA program including assurance of adequate payment for plans, quality of

care, HEDIS measure changes, beneficiary MOOP and cost-sharing policies, and network adequacy. A commenter suggested that beneficiaries are likely to have improved outcomes if enrolled in a plan that uses an established care delivery model, and several other commenters requested that CMS allow MA plans to participate in the Center for Medicare & Medicaid Innovation kidney models to improve the dissemination of best practices in kidney care. Another commenter requested that CMS develop and submit SSBCI benefits for these beneficiaries.

Response: We appreciate commenters for their feedback. Since those comments are outside the scope of the changes proposed in §§ 422.50(a)(2), 422.52(c), and 422.110(b), they will not be addressed in this section. To the extent that the comment is about other proposals in the notice of proposed rulemaking, it is, or will be, addressed in connection with that proposal elsewhere in this final rule or a future final rule.

After review and consideration of all comments on the proposal to remove the prohibition on ESRD beneficiaries enrolling in an MA plan and for the reasons in the proposed rule and these comments and responses, we are finalizing the revisions to §§ 422.50(a)(2), 422.52(c), and 422.110(b) as proposed.

B. Medicare Fee-for-Service (FFS) Coverage of Costs for Kidney Acquisitions for Medicare Advantage (MA) Beneficiaries (§ 422.322)

The MA organization is generally responsible for furnishing or providing coverage of all Medicare Part A and Part B benefits, excluding hospice, for its enrollees. The Medicare FFS program does not pay health care providers for furnishing these benefits to such enrollees. Section 1851(i) of the Act generally provides that, subject to specific exceptions, CMS pays only the MA organization for the provision of Medicare-covered benefits to a Medicare beneficiary who has elected to enroll in an MA plan. There are specific, statutory exceptions to this general rule in the statute, such as authority in section 1853(h) of the Act for FFS Medicare payment for Medicare-covered hospice services that an MA plan is prohibited by statute from covering. Section 17006(c) of the Cures Act amended section 1852(a)(1)(B)(i) of the Act to exclude from the list of items or services an MA plan is required to cover for an MA enrollee coverage for organ acquisitions for kidney transplants, including as covered under section 1881(d) of the Act. Effective January 1, 2021, these costs will be covered under the original Medicare FFS program, pursuant to an amendment by section 17006(c)(2) of the Cures Act to section 1851(i) of the Act. As amended, section 1851(i)(3) of the Act authorizes FFS Medicare payment for the expenses for organ acquisitions for kidney transplants described in section 1852(a)(1)(B)(i) of the Act. We proposed conforming regulatory changes to reflect the revision to the statute.

Specifically, we proposed to revise § 422.322, which describes the source of payment and effect of MA plan election on payment for Medicare-covered benefits. Paragraphs (b) and (c) of § 422.322 generally track the statutory requirements that, subject to specific exceptions, CMS payment to MA organizations is in lieu of the amounts that would otherwise be payable under the original Medicare FFS program for Medicare-covered benefits furnished to an MA enrollee and are the only payment by the government for those Medicare-covered services. Consistent with the amendments to sections 1851(i) and 1852(a)(1)(B)(i) of the Act, we proposed to amend § 422.322 to add a new paragraph (d) to reflect that expenses for organ acquisitions for kidney transplants are an exception to the terms outlined in paragraphs (b) and (c), and will be covered by original Medicare. Our new paragraph (d) generally tracks how section 17006(c) of the Cures Act amends section 1851(i)(3) of the Act.

The Cures Act does not provide for Medicare FFS coverage of organ acquisition costs for kidney transplants incurred by PACE participants. Therefore, PACE organizations must continue to cover organ acquisition costs for kidney transplants, consistent with the requirement described in section 1894(b)(1)(A)(i) of the Act that PACE organizations provide all Medicare-covered items and services. Accordingly, CMS will continue to include the costs for kidney acquisitions in PACE payment rates.

The following is a summary of the comments we received and our responses:

Comment: Several commenters expressed support for the implementation of this Cures Act requirement.

Response: We appreciate the commenters' support of our approach to implementing this change.

Comment: A commenter encouraged CMS to monitor the effects of the proposal's approach to organ acquisition costs.

Response: While we will continue to monitor and analyze the impact of this change, we must comply with the statutory requirement for FFS Medicare to cover kidney acquisition costs for MA beneficiaries.

Comment: A commenter noted that neither the proposed rule nor the calendar year 2021 Advance Notice, which was published on February 5, 2020, provided clear guidance on billing and reimbursement for organ acquisition costs. This commenter urged CMS to clarify whether these services are to be billed directly to Medicare Administrative Contractors (MACs) and paid directly to the providers involved, rather than being paid to MA plans for pass-through to providers. The commenter also requested that CMS clarify which organ acquisition costs will be payable by FFS Medicare.

Response: We appreciate the commenter's request for further clarification. We want to emphasize that the payment changes for organ acquisition costs apply only to kidneys. Effective January 1, 2021, FFS Medicare will cover kidney acquisition costs for MA beneficiaries in accordance with the processes and guidance outlined in the Claims Processing Manual,[17] CMS Pub. 100–04, chapter 3 and the Provider Reimbursement Manual,[18] CMS Pub. 15–1, chapter 31. Hospitals currently bill MA claims to their respective MACs for processing as no-pay bills so that the MA inpatient days can be accumulated on the Provider Statistics & Reimbursement Report (PS&R) (report type 118). These no-pay bills must identify kidney acquisition costs using revenue code 081X and the hospital must track each MA kidney transplant. For instructions on billing for kidney acquisition costs, please refer to chapter 3, sections 90.1 through 90.1.3, of the Claims Processing Manual. For details on services included as kidney acquisition costs, please refer to chapter 31, section 3101, of the Provider Reimbursement Manual. The MA kidney transplants will be used in the numerator and denominator on the Medicare cost report to determine Medicare's share of kidney acquisition costs. Final payment will be made to the hospital through the Medicare cost report.

Comment: A commenter questioned how CMS addresses the difference between cadaveric organ acquisition and living donor organ donation in assessing kidney acquisition.

[17] *https://www.cms.gov/Regulations-and-Guidance/Guidance/Manuals/internet-Only-Manuals-IOMs-Items/CMS018912.*

[18] *https://www.cms.gov/Regulations-and-Guidance/Guidance/Manuals/Paper-Based-Manuals-Items/CMS021929.*

Response: We appreciate the commenter's question. Please refer to the Provider Reimbursement Manual, CMS Pub. 15–1, chapter 31,[18] for more information on provider reimbursement for the costs related to acquiring living donor organs and cadaveric donor organs.

After careful consideration of all comments received and for the reasons outlined in the proposed rule and our responses to comments, we are finalizing the regulatory changes to § 422.322 to conform with the statutory amendments requiring FFS Medicare coverage of kidney acquisition costs for MA beneficiaries, effective January 1, 2021.

C. Exclusion of Kidney Acquisition Costs From Medicare Advantage (MA) Benchmarks (§§ 422.258 and 422.306)

Section 17006(b) of the Cures Act amended section 1853 of the Act to require that the Secretary's estimate of standardized costs for payments for organ acquisitions for kidney transplants be excluded from Medicare Advantage (MA) benchmarks and capitation rates, effective January 1, 2021. As amended, section 1853(k)(5) of the Act provides for the exclusion from the applicable amount and section 1853(n)(2) provides for the exclusion from the specified amount of the Secretary's estimate of the standardized costs for payments for organ acquisitions for kidney transplants covered under the Medicare statute (including expenses covered under section 1881(d) of the Act). As discussed in greater detail in the Medicare Program; Changes to the Medicare Advantage and the Medicare Prescription Drug Benefit Programs for Contract Year 2012 and Other Changes Final Rule (hereinafter referred to as the April 2011 final rule) (76 FR 21431, 21484 through 21485) and the annual Advance Notices and Rate Announcements starting with Payment Year 2012,[19] the applicable amount and the specified amount are used in the calculation of the MA benchmarks and capitation rates. We proposed to revise the relevant regulations to reflect these amendments.

Specifically, we proposed to revise § 422.258, which describes the calculation of MA benchmarks. Under section 1853(n)(1)(B) of the Act and § 422.258(d) of the regulations, for 2012 and subsequent years, the MA benchmark for a payment area for a year is equal to the amount specified in section 1853(n)(2) of the Act (that is, the ''specified amount''), but, as described in section 1853(n)(4) of the Act and § 422.258(d)(2)(iii), cannot exceed the applicable amount specified in section 1853(k)(1) of the Act and § 422.258(d)(2). Prior to enactment of the Cures Act, section 1853(n)(2)(A) of the Act described the specified amount as the product of the base payment amount for an area for a year (adjusted to take into account the phase-out in the indirect costs of medical education from capitation rates) and the applicable percentage for the area and year. The base payment amount is, for years after 2012, the average FFS expenditure amount specified in § 422.306(b)(2). Section 17006(b)(2)(A) of the Cures Act amended section 1853(n)(2)(A)(i) of the Act to require that, for 2021 and subsequent years, the base payment amount used to calculate the specified amount must also be adjusted to take into account the exclusion of payments for organ acquisitions for kidney transplants from the capitation rate. We proposed to make conforming amendments to paragraphs (d)(3), (5), and (6) of § 422.258. As amended, paragraph (d)(3) would specify that for 2021 and subsequent years, the base payment amount used to calculate the specified amount is required to be adjusted to take into account the exclusion of payments for organ acquisitions for kidney transplants. Also, as amended, paragraphs (d)(5) and (6) would specify that the average FFS expenditure amount used to determine the applicable percentage is adjusted to take into account the exclusion of payments for organ acquisitions for kidney transplants. To make these amendments, we proposed to insert references to the adjustment made under § 422.306(d) to modify the various references to the base payment amount in paragraphs (d)(3), (d)(5), (d)(5)(i) and (ii), and (d)(6).

We proposed to amend § 422.306 by revising the introductory text and adding a new paragraph (d). Proposed paragraph (d) described the required adjustment, beginning for 2021, to exclude the Secretary's estimate of the standardized costs for payments for organ acquisitions for kidney transplants covered under this title (including expenses covered under section 1881(d) of the Act) in the area for the year. By operation of § 422.258(d)(2), the applicable amount is established by reference to § 422.306 and the rules there for calculation of MA annual capitation rates. By adding § 422.306(d), we would implement the new language in section 1853(k)(5) of the Act (added by section 17006(b)(1)(B) of the Cures Act) to require the adjustment to exclude payments for organ acquisitions for kidney transplants. We requested comment on whether these proposed revisions to §§ 422.258(d) and 422.306 adequately implement the statutory changes made by section 17006 of the Cures Act to require exclusion of the costs of kidney acquisition from the applicable amount and the specified amount for purposes of setting MA benchmarks and capitation rates.

Per section 1853(a)(1)(H) of the Act, CMS is required to establish separate rates of payment to an MA organization for individuals with end stage renal disease (ESRD) who are enrolled in a plan offered by that organization. This special rule for ESRD payment rates is codified in the regulations at 42 CFR 422.304(c). Since the Cures Act requires FFS Medicare payment for kidney acquisition costs for all MA enrollees, including MA enrollees with ESRD, we proposed to apply the exclusion of kidney acquisition costs to the ESRD payment rates. As § 422.304(c) does not prescribe the specific methodology CMS must use to determine the separate rates of payment for ESRD enrollees described in section 1853(a)(1)(H) of the Act, the exclusion of kidney acquisition costs from ESRD rates does not require regulatory amendment. CMS addressed the methodology for excluding kidney acquisition costs from MA benchmarks (including the MA ESRD state rates) in the 2021 Advance Notice and Rate Announcement.

Section 1894(d)(2) of the Act requires that PACE capitation amounts be based upon MA payment rates established under section 1853 of the Act and adjusted to take into account the comparative frailty of PACE enrollees and such other factors as the Secretary determines to be appropriate. While capitated payments made to PACE organizations are based on the applicable amount under section 1853(k)(1) of the Act, we will include the costs for kidney acquisitions in PACE rates. Because PACE organizations are required to cover all Medicare-covered items and services under section 1894(b)(1)(A)(i) of the Act, including organ acquisition costs for kidney transplants, we will include kidney acquisition costs in PACE payment rates, including PACE ESRD rates. This approach is consistent with how PACE organizations have historically been paid for kidney acquisition costs for PACE enrollees. We did not propose any regulatory amendments to address this.

[19] The Advance Notice and Rate Announcement for each year are available online at: *https://www.cms.gov/Medicare/Health-Plans/MedicareAdvtgSpecRateStats/Announcements-and-Documents.html.*

We appreciate commenters' feedback on our approach to implementing this Cures Act requirement. We received the following comments on our proposed regulatory changes, to which we provide responses below:

Comment: Numerous commenters expressed concerns about the methodologies for excluding kidney acquisition costs from MA benchmarks and for developing MA ESRD state rates. Several commenters requested additional transparency and data regarding the carve-out methodology, voiced concerns about the magnitude of the carve-out, and provided suggestions for alternative ways to calculate and apply the kidney acquisition adjustment. A commenter specifically noted that if the kidney acquisition carve-out amounts were to be artificially high, excluding these costs from MA benchmarks would exacerbate the perceived issues of underpayment in MA for ESRD beneficiaries.

Response: Section 1853(b) provides for CMS to use the annual Advance Notice to provide notice of proposed changes to be made in the methodology for the MA capitation rates and risk adjustment factors from the methodology and assumptions used in the previous announcement. As discussed, the kidney acquisition carve-out is part of the methodology for developing the MA capitation rates. Pursuant to the statute, CMS proposed the methodology for calculating the kidney acquisition costs to be excluded from the MA benchmarks in the 2021 Advance Notice by providing a step-by-step description of the calculations to be used to adjust the rates. CMS also detailed in the calendar year 2021 Advance Notice the methodology used to develop ESRD state rates. After considering all public comments received and consistent with the statutory requirement to exclude the cost of kidney acquisitions for organ transplants from the primary components of the MA capitation rates, CMS finalized the kidney acquisition carve-out methodology, as well as the ESRD rate methodology, in the calendar year 2021 Rate Announcement. Similar comments regarding the need for transparency and accuracy in calculating the kidney acquisition cost, the methodology used by CMS, and the amount of payment to MA plans were raised in that context and addressed by CMS in the calendar year 2021 Rate Announcement. We direct readers to that document for a more detailed discussion of these issues.

Comment: A commenter requested that CMS explain whether the exclusion of kidney acquisition costs from MA benchmarks has an impact on Medicare-Medicaid Plans (MMPs).

Response: CMS develops annual Medicare capitation rates used for MMP payment. The MMP capitation rates are based on an estimate of what would have been spent in the payment year had the demonstration not existed. Beneficiaries enroll in the MMP demonstrations from both MA and Medicare FFS, and therefore the MMP Medicare capitation rates are developed with a weighted average of these populations' spending assumptions, proportional to the combination of enrolled dually eligible beneficiaries. Therefore, the MMP Medicare capitation rates are developed using both the published Medicare standardized FFS county rates (which are part of the MA ratebook calculation files that are released with the annual Rate Announcement) and an MA component that is based on MA plans' bids and rebates.

As discussed in the calendar year 2021 Rate Announcement, kidney acquisition costs will be carved out of the contract year 2021 Medicare standardized FFS county rates. MA plans will bid against benchmarks that exclude kidney acquisition costs, in accordance with the statutory amendments to sections 1853(k) and (n); this is also consistent with how MA plans are no longer responsible for the costs of kidney acquisitions. Therefore, both components of the MMP Medicare capitation rate (the Medicare standardized FFS county rates and the MA component of the MMP rate) will exclude kidney acquisition costs. MMPs (like MA plans) will no longer be responsible for organ acquisition costs for kidney transplants; such costs will be excluded from the MMP rates and instead covered under Medicare FFS.

Comment: A commenter noted that plans will need to re-contract for transplant services to remove the cost of kidney acquisitions. This commenter explained that it is unlikely that the new contracts will carve out costs that are comparable to (or lower than) the costs being removed from the MA benchmarks. This commenter also requested the precise amounts CMS has paid on behalf on MA enrollees to each provider.

Response: We appreciate the commenter's concerns regarding this issue but must comply with the statutory requirement to exclude kidney acquisition costs from MA benchmarks. To date, CMS has paid for kidney acquisition costs for MA beneficiaries through the county and ESRD state rates in the MA ratebooks.

Comment: Numerous commenters noted concerns about the adequacy and accuracy of the ESRD rates as well as the perceived underfunding of the underlying ESRD PPS. A few commenters also requested that CMS consider various options related to payment for dialysis services, including the establishment of a fee schedule cap for dialysis centers, implementation of zero cost sharing for dialysis services, and provision of an incentive payment for MA plans to offer home dialysis.

Response: As these comments did not address the impact, implementation, or consequences of the kidney acquisition carve-out required by the Cures Act, they are out of the scope of this rulemaking.

After careful consideration of all comments received and for the reasons outlined in the proposed rule and out responses to the comments, we are finalizing the proposed changes to § 422.258(d)(3), (d)(5) introductory text, (d)(5)(i) introductory text, (d)(5)(ii), and (d)(6)(i) and the introductory text of § 422.306 and paragraph (d).

IV. Enhancements to the Part C and D Programs

A. Reinsurance Exceptions (§ 422.3)

Section 1855(b) of the Act requires MA organizations to assume full financial risk on a prospective basis for the provision of basic benefits (and, for plan years before 2006, additional benefits required under section 1854 of the Act) furnished to MA plan enrollees, subject to the exceptions listed in the statute at section 1855(b)(1)–(4) of the Act. The exception at section 1855(b)(1) of the Act states that an MA organization may obtain insurance or make arrangements for the cost of providing to any enrolled member such services the aggregate value of which exceeds a per-enrollee aggregate level established by the Secretary. Section 1855(b)(1) of the Act describes stop loss insurance arrangements but we explained in the proposed rule that our proposal did not use those terms in order to be specific in describing the form of the arrangement. Section 1855(b)(1) of the Act permits an MA organization to obtain insurance or make other arrangements under which the MA organization bears less than full financial risk for the costs of providing basic benefits for an individual enrollee that exceed a certain threshold. In the proposed rule, we proposed to adopt a new § 422.3 to implement the exception at section 1855(b)(1) of the Act and establish in regulation options for MA organizations to use insurance for costs beyond a specified threshold. We

proposed that an MA organization may obtain insurance (that is, reinsurance) or make other arrangements for the cost of providing basic benefits to an individual enrollee the aggregate value of which exceeds $10,000 during a contract year or, alternatively, such costs may be shared proportionately on a first dollar basis, the value of which is calculated on an actuarially equivalent basis to the value of the insurance for costs that exceed $10,000 in a contract year. We also proposed that if the MA organization chooses to purchase pro rata coverage that provides first dollar coverage, the value of that coverage cannot exceed the value of the option of purchasing stop loss insurance for enrollee health care costs that exceed a threshold of $10,000 in a contract year. We noted in the proposed rule that the statutory exceptions at section 1855(b)(2) through (b)(4) of the Act still apply and that our proposal would serve to establish in regulation the threshold described in section 1855(b)(1) of the Act.

Because we interpret section 1855(b) of the Act as requiring an MA organization to remain at full financial risk for basic benefits, subject to the exceptions listed in subsections (b)(1) through (b)(4), we proposed that the limits in § 422.3 apply for purposes of insuring (or making other arrangements) for costs of providing basic benefits in excess of the established threshold and that those limits would not apply to supplemental benefits offered by MA organizations. We proposed to implement the exception at section 1855(b)(1) of the Act because of concerns raised to CMS that absent the implementation of specific standards by CMS under section 1855(b)(1) of the Act, there was ambiguity about the legal basis of MA organizations sharing risk through reinsurance. We noted in our proposed rule that a number of MA organizations expressed concern to CMS about this legal uncertainty as they have utilized reinsurance within the MA program. To resolve this uncertainty, we proposed to formally establish reinsurance standards implementing section 1855(b)(1) of the Act. Our proposal was generally not about subsections (b)(2) through (b)(4) of section 1855 of the Act.

Under our proposed implementation of the exception at section 1855(b)(1) of the Act, MA organizations that voluntarily choose to purchase insurance to limit their exposure to losses in furnishing basic benefits to individual enrollees would have two options. In the first option, an MA organization could purchase insurance (or make other arrangements) that would stop losses for the MA organization for individual plan enrollees when an individual enrollee's covered costs for basic benefits exceed $10,000 during a contract year. Stated another way, the MA organization could have insurance for costs that exceed $10,000 for covering or furnishing basic benefits to an individual plan enrollee in the contract year. In the second option, an MA organization could purchase pro rata insurance coverage that would provide first dollar coverage provided that the value of the insured risk is actuarially equivalent to costs that exceed $10,000 and the insurance coverage is priced at an actuarial value not to exceed the value of the stop loss insurance for medical expenses exceeding $10,000 per member per year. Specifically, the value of first dollar pro rata insurance could not exceed the value of $10,000 per member per year stop loss insurance.

In the proposed rule, we noted that in discussions with the National Association of Insurance Commissioners (NAIC) and in 2018 Call Letter comments we previously received, CMS was advised that the use of insurance by health care insurers is a common and long standing market practice for both commercial health insurers and MA organizations and that the practice has the purpose of reducing financial exposure to changes in health care costs, helps manage capital requirements, and allows health care insurers to grow enrollment. As we explained in our proposed rule, discussions with the NAIC and earlier information we received from the industry indicated that MA organizations located in areas with fewer beneficiary choices (for example, rural, underserved areas) particularly benefit from access to reinsurance because of how it provides financial stability for the MA organization, which in turn can lead to enhanced competition and consumer choice, especially in small and mid-sized market areas. Insuring part of the risk assumed under an MA plan is important for smaller MA organizations to compete with larger organizations that can independently finance their operations.

We also noted that excessive reinsurance can be viewed as a hazard to the extent that the direct health insurer (here, the MA organization) might pass such a large share of their risk and premium through insurance and that the MA organization could then be viewed as no longer possessing the primary responsibility for furnishing the health care services. We further explained in our proposed rule that while the statute identifies the category of risk for which an MA organization may seek insurance or other arrangements (such as, in section 1855(b)(1) of the Act, the cost of providing to any enrolled member such services the aggregate value of which exceeds an established threshold), it is in the context of a mandate that MA organizations assume full financial risk on a prospective basis for providing basic benefits to enrollees. We stated that we are cognizant of the need to ensure that MA organizations are not transferring all the risk of providing services to enrollees to a third party that is not under contract with CMS. We also stated that we seek to balance these different interests in setting the threshold for the individual stop loss insurance coverage authorized by the statute.

We also explained that the $10,000 threshold we proposed has its roots in our review of the Conference Report for the BBA of 1997 (H.R. Conf. Rep. 105–217) and the difference between the House bill and the Senate amendment on the threshold at which a Part C plan could reinsure per-enrollee costs. The Conference Report indicates that the House bill tracked existing language in section 1876(b)(2)(D)(i) of the Act in using a $5,000 per year threshold while the Senate amendment provided for an amount established by the agency with an annual adjustment using the Consumer Price Index-Urban (CPI–U) for the 12-month period ending with June of the previous year. The conference agreement was to adopt the language in section 1855(b)(1) of the Act that remains today: A threshold established by the agency from time to time. To develop the $10,000 threshold we are proposing, we started with the amount of $5,000 identified in the Conference Report and used the following methodology: We multiplied the amount identified in the Conference Report ($5,000) by the increase in the CPI–U. Our policy choice was heavily influenced by the description in the Conference Report of the Senate amendment: ''the applicable amount of insurance for 1998 is the amount established by the Secretary and for 1999 and any succeeding year, is the amount in effect for the previous year increased by the percentage change in the CPI-urban for the 12-month period ending with June of the previous year.'' In updating the threshold this way, we rounded the amount for each year to the nearest whole dollar. Actual CPI–U values through June 2019 were used to perform these calculations. After 2019, the CPI–U values are estimated using the Congressional Budget Office's

August 2019 report: An Update to the Economic Outlook: 2019 to 2029.

In our discussion, we stated that based on a scan of the market and current practices of commercial health insurers, we believed that the $10,000 threshold for stop loss insurance that we proposed reflected a level of risk transfer that was reasonable and consistent with supporting robust competition in Medicare Advantage. We also explained our positon that the proposed level of risk transfer would be acceptable given that CMS closely monitors MA organizations in terms of their administration of their MA plans, specifically their timely provision of medically necessary health care services to enrollees and their overall financial solvency. We further clarified that CMS has a direct contract with each MA organization and despite any insurance arrangements, the MA organization remains responsible and liable to each individual enrollee for furnishing the covered benefits. In addition, we explained that CMS through its regional offices, plan audits, review of enrollee appeals and stakeholder letters closely monitors the performance of MA organizations and intervenes whenever it has evidence an MA organization is not meeting its contractual obligations. We also noted that any insurance arrangement used by MA organizations is subject to state insurance regulation and oversight regarding solvency because section 1856(b)(3) of the Act does not preempt those solvency laws or provide that CMS regulation supersedes them. We noted our understanding that the NAIC model laws (Model 785); NAIC Credit for Reinsurance Regulation (Model 786); and the NAIC Life and Health Reinsurance Agreements Model Regulation (Model 791) have been substantially adopted by all states. We believe the wide adoption of the NAIC reinsurance model laws by states ensures reasonable consistency for MA organizations subject to reinsurance review as part of the state's financial solvency determination. Finally, we stated that CMS oversight along with the states' oversight of financial solvency substantially would ensure that CMS would be able to intervene on a timely basis when an MA organization is experiencing solvency problems or is not meeting its obligation to appropriately furnish its enrollees with benefits covered under the MA plan.

We also acknowledged that the reinsurance marketplace is complex and evolving. Therefore, we asked for comments regarding our proposed reinsurance regulation generally and the specific threshold proposed. We stated that we were particularly interested in comments whether the $10,000 threshold is a reasonable level and if the flexibility we proposed for MA organizations in permitting insurance or other arrangements that are actuarially equivalent to the $10,000 threshold for individual medical costs is sufficient to remove the uncertainty about the use of reinsurance by MA organizations. We also solicited comments that would provide additional information about insurance or other arrangements for addressing the risk of costs that exceed specific thresholds on an individual enrollee basis.

In our proposed rule, we also explained that we would consider an MA organization to include its parent organization when evaluating compliance with the proposed standard for reinsurance and compliance with the statute. The result of that would be to evaluate compliance with section 1855(b) of the Act (not just subsection (b)(1)) and proposed § 422.3 at the parent organization level, such that risk sharing or allocations of losses and costs among wholly-owned subsidiaries would not be evaluated. We requested comments on this approach and whether CMS should consider a parent organization to be part of an MA organization for purposes of section 1855(b) of the Act or whether CMS should consider a parent organization to be a separate entity from an MA organization.

We thank commenters. We received 13 comments on this proposal; we summarize these comments and our responses follow:

Comment: Several commenters were generally supportive of § 422.3(a)(1) affirming the ability of MA organizations to purchase stop loss insurance for basic Medicare covered medical expenses for an individual enrollee that exceed with an aggregate value of $10,000 or more per member per year in any year. However, several commenters expressed concerns about the proposed pro rata insurance requirement at § 422.3(a)(2), requiring that this option not exceed the actuarial cost of purchasing stop loss insurance for enrollee health care costs that exceed a threshold of $10,000 in a contract year. A commenter stated that they read the proposed regulation as requiring that the value of the insured risk does not exceed a value which is actuarially equivalent to the aggregate value of the costs of providing basic benefits to an individual enrollee which exceeds an aggregate level that is greater than or equal to $10,000 during a contract year. The commenter said that they found this language difficult to follow. This commenter also said that, further complicating the matter, excess of loss insurance (that is, stop loss) and first dollar proportional (that is, pro rata) insurance are very different forms of reinsurance. Other commenters were also concerned that because of the differences in these types of insurance it would be difficult calculating an actuarial value for the cost of purchasing annual pro rata insurance, which shares costs with an insurer on a first dollar proportional basis. The commenters also said that their uncertainly about how to calculate this actuarial equivalency would make it difficult for them to ensure they would be in compliance with the proposed regulatory requirement. Several commenters recommended that instead of an actuarial equivalence that we set a limit on the amount of risk that an MA organization would be allowed to transfer to a reinsurer. Several commenters specifically proposed that CMS adopt a 10 percent standard under which an MA organization would be required to maintain a minimum of 10 percent of the financial risk in any reinsurance arrangement involving the sharing of costs proportionately with an insurer on a pro rata first dollar basis.

Response: We agree that the reinsurance options under proposed § 422.3(a)(1) and (2) are different and acknowledge this potentially creates uncertainty and difficulties in determining actuarial equivalency, as pointed out by the commenters. As we noted above the statute permits an MA organization to use insurance or make other arrangements for the cost of providing basic benefits to an individual enrollee that exceed a certain threshold. In order to provide an option for using insurance or other arrangements for some of the cost of providing basic benefits to an individual enrollee before the threshold is exceeded, we sought to establish a way to equate the $10,000 stop loss threshold to sharing the risk proportionally on a first dollar basis (that is, pro rata insurance) to provide additional flexibility to MA organizations while ensuring compliance with the statute.

In considering these comments we appreciate that there could be difficulty for some organizations in determining whether and when the two reinsurance options were actuarially equivalent or in determining an actuarially equivalent dollar amount for the two reinsurance options. We also recognize that it would be administratively simpler if we were to adopt a single standard for the amount of risk an MA organization can transfer to an insurer under this regulation. As we discuss below we are finalizing regulation text to clarify how

MA organizations can make an actuarial equivalency determination between the $10,000 stop loss insurance option and the option to purchase first dollar proportional (that is, pro rata) insurance. In addition, we have determined that the ability to purchase pro rata insurance affords the MA organizations the necessary flexibility to purchase different types of reinsurance. We are specifically finalizing this regulation to allow an MA organization to have insurance or make another arrangement for the cost of providing basic benefit to an enrollee, the aggregate value of which exceed an aggregate value that is equal to or greater than $10,000. In effect, an MA organization can have stop-loss insurance per enrollee with a $10,000 attachment point. In addition, the MA organization may use insurance to share costs proportionately on a per member per year first dollar basis as long as the amount of risk retained by the MA organization is actuarially equivalent to the risk retained in purchasing $10,000 per member per year first dollar stop loss insurance. To specifically address the concerns about actuarial equivalence valuations we have determined that actuarial equivalence may be calculated as the expected percentage of the MA organization's claim cost of providing basic benefits to an individual enrollee that is greater than or equal to $10,000 during a contract year. The MA organization may share its costs proportionately on a first dollar basis up to the expected percentage. For example, assume that the actuarially supported expected percentage is 66 percent. In this example, the MA organization may reinsure (cede) up to 66 percent of such costs proportionately on a first dollar basis. However, we recognize that there are other reasonable actuarial approaches that could be used to determine the actuarial equivalence cost when purchasing pro rata insurance. We will accept approaches that are based on a reasonable actuarial methodology. An MA organization may also value its pro rata insurance by establishing a specific percentage level of risk that it can reinsure that is not more than the actuarial value of $10,000 individual stop loss insurance. Appreciating that some commenters indicated that the proposed regulation text describing the permissible stop-loss arrangement was confusing, we are clarifying this in the final regulation text. The regulation now states the permissible insurance or other arrangement by describing the permissible reinsurance or other arrangement in terms of how much and which financial risk the MA organization must retain: The MA organization must retain the risk for at least the first $10,000 in costs of providing basic benefits per individual enrollee during the contract year.

To specifically address the concerns about actuarial equivalence valuations, we are finalizing regulation text to clarify that MA organization may make a determination of actuarial equivalence based on reasonable actuarial methods. We are finalizing that an MA organization may share the costs of providing basic benefits on a per member per year first dollar basis when: (i) The actuarial value of the risk retained by the MA organization is actuarially equivalent to the value of the risk that must be retained using the permissible stop-loss arrangement that is described in paragraph (a)(1) and (ii) the determination of actuarial equivalence is based on reasonable actuarial methods. For example, actuarial equivalence may be reasonably calculated using the expected percentage of the MA organization's claim cost of providing basic benefits to an individual enrollee that is greater than or equal to $10,000 during a contract year. The MA organization may share its costs proportionately on a first dollar basis up to that expected percentage. For example, assume that the actuarially supported expected percentage is 66 percent. In this example, the MA organization may reinsure (cede) up to 66 percent of such costs proportionately on a first dollar basis. However, we recognize that there are other reasonable actuarial approaches that could be used to determine the actuarial equivalence cost when purchasing pro rata insurance. We will accept approaches that are based on a reasonable actuarial methodology. An MA organization may also value its pro rata insurance by establishing a specific percentage level of risk that it can reinsure that is not more than the actuarial value of $10,000 individual stop loss insurance.

Comment: Several commenters asked for clarification about the applicability of the proposed reinsurance rule, asking if it would apply to quota share reinsurance arrangements under section 1855(b)(1) of the Act alone, or will it also apply to quota share reinsurance arrangements under subsections (b)(2), (b)(3) and (b)(4) of section 1855 of the Act as well. The commenters wanted to know if quota share arrangements would be permissible only in the specific circumstances described in our proposed rule to implement section 1855(b)(1) of the Act.

Response: Our proposal and this final rule at § 422.3(a) are specifically about implementing section 1855(b)(1) of the Act. Section 1855(b)(1) permits MA organizations to insure or make other arrangements for the cost of providing to any enrolled member basic benefits the aggregate value of which exceed a threshold set by the agency. We proposed that threshold ($10,000) and a way that MA organizations could share *that particular risk* proportionately by tying the parameters for the proportionate-risk arrangement to the actuarial value of the financial risk where the stop loss threshold is over $10,000.

MA organizations are only permitted to share risk proportionally so long as the risk (the type and amount) is in the statutory exceptions at section 1855(b) of the Act. Section 1855(b) of the Act describes types of risk for which an MA organization may use insurance or make other arrangements. For example, section 1855(b)(2) permits an MA organization to obtain insurance or make other arrangements for the cost of basic benefits provided to its enrollees other than through the organization because medical necessity required the provision of those basic benefits before that organization could furnish them; an MA organization could use insurance to cover all of the costs described in subsection (b)(2), use a quota share arrangement for those costs, or use some other reinsurance arrangement for those costs. However, section 1855(b)(2) only permits the use of reinsurance or risk sharing arrangements for those specifically described costs. Our proposal and this final rule at § 422.3(a) do not address the other statutory exceptions at section 1855(b) of the Act.

Comment: Several comments asked that CMS acknowledge that CMS policy has, in the past, permitted MA organizations to utilize quota share reinsurance arrangements with captive insurance companies and risk bearing entities including provider-affiliated captive insurance companies, or other risk-bearing entities under the authority of section 1855(b)(4) of the Act, and that CMS will continue to allow this. Commenters also asked that CMS further clarify whether the provider-affiliated entity must be wholly-owned by the provider, or whether a lower percentage of ownership is required.

Response: Section 1855(b)(4) of the Act permits an MA organization to make arrangements with physicians or other health care professionals, health care institutions, or any combination of such individuals or institutions to assume all or part of the financial risk on a prospective basis for basic benefits

furnished by such physicians, by such other health professionals or through such institutions. The type of payment arrangement used between the MA organization and contracting physicians, other health professionals or institutions for this specified financial risk is not limited by § 422.3(a). To be clear on this point, we are finalizing § 422.3(c) to state that the type of payment arrangement between an MA organization and contracting physicians, other health professionals or institutions for the financial risk on a prospective basis for the provision of basic benefit by those physicians or other health professionals or through those institutions) is not limited by § 422.3(a).

Comment: Two commenters asked if reinsurance options under § 422.3(a)(1) and (2) can also include MA supplemental benefits. A commenter stated that it is operationally very challenging to separate the revenues and expenses associated with supplemental benefits from the revenues and expenses associated with basic benefits.

Response: As we stated in the proposed rule, we interpret section 1855(b) of the Act as requiring an MA organization to remain at full financial risk for basic benefits, subject to the exceptions listed in subsections (b)(1) through (b)(4). The limits in proposed § 422.3(a) and finalized in this rule apply for purposes of insuring (or making other arrangements) for costs of providing basic benefits and therefore do not apply to supplemental benefits offered by MA organizations. MA organizations are not prohibited from obtaining reinsurance for supplemental benefits and this final rule does not limit either the form or amount of reinsurance for supplemental benefits.

Comment: Commenters were supportive of our proposal with respect to section 1855(b) to broaden our interpretation of MA organization to include the parent organization. This would mean that CMS would evaluate compliance with 1855(b) of the Act and proposed § 422.3 at the parent organization level, such that risk sharing or allocations MAO of losses and costs among wholly-owned subsidiaries would not be evaluated. Commenters also asked if CMS will accommodate situations where an MA organization obtains reinsurance from captive insurance companies, an affiliate and/or a joint venture or alliance partner. A commenter noted that reinsurance is a useful means by which to share profits/losses in joint ventures and alliances, an entity may choose to allocate its risk to a reinsurer that is an affiliate of the MA organization and to another joint venture or alliance partner. The comment states that these arrangements serve as a mechanism to facilitate the allocation of profits/losses under a joint venture or alliance.

Response: In this final rule we are affirming that for purposes of 1855(b) of the Act and for § 422.3, we will evaluate compliance at the parent organization level, such that risk sharing or allocations of losses and costs among wholly-owned subsidiaries will not be evaluated. These internal arrangements would be treated as the MA organization retaining full financial risk for the losses or risks that are covered through the internal arrangement. We are adding language to the final regulation at § 422.3(b) confirming this position. Reinsurance arrangements facilitated for purposes of joint venture and alliance partner must comply with 1855(b) of the Act, CMS regulations and requirements, other federal laws and regulations, and state laws and requirements.

We thank the commenters for sharing their concerns and recommendations regarding our proposed implementation of Section 1855(b)(1) in the MA regulations at § 422.3. After careful examination of all comments received and for the reasons set forth in the proposed rule and our responses to comments, we are finalizing § 422.3 with modifications from the proposal. As finalized, paragraph (a) provides that an MAO may obtain insurance or make other arrangements for the cost of providing basic benefits to an individual enrollee during the contract year in one of two ways. We are finalizing § 422.3(a)(1) to permit an MA organization to use insurance or make other arrangements for the cost of providing basic benefits to an individual enrollee during the contract year so long as the MA organization retains risk for at least the first $10,000 of that cost. We are finalizing § 422.3(a)(2)(i) permitting reinsurance on a per member per year first dollar basis so long as the MA organization retains at least an amount of risk that is actuarially equivalent to the value of risk retained in paragraph (a)(1). We also clarify in the final regulation at § 422.3(a)(2)(ii) that MA organizations obtaining such reinsurance under the option described at § 422.3(a)(2)(i) may utilize any reasonable actuarial methodology to determine actuarial equivalence.

We are also adding § 422.3(b) clarifying that CMS will consider a parent organization to be part of an MA organization for purposes of section 1855(b) of the Act. Finally, we are adding regulation text at § 422.3(c) to clarify the type of payment arrangement used between an MA organization and contracting physicians, other health professionals or institutions for the financial risk specified in section 1855(b)(4) of the Act is not limited by paragraph (a).

B. Medicare Advantage (MA) and Part D Prescription Drug Program Quality Rating System (§§ 422.162, 422.166, 423.182, and 423.186)

1. Introduction

In the April 2018 final rule, CMS codified at §§ 422.160, 422.162, 422.164, and 422.166 (83 FR 16725 through 83 FR 16731) and §§ 423.180, 423.182, 423.184, and 423.186 (83 FR 16743 through 83 FR 16749) the methodology for the Star Ratings system for the MA and Part D programs, respectively. This was part of the Administration's effort to increase transparency and give advance notice regarding enhancements to the Part C and D Star Ratings program. CMS must propose through rulemaking any future changes to the methodology for calculating the ratings, addition of new measures, and substantive changes to the measures. Sections 422.164(e) and 423.184(e) provide authority and a mechanism for the removal of measures for specific reasons (low statistical reliability and when the clinical guidelines associated with the measure change such that the specifications are no longer believed to align with positive health outcomes). In the April 2019 final rule, CMS amended §§ 422.166(a)(2)(i) and 423.186(a)(2)(i) to update the methodology for calculating cut points for non-Consumer Assessment of Healthcare Providers and Systems (non-CAHPS) measures by adding mean resampling and guardrails, codified a policy to adjust Star Ratings for disasters, and finalized some measure updates. In the Medicare and Medicaid Programs; Policy and Regulatory Revisions in Response to the COVID–19 Public Health Emergency Interim Final Rule (85 FR 19230; CMS–1744–IFC) published in the **Federal Register** website on April 6, 2020, CMS adopted a series of changes to the 2021 and 2022 Star Ratings to accommodate the disruption to data collection posed by the COVID–19 pandemic. Specifically, the IFC:

- Eliminates the requirement to collect and submit Healthcare Effectiveness Data and Information Set (HEDIS) and Medicare Consumer Assessment of Healthcare Providers and Systems (CAHPS) data otherwise collected in 2020 and replaces the 2021 Star Ratings measures calculated based on those HEDIS and CAHPS data collections with earlier values from the 2020 Star Ratings (which are not

affected by the public health threats posed by COVID–19);

- Establishes how we will calculate or assign Star Ratings for 2021 in the event that CMS's functions become focused on only continued performance of essential agency functions and the agency and/or its contractors do not have the ability to calculate the 2021 Star Ratings;
- Modifies the current rules for the 2021 Star Ratings to replace any measure that has a systemic data quality issue for all plans due to the COVID–19 outbreak with the measure-level Star Ratings and scores from the 2020 Star Ratings;
- In the event that we are unable to complete Health Outcomes Survey (HOS) data collection in 2020 (for the 2022 Star Ratings), replaces the measures calculated based on HOS data collections with earlier values that are not affected by the public health threats posed by COVID–19 for the 2022 Star Ratings;
- Removes guardrails for the 2022 Star Ratings by delaying their application to the 2023 Star Ratings;
- Expands the existing hold harmless provision for the Part C and D Improvement measures to include all contracts for the 2022 Star Ratings; and
- Revises the definition of ''new MA plan'' so that for purposes of 2022 quality bonus payments based on 2021 Star Ratings only, new MA plan means an MA contract offered by a parent organization that has not had another MA contract in the previous 4 years, in order to address how the 2021 Star Ratings will be based in part on data for the 2018 performance period.

Please see the IFC for further information on these changes for the 2021 and 2022 Star Ratings.

In the February 2020 proposed rule, we proposed enhancements to further increase the stability of cut points by modifying the cut point methodology for non-CAHPS measures through direct removal of outliers. We also proposed to increase the weight of patient experience/complaints measures and access measures and remove the Rheumatoid Arthritis Management (Part C) measure from the Star Ratings because the measure steward is retiring the measure from the HEDIS measurement set. We proposed to modify the classification of the Statin Use in Persons with Diabetes (SUPD) measure from an intermediate outcome measure to a process measure, starting with the 2023 Star Ratings, due to feedback in response to the Draft 2020 Call Letter and to align with the measure steward's clarification regarding the measure's classification. In addition, we proposed other policies to amend the Part C and Part D Star Ratings but are not addressing those proposals in this final rule; those other proposals will be addressed in a future final rule.

Our proposal was for the changes we address here—the removal of outliers, increasing the weight of certain classes of measures, removing the Rheumatoid Arthritis Management measure, and reclassifying the SUPD measure—to be effective for the 2021 performance period and the 2023 Star Ratings. As discussed in this section, we are finalizing the proposed changes with some modifications. As finalized, the change to the weight of the patient experience/complaints measures and access measures, the removal of the Rheumatoid Arthritis Management measure, and the reclassification of the SUPD measure are applicable (that is, data would be collected and performance measured) for the 2021 measurement period and the 2023 Star Ratings. Under this final rule the direct removal of outliers will apply for the 2022 measurement period and the 2024 Star Ratings.

CMS appreciates the feedback we received on our proposals. In the sections that follow, which are arranged by topic area, we summarize the comments we received on each proposal and provide our responses. Below we summarize some general comments we received about the potential impact of the COVID–19 public health emergency on our Star Ratings proposals.

Comment: Numerous commenters requested that CMS refrain from making any changes to the Star Ratings system until the COVID–19 pandemic's impact on the healthcare system is better understood. They suggested we delay any changes to the quality rating system until after the public health emergency resulting from COVID–19 subsides due to the significant uncertainties around the duration and impact of COVID–19 on the healthcare system.

Response: CMS agrees that there is a lot of uncertainty about how COVID–19 will impact the healthcare system. However, we still believe that it is important to move forward with some limited Star Ratings changes to further emphasize the importance of patient experience/complaints measures and access measures and to help stabilize the movement in the cut points from year to year. The changes to the weighting of patient experience/complaints measures and access measures apply to the 2021 measurement year, not the 2020 measurement year when the pandemic first started. The implementation of Tukey outlier deletion has been delayed an additional year. Although there is some uncertainty how COVID–19 will impact the healthcare system and quality measurement, plans will have until the 2021 measurement year to adjust their processes to account for the impact of COVID–19 on Star Ratings measures.

Comment: Commenters raised concerns that additional Star Ratings changes may be needed to account for COVID–19 in future years. For example, several commenters noted data collection challenges could impact 2021, 2022, 2023, and 2024 Star Ratings for some measures. A commenter noted COVID–19 may overwhelm our healthcare systems leading to significant impacts on many measures. A few commenters specifically noted concerns about supply chain disruptions and prescription drug shortages. A commenter noted that plan activities in response to emergency situations can create unintended consequences in the years following, including for Star Ratings. Another commenter suggested CMS revisit the capacity and capability expectations defined in specific measures and meet with provider and plan stakeholders when the crisis has abated; they suggest some measures may need to be re-tooled so that scarce resources are devoted to building capacity and functionality of the health and social delivery systems.

Response: CMS is continuing to monitor the situation to see if additional Star Ratings changes are necessary and appropriate. As noted above, the IFC includes a series of changes for the 2021 and 2022 Star Ratings to accommodate challenges arising from the COVID–19 pandemic. Please see the IFC for further information on these changes for the 2021 and 2022 Star Ratings. CMS recognizes that there may be impacts from COVID–19 on measure scores and is delaying the implementation of Tukey outlier deletion for an additional year to allow these impacts to play out before adding an additional methodological change for the cut point calculations.

Comment: A commenter asked that CMS remain cautious on pursuing changes that could weaken the ability of plans to make quality improvements in the aftermath of COVID–19.

Response: CMS recognizes the challenges that COVID–19 has placed on the healthcare system and Part C and Part D plans that are subject to the Quality Star Rating System. CMS continues to monitor whether additional Star Ratings adjustments are necessary and appropriate.

Comment: A commenter requested that CMS ensure that policy changes that allow pharmacies to meet prescription drug therapy needs during the COVID–19 outbreak are not used to penalize pharmacies in their performance ratings.

Response: CMS will continue to monitor the impact of COVID–19 on the healthcare system. The Part C and D Star Ratings are for rating the Medicare health and drug plans not pharmacies.

Comment: Several commenters noted that different areas of the country may experience the pandemic differently, and there may also be differences by health plan populations, such as those with high dual eligible or low-income populations. A commenter noted that CDC's recommendation for social distancing, especially for more vulnerable populations, may result in Medicare beneficiaries not pursuing preventive screenings, and that this may be more impactful for beneficiaries in geographies more heavily impacted by COVID–19 and for beneficiaries in rural areas with less access to care.

Response: CMS will continue to monitor the impact of COVID–19 on the healthcare system and Part C and D plans. The IFC addressed the immediate impact of the pandemic on the Part C and D Star Ratings program and made additional modifications for the 2022 Star Ratings, in recognition that the COVID–19 pandemic may impact performance on the Star Ratings measures during the 2020 measurement period. CMS delayed the implementation of guardrails to allow cut points to adjust to changes in industry performance for the 2020 measurement period. Additionally, CMS expanded the hold harmless provisions for the Part C and D improvement measures that are based on the 2020 measurement period so that those measures where there is a significant decrease in performance will not bring down a contract's overall or summary ratings for the 2022 Star Ratings. CMS continues to monitor to what extent our current policy for extreme and uncontrollable circumstances codified at §§ 422.166(i) and 423.186(i) will help address the issue of some geographic areas being more impacted than others and whether additional Star Ratings adjustments are necessary and appropriate.

Comment: A commenter asked that CMS consider the longer-term economic ramifications that COVID–19 is causing to highly impacted areas when considering Star Ratings policies.

Response: CMS will continue to monitor the impact of COVID–19 on the healthcare system and Part C and Part D plans that are subject to the Quality Star Rating System. CMS continues to monitor whether additional Star Ratings adjustments are necessary and appropriate.

Comment: A commenter suggested that given the strain COVID–19 is placing on the healthcare system, CMS should suspend Effectiveness of Care measures based on 2020 data. Another asked whether the Part D appeals measures would still be removed for 2021.

Response: Generally, these comments are out of the scope of the proposed rule and the policies we are addressing in this final rule. The IFC addressed the immediate implications of the pandemic on the Part C and D Star Ratings program. Specifically, for the 2020 measurement year, it delays the implementation of guardrails so cut points will adjust downward if industry performance broadly declines as a result of the pandemic. CMS is proceeding to remove the Part D appeals measures for the 2020 measurement year and the associated 2022 Star Ratings, as outlined in the 2020 final Call Letter, under § 423.184(e)(1) and based on our determination that the measure is no longer reliable.

Comment: Several commenters gave specific feedback related to the IFC and the 2021 and 2022 Star Ratings.

Response: We thank commenters for this feedback, but these comments are out of scope for this rule. We will discuss comments to the IFC policies in a future final rule.

2. Measure-Level Star Ratings (§§ 422.166(a), 423.186(a))

Over the past 2 years, we have codified and refined the methodology for calculating the Star Ratings from the performance scores for non-CAHPS measures. At §§ 422.166(a) and 423.186(a), we initially codified the historical methodology for calculating Star Ratings at the measure level in the April 2018 final rule. The methodology for non-CAHPS measures employs a hierarchical clustering algorithm to identify the gaps that exist within the distribution of the measure-specific scores to create groups (clusters) that are then used to identify the cut points. The Star Ratings categories are designed such that the scores in the same Star Ratings category are as similar as possible and the scores in different Star Ratings categories are as different as possible. The current methodology uses only data from the most recent Star Ratings year; therefore, the cut points are sensitive to changes in performance from 1 year to the next.

The primary goal of any cut point methodology is to disaggregate the distribution of scores into discrete categories or groups such that each grouping accurately reflects true performance. The current MA Star Ratings methodology converts measure-specific scores to measure-level Star Ratings so as to categorize the most similar scores within the same measure-level Star Rating while maximizing the differences across measure-level Star Ratings. We solicited comments in the Medicare Program; Contract Year 2019 Policy and Technical Changes to the Medicare Advantage, Medicare Cost Plan, Medicare Fee-for-Service, the Medicare Prescription Drug Benefit Programs, and the PACE Program Proposed Rule (hereinafter referred to as the November 2017 proposed rule) regarding the approach to convert non-CAHPS measure scores to measure-level Star Ratings (82 FR 56397 through 56399). We requested input on the desirable attributes of cut points and recommendations to achieve the suggested characteristics in the Medicare and Medicaid Programs; Policy and Technical Changes to the Medicare Advantage, Medicare Prescription Benefit, Programs for All-inclusive Care for the Elderly (PACE), Medicaid Fee-for-Service, and Medicaid Managed Care Programs for Years 2020 and 2021 Proposed Rule (hereinafter referred to as the November 2018 proposed rule). In addition, we requested that commenters either suggest alternative cut point methodologies or provide feedback on several options detailed in the November 2018 proposed rule, such as setting the cut points by using a moving average, using the mean of the 2 or 3 most recent years of data, or restricting the size of the change in the cut points from 1 year to the next.

The commenters identified several desirable attributes for cut points that included stability, predictability, and attenuation of the influence of outliers; commenters also suggested restricting movement of cut points from one year to the next and recommended that CMS either pre-announce cut points before the plan preview period or pre-determine cut points before the start of the measurement period. In the April 2018 final rule (83 FR 16567), we expressed appreciation for our stakeholders' feedback and stated our intent to use it to guide the development of an enhanced methodology while maintaining the intent of the cut point methodology to accurately reflect true performance.

Using the feedback from the comments we received in response to

the November 2018 proposed rule, we considered enhancements to the methodology that would increase the stability and predictability of the cut points and finalized in the April 2019 final rule two enhancements to the historical methodology. In the April 2019 final rule, we amended §§ 422.166(a)(2)(i) and 423.186(a)(2)(i) to add mean resampling of the current year's data to the current clustering algorithm to attenuate the effect of outliers; we also added measure-specific caps in both directions to provide guardrails so that the measure-threshold-specific cut points do not increase or decrease more than the cap from one year to the next. The IFC (CMS–1744–IFC) delays the implementation of guardrails for an additional year; thus, it will be implemented for the 2021 measurement year and the 2023 Star Ratings.

Some commenters to the November 2018 proposed rule believed mean resampling would not be sufficient to address outliers and expressed support for directly removing outliers before clustering. We did not finalize an approach for directly removing outliers in the April 2019 final rule in order to provide the public prior notice of a proposal for incorporating removal of outliers and an opportunity to comment on a specific approach and so that we could continue to evaluate the methodologies for outlier removal (84 FR 15761).

As we stated in the April 2019 final rule in response to public comments on this topic, we evaluated two options to address direct removal of outliers—trimming and Tukey outer fence outlier deletion. Under trimming, all contracts with scores below the 1st percentile or above the 99th percentile are removed prior to clustering. Although trimming is a simple way to remove extreme values, it removes scores below the 1st percentile or above the 99th percentile regardless of whether such scores are true outliers. This means in cases when true outliers are between the 1st and 99th percentile, they would not be removed by trimming, and in cases when the distribution of scores is skewed, scores that are not true outliers would be trimmed.

In the February 2020 proposed rule, we proposed to use Tukey outer fence outlier deletion as the method to identify and delete outliers before applying the already-applicable mean resampling and hierarchical clustering processes. With mean resampling, measure-specific scores for the current year's Star Ratings are randomly separated into 10 equal-sized groups. The hierarchical clustering algorithm is done 10 times, each time leaving one of the 10 groups out. The method results in 10 sets of measure-specific cut points. The mean cut point for each threshold per measure is calculated using the 10 values. Tukey outer fence outlier deletion is a standard statistical method. Tukey outer fence outliers are sometimes called Whisker outliers. Under this methodology, outliers are defined as measure scores below a certain point or above a certain point. We proposed that the lower point or the ''lower outer fence'' would be identified with this formula: (first quartile − 3.0 × (third quartile − first quartile)); and the higher point or the ''upper outer fence'' would be identified with this formula: (third quartile + 3.0 × (third quartile − first quartile)). The Tukey outer fence outlier deletion will remove all outliers based on the previous definition for the two points (that is, the lower and upper outer fences) and does not remove any cases that are not identified as outliers. Values identified as outside the Tukey outer fences would then be removed immediately prior to clustering.

We explained in the proposed rule that if Tukey outer fence outlier deletion and a 5 percent guardrail had been implemented for the 2018 Star Ratings, 2 percent of MA–PD contracts would have seen their Star Rating increase by half a star, 16 percent would have decreased by half a star, and one contract would have decreased by 1 star. For PDP contracts, 2 percent would have increased by half a star, and 18 percent would have decreased by half a star. This simulation of the impact of Tukey outlier deletion also takes into account the removal of the two Part D appeals measures (Appeals Auto-Forward and Appeals Upheld) and the Part C measure Adult BMI Assessment, because these measures will be removed starting with the 2022 Star Ratings. In general, there tends to be more outliers on the lower end of measure scores. As a result, the 1 to 2 star thresholds often increased in the simulations when outliers were removed compared to the other thresholds which were not as impacted.

We requested comments on our proposal to use Tukey outer fence outlier deletion as an additional step prior to hierarchal clustering. We explained that under our proposal in the first year of implementing this process, the prior year's thresholds would be rerun, including mean resampling and Tukey outer fence deletion so that the guardrails would be applied such that there is consistency between the years. We proposed to amend §§ 422.162 and 423.182 to add a definition of the outlier methodology (''Tukey outer fence outliers'') and to amend §§ 422.166(a)(2)(i) and 423.186(a)(2)(i) to apply the outlier deletion using that methodology prior to applying mean resampling with hierarchal clustering.

We received the following comments related to our proposal, and our responses follow:

Comment: Most commenters opposed moving forward with the Tukey outlier deletion at this time, citing a variety of different reasons. A handful of commenters raised general concerns about the Tukey outlier deletion method, mentioning criticism in academic communities about applying Tukey fences to skewed data, given what the commenters characterized as the Tukey approach's assumption of a normal distribution. Other commenters suggested additional research is needed on alternatives for removing outliers. Some commenters did not support the use of Tukey outlier deletion without more information about how the Tukey outlier fence models will be applied and more detail on CMS analyses. A couple of commenters did not support adding Tukey outlier deletion given the fluctuation it may cause in the ratings.

Response: CMS is concerned about extreme outliers influencing cut point determinations and has selected an approach to identify and remove outliers prior to clustering contract scores to determine cut points for assigning measure stars. The main objective of removing outliers is to stabilize cut points and prevent large year-to-year fluctuations in cut points caused by the scores of a few contracts. CMS selected the conservative outer-fence form of the Tukey outlier deletion method because it is transparent (easily understood and can be implemented by stakeholders with widely-available software) and robust to distributional shape (it performs as intended for this purpose across the range of score distributions seen in Star Ratings data).

CMS disagrees that the Tukey outer fence outlier approach is inappropriate for identifying the outliers to be removed from the performance score data. Even when the data are not normally distributed (for example, in a skewed distribution), the Tukey approach performs as intended. The Tukey outer fence outlier deletion approach is a standard statistical method that is non-parametric, that is, it is not dependent on distributional assumptions. We plan to adopt a more conservative definition, based on Tukey *outer* fences, that only removes scores that are extreme outliers. This approach removes fewer outliers at both extremes of the score distribution than the inner

fence approach. We plan to identify and remove extreme outliers immediately prior to applying the clustering algorithm to set cut points. The Tukey outer fences would be calculated from the set of measure scores after removing contracts that are to be excluded from clustering (such as because the measure is voluntary for that contract).

The first step in applying the Tukey outlier deletion method is calculating the first quartile (Q1) and third quartile (Q3) of the score distribution: 25 percent of scores fall below Q1, another 25 percent of scores fall above Q3, and the remaining 50 percent of scores fall between Q1 and Q3. Next, we calculate the interquartile range (IQR), the difference between the third and first quartiles (IQR = Q3 − Q1), which refers to the range of the middle 50 percent of all scores. The Tukey outer fence method identifies extreme outlier as those that are below (Q1 $-3\times$IQR) or above (Q3 + $3\times$IQR).

We examined the use of trimming as an alternative outlier removal approach and found very similar results as those described in the proposed rule from using the Tukey approach. We performed simulations that trimmed any scores that were above the 99th percentile or below the 1st percentile, trimming values at the tail ends of the distribution prior to clustering. The method had effects on Star Ratings similar to those of the Tukey method. An important strength of the Tukey outer fence outlier deletion method over the trimming method is that trimming removes a fixed proportion of plan scores for each measure, regardless of whether those scores are distant from the center of the score distribution. In contrast, the Tukey outer fence method removes only true outliers that are the most distant from the center of scores.

Comment: Some commenters suggested alternatives to outlier deletion to help improve the stability of cut points. A commenter suggested that CMS might consider cut points using plans in similar geographic areas with similar characteristics. Another suggested CMS explore other classification methods such as Isolation Forest, DBSCAN, or k-means clustering. A couple of commenters recommended a guardrail cap less than 5 percent.

Response: CMS agrees that stability is a goal for the cut points, but we disagree with the recommendations of the commenters to achieve that stability. Setting regional or geographic benchmarks (cut points) would lead to a 5-star contract in one area differing in terms of performance from a 5-star contract in another area. The Medicare program does not set regional standards, but rather applies a single national standard to evaluate plan performance. As required under section 1851(d), CMS disseminates information to Medicare beneficiaries (and prospective Medicare beneficiaries) on the different coverage options to promote an active, informed selection among such options. This includes plan quality and performance indicators to compare plan options. In order to compare in a consistent way, CMS uses a single national standard since different regional cut points could hide deficiencies in different areas. Additionally, many measures are based on compliance with Medicare rules and requirements (for example, call center measures and appeals measures) and reflect compliance with Medicare program requirements, not comparative compliance. Using regional cut points would warp the results and complicate our use of Star Ratings under §§ 422.504(a)(17), 422.510(a)(4)(ix), 423.505(a)(26), and 423.509(a)(4)(x).

Regarding the choice of clustering method, hierarchical clustering is one of the most commonly used methods for clustering observations into groups. There are pros and cons of all methods for clustering, including those identified by the commenters. We have considered other methods and believe hierarchical clustering is the best option for the Part C and D Star Ratings program because it is well understood, easily implemented, and performs well for a variety of different data distributions. The other very commonly used clustering algorithm is k-means, however one key weakness of that approach is that the final set of clusters depends on the initial random assignment of points to clusters and it is highly sensitive to the initial placement of cluster centers. Specifically, when the algorithm is repeated on the same dataset it may result in different cluster assignments. Additionally, the k-means method is sensitive to outliers (for example, Gan and Ng (2017),[20] Govender and Sivakumar (2020) [21]), and therefore it would not resolve the issue that outliers can influence estimated thresholds. The commenter also noted other clustering algorithms that are less commonly used. For example, weaknesses of DBSCAN include sensitivity to parameters and inability to handle clusters of points of varying densities, which makes DBSCAN less attractive for clustering measure scores. Isolation Forest is an outlier or anomaly detection technique on the basis of decision trees that is not directly related to clustering measure scores into 5 groups.

Comment: A couple of commenters opposed Tukey outlier deletion since they were concerned it would make it harder for plans with more complex populations to perform well, including SNP plans. A commenter noted the current national emergency emphasizes the need for the cut point methodology to separate out plans with high proportions of dually-eligible, disabled, and low-income individuals.

Response: The issues of whether it is harder for plans with complex populations to perform well in Star Ratings and the method by which we stabilize thresholds for cut points are unrelated. The strategy of removing outliers for stability of cut points does not affect how performance is compared across plans with and without complex populations.

In simulations of Star Ratings calculated using the Tukey outer fence outlier approach, we found that the effect of outlier removal on SNP versus non-SNP contracts was not very different. When outlier measure scores were removed as a part of our simulation using the data for the 2018 Star Ratings, overall summary ratings shifted from 4 to 3.5 stars for approximately 4 percent of contracts without a SNP, and for about 5 percent of contracts with a SNP for the contracts with overall ratings. The removal of outliers will not necessarily have consistent year-to-year impacts, and is dependent on where contracts fall in the measure score distributions, with contracts near the bottom of a score range being the most likely affected.

CMS adopted the categorical adjustment index (CAI) to address the concern that plans with more complex populations have lower ratings based on the population served under the contract. The CAI advances more equitable plan comparisons because it generates Star Ratings that contracts would have received if they had all served the same patient population. That is, the CAI adjusts for within-contract disparities based on measures that are not otherwise adjusted for patient characteristics. CAI coefficients are estimated each year so if there is a differential impact of COVID–19 on the measures of performance for contracts with a higher percentage of dual eligible and disabled beneficiaries versus contracts with a lower percentage of enrollees with those social risk factors, the CAI values would reflect these

[20] Gan, G., & Ng, M.K. (2017). K-means Clustering with Outlier Removal. *Pattern Recognit. Lett., 90,* 8–14.

[21] Govender, P. & Sivakumar, V. (2020). Application of k-means and hierarchical clustering techniques for analysis of air pollution: A review (1980–2019). Atmospheric Pollution Research. 11(1), 40–56.

differences. The CAI will continue to adjust for the percentage of LIS/DE and disabled beneficiaries within the contract in accordance with §§ 422.166(f)(2) and 423.186(f)(2), and therefore will adjust for these differences for contracts with and without a SNP.

Comment: A commenter suggested that CMS retire measures from the program when there are one percentage point differences in the same direction between cut points year over year.

Response: CMS does not consider the size of changes in performance from year-to-year to be a criterion for retirement of a measure, particularly when there is still room for improvement on the measure. CMS retires or removes measures from Star Ratings when there is a change in clinical guidelines that mean that the measure specification is no longer believed to align with or promote positive health outcomes and when measures show low statistical reliability. These standards are in §§ 422.164(e)(1) and 423.184(e)(1), and we explained how we interpret and apply the standards in the April 2018 final rule. When measure scores are ''topped out'' (that is, show high performance across all contracts), this decreases the variability across contracts and makes the measure unreliable. On average, measures improve year-to-year in the 1 to 3 percentage point range, with the exception of new measures where the performance generally has more substantial room for improvement or in situations where a structural change occurs (for example, implementation of EHR tools) that significantly alter performance on the measure.

Comment: A couple of commenters suggested convening a Technical Expert Panel (TEP) to provide input into the Tukey outlier deletion.

Response: A TEP comprised of representatives across various stakeholder groups convened on May 31, 2018 to provide feedback to the RAND Corporation, the current CMS contractor for the Part C and D Star Ratings program to obtain input on a number of issues, including increasing the stability of cut points (*https://www.rand.org/pubs/conf_proceedings/CF391.html*). This TEP focused on different ways to increase stability of cut points, including outlier deletion, but did not focus on the different methods for deleting outliers. We do not believe another TEP is necessary to specifically address this topic given the RAND TEP already expressed strong support for directly addressing outliers and this methodology for removing outliers is a widely accepted methodology for removing outliers.

Comment: A handful of commenters wanted to see the impact on their individual plans to be able to fully understand the effect of Tukey outlier deletion.

Response: CMS plans to display simulations of Tukey outlier deletion with mean resampling and guardrails for contracts to view in HPMS for the 2021, 2022, and 2023 Star Ratings prior to implementing the Tukey outlier change effective with the 2024 Star Ratings. These simulations will use the actual data that will be populating the 2021, 2022 and 2023 Star Ratings and will include all of the changes finalized related to cut point calculations. As noted in the NPRM, for the first year (2024 Star Ratings), we will rerun the prior year's thresholds, using mean resampling and Tukey outer fence deletion so that the guardrails would be applied such that there is consistency between the years. This, therefore, will be done for the simulations using the 2021 Star Ratings. This will provide information for multiple years for plans to see how the cumulative impact of the changes will impact the cut points going forward. Please note that currently mean resampling will be implemented with the 2022 Star Ratings, guardrails will be added with the 2023 Star Ratings, and Tukey outlier deletion will be implemented with the 2024 Star Ratings. Our planned simulations will illustrate the cumulative effect of all of these policies.

Comment: A commenter said CMS could further address outliers by removing contracts that are not eligible for Quality Bonus Payments such as 1876 cost plans and Medicare-Medicaid Plans.

Response: CMS does not include Medicare-Medicaid Plans in the calculation of cut points for the Part C and D Star Ratings since they currently do not receive Star Ratings on Medicare Plan Finder; however, although not eligible for bonuses, 1876 cost plans are part of the Part C and D Star Ratings program (see § 417.472(k)) and have historically received Star Ratings on Medicare Plan Finder so these contracts are included in the cut point calculations. Otherwise, the ratings for public reporting would not be comparable for beneficiaries to use in evaluating their coverage choices.

Comment: A commenter asked for clarification about whether measures in the program for three or fewer years would be included in the Tukey outlier deletion.

Response: We are finalizing the proposed amendment to apply Tukey outlier deletion to all non-CAHPS measures, beginning with the 2024 Star Ratings. This application will be for all such measures regardless of the number of years the specific measure has been used in the Star Ratings program.

Comment: A number of commenters suggested publishing cut points in advance of the measurement year by relying on the data from earlier time periods, reinstituting pre-determined 4-star thresholds, or designing cut points that establish clear national standards of care. Some of the commenters noted that announcing cut points prior to the measurement period would help plans and providers engage in value-based contracts that incentivize higher quality.

Response: CMS understands the interest in setting pre-determined cut points prior to the measurement year, but as stated previously in the April 2019 final rule (84 FR 15752–15754) there are numerous challenges in setting pre-determined cut points, including older data not being reflective of current performance, average performance not always increasing in a linear manner, external factors resulting in significant changes in performance from year to year, larger gains in performance generally seen for newer measures, and the rate of change differing for low performing contracts compared to higher performing ones. Additionally, the measures included in the Star Ratings program do not have national standards of care that plans or providers should meet; thus, it would be challenging to come to consensus on national standards to rate plans in the Star Ratings program. If using older data to predict or establish cut points, we risk causing unintended consequences such as disincentivizing quality improvement or setting cut points that are not aligned to significant changes in industry performance. For example, no one could have predicted the significant impacts the COVID–19 pandemic would have on industry performance for various Star Ratings measures. The current methodology of hierarchal clustering using the current year's data will adjust cut points for the unforeseen impact on plan performance across the program. Since the clustering methodology compares relative performance, it protects plans from unanticipated impacts on industry performance. If there were pre-determined thresholds based on historical data or an independent standard, plans could end up all with uniformly low ratings when unanticipated situations such as the COVID–19 pandemic occur.

Comment: A number of commenters recommended including outliers in the

cut point calculations since they represent the true performance of contracts on the measures. Commenters stated that without including these outliers, CMS would not fully be representing industry performance. Other commenters noted that with the current data integrity polices in place for the Star Ratings program, these outliers are legitimate measure-level contract scores.

Response: CMS agrees that an outlier may be a legitimate score for a particular contract, but we also know that extreme outliers for a measure in a given year can impact statistical analyses such as clustering. In the April 2019 final rule (84 FR 15755–15758) we received stakeholder feedback that in addition to guardrails and mean resampling we should directly address the impact of outliers. Although mean resampling does not directly address outliers, it helps mitigate the effect of outliers because when establishing the thresholds each data point (including outliers) is omitted from 10 percent of the cut points that are estimated (cut points are repeatedly estimated on ten subsets each containing 90 percent of the measure scores) and then averaged across the ten 90 percent samples following resampling. However, based on feedback from the industry to further increase the stability of the cut points and to prevent large fluctuations in cut points from one year to the next caused by the scores of a few contracts, we proposed in the February 2020 proposed rule to more directly remove extreme outliers and are finalizing that policy.

Comment: A handful of commenters supported the addition of Tukey outlier deletion to the cut point methodology, while some suggested delaying implementation or viewing Tukey outlier deletion as an interim solution to improving the stability of the cut points. A commenter suggested phasing in outlier deletion over a multi-year period by putting the cut points with Tukey outlier deletion on display for two years.

Response: We appreciate the support for the addition of Tukey outlier deletion to the cut point methodology and have decided to delay the implementation for an additional year recognizing that there may be fluctuations in measure-level scores as a result of the COVID–19 pandemic. We will also display simulations for the 2021, 2022, and 2023 Star Ratings in HPMS for contracts to see the impact of removing outliers on their stars.

Summary of Regulatory Changes

After consideration of the comments and for the reasons indicated in the proposed rule and our responses to the related comments, we are finalizing as proposed the definition ''Tukey outer fence outliers'' and the specific formulae used. We are finalizing revisions to §§ 422.166(a)(2)(i) and 423.186(a)(2)(i) to apply the Tukey outlier deletion methodology prior to applying mean resampling with hierarchal clustering as proposed with one modification. To allow for potential fluctuations in measure-level scores as a result of the COVID–19 pandemic during the 2021 measurement year, we are delaying the addition of Tukey outer fence outlier deletion to the clustering methodology for non-CAHPS measures until the 2022 measurement year and the corresponding 2024 Star Ratings. Moving the effective date will provide an opportunity for MA and Part D contracts to view simulated results using Tukey outlier deletion for the 2021, 2022, and 2023 Star Ratings in HPMS. We note that the regulation text in this final rule incorporates the changes made by the IFC to §§ 422.166(a)(2)(i) and 423.186(a)(2)(i) during the period between the proposed rule and this final rule. The effect of Tukey outlier deletion would create a savings of $935 million for 2025, increasing to $1,449.2 million by 2030.

3. Removing Measures (§§ 422.164, 423.184)

The regulations at §§ 422.164 and 423.184 specify the criteria and procedure for adding, updating, and removing measures for the Star Ratings program. Due to the regular updates and revisions made to measures, CMS does not codify a list in regulation text of the measures (and specifications) adopted through rulemaking for the MA and Part D Star Ratings Program (83 FR 16537). CMS lists the measures used for the Star Ratings each year in the Technical Notes or similar guidance document with publication of the Star Ratings. In the February 2020 proposed rule, CMS proposed the removal of the Rheumatoid Arthritis Management measure from the Star Ratings program for performance periods beginning on or after January 1, 2021.

CMS proposed to remove the Rheumatoid Arthritis Management measure from the Part C Star Ratings for the 2021 measurement year and the 2023 Star Ratings. The measure steward, NCQA, is retiring this measure from the HEDIS measurement set for the 2021 measurement year due to multiple concerns. For example, there are concerns that the performance on the measure may not reflect the rate at which members get anti-rheumatic drug therapy because sometimes these medications are covered by Patient Assistance Programs, which do not generate claims. In terms of the measure construction, the measure assesses only if members received a disease-modifying anti-rheumatic drug once during the measurement year, rather than assessing if members remain adherent to the medication. Additionally, it is unclear, based on the evidence, whether patients in remission should remain on these medications. Since NCQA plans to retire this measure from the HEDIS measurement set, CMS proposed to remove it starting with the 2023 Star Ratings.

Below we summarize the comments we received and provide our responses and final decisions.

Comment: Most commenters supported the retirement of the Rheumatoid Arthritis Management measure and offered a number of reasons for their support. Approximately half of the commenters who supported removal believed current measure specifications erroneously include certain patients in the measure denominator: Those receiving medication through clinical trials, patient assistance programs, or other ways of paying; patients in remission or managing their illness with other drugs; and patients who have side effects or cannot tolerate disease-modifying anti-rheumatics drugs (DMARDS). A couple of commenters noted that the rate of medication adherence would be a better measure of patient outcomes than the current focus on DMARD dispensing. Individual commenters raised a number of additional issues with the measure: The role of the rheumatologist is not captured by the current measure; the measure has low reliability; there is no clinical consensus on whether patients in remission should remain on DMARD medications or should stop taking them at some point; removal of the measure will streamline ratings systems since NCQA has retired the measure from HEDIS; and continued use of the measure would promote unnecessary use of DMARDS.

Response: CMS will pass along to the measure developer suggestions made by commenters for additional research and new directions. NCQA has retired this measure and therefore there will be no data for CMS to use in the Star Ratings program for the 2023 Star Ratings and beyond, so CMS will remove the measure from the Parts C and D Star Ratings.

Comment: A couple of commenters disagreed with CMS's proposal and offered similar explanations and recommended actions for CMS to take

instead of removing the measure. The commenters note that there is room for improvement in the measure in some populations and in some regions. They also note that research is only beginning into the long-term outcomes of patients recovering without use of DMARDS. For these reasons, they suggest it is premature to update the specifications of the measure or to retire the measure. Instead, they suggest additional research into the long-term outcomes and functional status of patients recovering without use of DMARDS.

Response: CMS will pass along the suggestions for future research to the measure developer, NCQA. NCQA has retired this measure starting with the 2021 measurement year, so starting in 2021 this measure will no longer be submitted by plans and audited as part of the HEDIS measurement set. Thus, there will be no data for CMS to use in the Star Ratings program for the 2023 Star Ratings and beyond. Additionally, CMS agrees with NCQA's assessment of the need to retire this measure at this time.

Summary of Regulatory Changes

After consideration of the comments and for the reasons set forth in the proposed rule and our responses to the related comments summarized earlier, we are finalizing the removal of the Rheumatoid Arthritis Management measure.

4. Measure Weights (§§ 422.166(e), 423.186(e))

As finalized in the April 2018 final rule, beginning with the 2021 Star Ratings, §§ 422.166(e)(1)(iii) and (iv) and 423.186(e)(1)(iii) and (iv) provide that the weight for patient experience/complaints measures and access measures will increase to 2. We stated in the April 2018 final rule (83 FR 16575–16576) that given the importance of hearing the voice of patients when evaluating the quality of care provided, CMS intends to further increase the weight of patient experience/complaints measures and access measures in the future. The measures include the patient experience of care measures collected through the CAHPS survey, Members Choosing to Leave the Plan, Appeals, Call Center, and Complaints measures. We stated the majority of the measures impacted by the proposed weight change are the CAHPS measures that focus on critical aspects of care from the perspective of patients such as access and care coordination issues. The experience of care measures focus on matters that patients themselves say are important to them and for which they are the best or only source of information.

We explained the proposed increase in the weight would not impact the assignment of stars at the measure level, just the calculation of the overall and summary ratings, and would not impact the distribution of stars which varies for each of these measures. The statistical reliability of the CAHPS measures is high, exceeding standards for quality measurement so that higher star categories correspond to meaningfully better performance (generally, reliabilities of 0.7 or more are considered high for a quality measure [22]). The inter-unit reliability of the CAHPS measures range from 0.7638 for Customer Service to 0.9215 for Rating of Health Plan measure. The reliability for the other measures is as follows: Care Coordination is 0.8155, Getting Appointments and Care Quickly is 0.9059, Getting Needed Care is 0.8543, Getting Needed Prescription Drugs is 0.7895, Rating of Drug Plan is 0.8937, and Rating of Health Care Quality is 0.8263.

CMS has pledged to put patients first and to empower patients to work with their providers to make health care decisions that are best for them. To best meet the needs of beneficiaries, CMS believes we must listen to their perceptions of care, as well as ensure that they have access to needed care. Thus, CMS proposed to modify §§ 422.166(e) and 423.186(e) at paragraphs (e)(1)(iii) and (iv) to increase the weight of patient experience/complaints measures and access measures to 4 to further emphasize the importance of patient experience/complaints and access issues.

We received the following comments related to our proposal, and our responses follow:

Comment: The majority of commenters opposed the weight increase of patient experience/complaints and access measures from 2 to 4. Most of these commenters argued that CMS should not value patient experience over clinical outcomes (currently weighted as 3) as they believe clinical outcome measures are the most important. Because some plans may not have enough enrollees to report all of the outcome measures included in the Star Ratings program, some commenters argue the proposed weighting changes would create an even greater imbalance between the total weight given to patient experience measures versus clinical outcome measures for these plans. A commenter stated that since the intended purpose of the Star Ratings program is to compare plan performance on measures related to beneficiary health outcomes and experience, the increase has the potential to erode the integrity of the Star Ratings program by basing the majority of the Star Rating score on patient experience and complaints measures instead of clinical outcomes.

Response: CMS appreciates the value commenters place on outcome measures and will continue to advance work in the area of developing new outcome measures. That being said, it is important to make sure the voice of patients is heard and that patient experience is a key component of the overall and summary Star Ratings. Part of putting patients first and promoting patient-centered care is focusing on patients' perspectives. Additionally, for those plans that may not have enough enrollees to report all of the outcome measures included in the Star Ratings program, we believe that this increased weighting of experience measures would provide such plans an opportunity to focus on improving patient experience and differentiate themselves in the market as a plan that anticipates members' needs and works with enrollees in a customized way. Consequently, we are emphasizing CMS's goal of listening to the voice of the patient to identify opportunities to improve care delivery. Under 1851(d) of the Act, CMS must provide information to promote an active, informed selection among plans, and hearing the perspective of beneficiaries is critical to understanding the differences among options. Weighting these measures higher will accomplish this goal.

Comment: A number of commenters argued that by increasing the patient experience/complaints measures and access measures from a weight of 2 to 4, CMS will be downplaying the importance of the provision of high quality clinical care. Some commenters also noted that this would not align with other CMS quality measurement programs, such as the Health Insurance Exchanges Quality Rating System (QRS), the underlying goals of the Part C and D Star Ratings program and non-Medicare quality improvement efforts, or with CMS's guiding principles for the Star Ratings program. A commenter noted that this contradicts the U.S. Department of Health and Human Services' (HHS') efforts as part of the Quality Summit to align federal healthcare quality rating programs. A commenter noted that the proposal also runs counter to the quality measurement principles of MedPAC, which establish the importance of outcome measures.

[22] *https://www.rand.org/content/dam/rand/pubs/technical_reports/2009/RAND_TR653.pdf.*

Response: The proposed increase in weight for patient experience/complaints measures and access measures is a new direction for the Part C and D Star Ratings program to advance the agency's goal of putting patients first and listening to their voice. While this direction differs from current policies in other quality programs, it is part of the agency's effort to strive to ensure we are meeting the needs of our beneficiaries by listening to their feedback through the CAHPS survey measures, disenrollment rates, and complaints measures. A primary function of Medicare health and drug plans is the provision of health care and drug services to beneficiaries. Measuring, and highly weighting, the importance of access to these services greatly encourage the industry to focus on their fundamental functions. Without access to care and needed prescription medications, optimal clinical outcomes are not probable. CMS believes access to services, care coordination, and patient engagement are intrinsic to positive clinical outcomes. A beneficiary's confidence in the health and drug plan helps facilitate continuation of care which could lead to better clinical outcomes. We agree with MedPAC's recommendation that population-based outcome and patient experience measures are critical in evaluating MA quality.

Comment: Commenters also raised concerns that this would take focus away from physician care and the clinical measures collected through HEDIS. Other commenters noted that the overwhelming emphasis on patient experience could have the unintended consequence of MA plans and providers not focusing on preventive screenings, such as colorectal cancer screening, which can save lives.

Response: Plans and providers should continue to focus on preventive care, screenings, and physician care. This weight change puts more emphasis on the voice of the beneficiary and access issues. We disagree with the characterization that this emphasis is overwhelming, and it in no way suggests that plans and providers should not be continuing to provide important preventive care and screenings. All MA and Part D sponsors are still required to have quality improvement (QI) programs described at §§ 422.152 and 423.153(c), respectively, in place. The primary goal of the MA organization's QI program is to effect sustained improvement in patient health outcomes. Additionally, by not continuing to focus on preventive screenings and primary care, this will have a detrimental effect on health outcomes and would have an impact on patient experience measure scores, disenrollment rates, and complaint rates, all measures included in the weight increase. Therefore, the risk of this particular negative outcome from the change in weighting the patient experience/complaints measures and access measures is minimized.

Comment: A number of commenters expressed concerns about what they perceive to be a fundamental, unprecedented shift away from the objective data-driven clinical Star Ratings measures to more subjective patient experience measures and encouraged a more thoughtful approach to ensure that the weight increase would not result in unintended consequences. Commenters raised issues regarding CMS creating incentives for plans and providers to provide care that would lead to increased CAHPS scores, and they argued this may not be in the best interest of Medicare beneficiaries and better health outcomes.

Response: Plans and providers should always be providing professional, appropriate clinical care to Medicare beneficiaries, thereby focusing broadly on quality, rather than on narrowly targeted metrics represented by individual Star Ratings measures. Patient experience is a fundamentally important aspect of healthcare quality. Most of the evidence shows that better patient experience is associated with better patient adherence to recommended treatment, better clinical processes, better hospital patient safety culture, better clinical outcomes, reduced unnecessary healthcare use, and fewer inpatient complications (Anhang Price et al., 2014; Anhang Price et al., 2015 [23]). The Anhang Price et al., 2014 article which consisted of a review of relevant literature related to CAHPS surveys and their relationship to health care quality found that all but one out of almost three dozen studies reviewed showed a positive correlation between patient experiences and clinical care quality or were neutral. The empirical evidence in the studies highlights that health care providers and plans can concurrently provide better patient experiences and better clinical quality. As discussed in the article, patient experience of care surveys such as the CAHPS surveys evaluate a critical component of care and focus on whether the care is patient-centered. This is an important goal as we continue to emphasize the importance of putting patients first.

Comment: A few commenters expressed concerns that this change would encourage plans to abandon efforts to drive clinically appropriate care in lieu of catering to popular opinion that may be biased by advertisements and media. Such behavior, it was noted, could result in degraded health outcomes long-term for Medicare beneficiaries. They argue programs that promote member health and safety, such as drug management and utilization programs, could be damaged or abandoned. A number of commenters stated that the improvement of health outcomes is one of the largest drivers of the long-term goal of reducing American health care costs and that shifting emphasis from clinical outcomes to member experience could lead to increased medical and pharmaceutical spending.

Response: Plans and providers should continue to focus on improving health outcomes, while also ensuring that Medicare beneficiaries have access to clinically appropriate and needed care, for example as measured through the CAHPS surveys, Appeals, Members Choosing to Leave the Plan, and Complaints measures. Outcome measures are still heavily weighted in the Star Ratings program with a weight of 3. We believe high quality care is meaningless unless the enrollee has access to that care. All MA and Part D sponsors are required to have quality improvement (QI) programs described at §§ 422.152 and 423.153(c), respectively, in place. The primary goal of the MA organization's QI program is to effect sustained improvement in patient health outcomes and providing health care using evidence-based clinical protocols. The QI program must also include a health information system to collect, analyze, and report Medicare Parts C and D quality performance data, including HEDIS, HOS, and CAHPS data. Additionally, as described at § 422.152(c), an MA organization's QI program must include a chronic care improvement program. Part D sponsors must also have established quality assurance measures and systems in place to reduce medication errors and adverse drug interactions and improve medication use. In addition to the requirements to focus on clinical-based care, MA and Part D plans, given their payment structures should have

[23] Anhang Price, R., Elliott, M.N., Zaslavsky, A.M., Hays, R.D., Lehrman, W.G., Rybowski, L., Edgman-Levitan, S. & Cleary, P.D. (2014). Examining the role of patient experience surveys in measuring health care quality. Medical Care Research and Review, 71(5), 522–554.

Anhang Price, R., Elliott, M.N., Cleary, P.D., Zaslavsky, A.M., & Hays, R.D. (2015). Should health care providers be accountable for patients' care experiences?. Journal of general internal medicine, 30(2), 253–256. *https://doi.org/10.1007/s11606-014-3111-7.*

incentives to decrease inappropriate medical and pharmaceutical spending.

Comment: Some commenters argued that if physicians do not proceed thoughtfully, patient experience measures could easily result in adverse consequences that are potentially dangerous to the patient. A commenter noted that if a person who is addicted to opioids seeks a prescription and the physician does not provide one, the patient could retaliate by leaving a negative review. It was suggested that in some cases physicians who overprescribe opioids may have very high reviews from patients, despite putting patients in real danger and contributing to the nation's opioid epidemic.

Response: The CAHPS survey questions are based on statistically valid samples of Medicare enrollees in each contract and should not be influenced by a particular physician providing opioids or not. They are not like crowd-sourced reviews. Most of the CAHPS survey questions focus on enrollees' experiences of care such as whether they got an appointment to see a specialist as soon as they needed, whether they got care as soon as they needed, whether the health plan's customer service gave them the information or help needed, and whether the doctor's office followed up on test results.[24] There are also global ratings of the health care quality, health plan, and drug plan. The change in measure weights does not suggest that any physicians behave in a manner that puts patients in danger, nor does it provide an excuse for a physician who does so.

Comment: A few commenters supported the increased weight of patient experience/complaints measures and access measures but only if the increase is gradual by moving it to a weight of 2.5 or 3 first to promote stabilization of the Star Ratings. It was noted that this proposal is a radical increase considering that CMS had maintained for eight consecutive Star Ratings cycles (2012–2019) the original weight of these measures (at a weight of 1.5). Commenters argued that when changes are made to an organization's culture, it can take years to see the improvements in patient experience scores since many beneficiaries interact with the health care system only a few times a year.

Response: We disagree that this is an unexpected and sudden change. The April 2018 final rule adopted an increase from 1.5 to 2 in the weight of patient experience and complaints measures and access measures. CMS signaled in that final rule that, given the importance of hearing the voice of patients when evaluating the quality of care provided, we intended to further increase the weight of these measures in the future. While we appreciate that organizations are being incentivized to quickly adjust to this weighting change, we believe it is important to proceed at this time, in particular, in light of the COVID–19 pandemic. The uncertainty from the pandemic is a critical time for plans to be focused on patient experience. Plans need to enhance patient experience to deal with the challenges of COVID–19 pandemic, to work with beneficiaries in customized ways, and be as supportive as possible. This is also an opportunity for them to distinguish themselves and be innovative in maintaining access to care. A goal of the Star Ratings program is to foster continuous improvement.

Comment: A handful of commenters opposed the weight increase for measures from the CAHPS survey. These commenters argued that the CAHPS survey measurement tool and methodology are outdated and need to be updated to accurately capture beneficiaries' perspectives of care since the private insurance market has significantly changed over time. Some commenters opposed the survey due to a variety of other reasons, including what they perceive as a lack of statistical reliability, small sample sizes, compression of cut points, differences in methodologies across CAHPS surveys and with the NCQA rating system, cut point variability, contract-level rating volatility, and lack of clinical relevance. A commenter stated that the measures are based on a limited sample that may yield inaccurate, unreliable, or biased data. A commenter stated that younger patients, those with disabilities, and members enrolled in a D–SNP are underrepresented in the survey. A couple of commenters stated that the CAHPS survey has no mechanism for health plans to identify and address negative experiences for a particular enrollee; therefore, these commenters encouraged CMS to release secure beneficiary-level CAHPS response data. A commenter said survey data should receive third-party validation.

Response: CAHPS measures focus on critical aspects of care from the perspective of patients such as access and care coordination issues. The experience of care measures focus on matters that patients themselves say are important to them and for which they are the best or only source of information. As a result of more than twenty years of research that is ongoing and leading to continuous improvement, CAHPS surveys are very good measures of patient experience. The CAHPS program, initiated in 1995, which includes the Medicare CAHPS Health Plan Surveys, seeks to advance the scientific understanding of patient experience with healthcare. Since then, CAHPS surveys have become recognized as the most widely validated, reliable, and applied patient experience surveys in the United States (Holt et al. 2019). Many articles documenting the reliability and face, content, and construct validity of the CAHPS surveys have been published (for example, Crofton, Lubalin, & Darby, 1999; Darby, Hays, & Kletke, 2005; Hays et al., 2014; Martino et al., 2009). In addition, many studies establish the validity of CAHPS measures by assessing their association with measures of structures, processes, and outcomes. For example, the 2014 review article (Anhang Price et al., 2014), in reviewing 34 studies, found that evidence indicated positive associations between patient experiences and other aspects or indicators of health care quality, including patient behavior (adherence), best practice clinical processes, better patient safety culture, and lower unnecessary utilization.[25]

The Medicare CAHPS survey is designed to capture changes in the insurance market that may adversely affect patient experience. The survey measures patient experience with care and captures whether enrollees in MA

[24] CAHPS composite items included in the Part C & D Star Ratings are: Getting Needed Care, Getting Appointments and Care Quickly, Customer Service, Care Coordination, and Getting Needed Prescription Drugs. All of these measures are considered patient experience of care measures.

[25] Anhang Price, R., Elliott, M.N., Zaslavsky, A.M., Hays, R.D., Lehrman, W.G., Rybowski, L., Edgman-Levitan, S. & Cleary, P.D. (2014). Examining the role of patient experience surveys in measuring health care quality. Medical Care Research and Review, 71(5), 522–554.

Crofton, C., Lubalin, J.S., & Darby, C. (1999). Consumer Assessment of Health Plans Study (CAHPS). Foreword [Review]. Medical Care, 37(3 Suppl.), MS1–MS9.

Darby, C., Hays, R.D., & Kletke, P. (2005). Development and evaluation of the CAHPS hospital survey. Health Services Research, 40(6 Pt 2), 1973–1976.

Hays, R.D., Martino, S., Brown, J.A., Cui, M., Cleary, P., Gaillot, S., & Elliott, M. (2014). Evaluation of a care coordination measure for the Consumer Assessment of Healthcare Providers and Systems (CAHPS) Medicare survey. Medical Care Research and Review, 71, 192–202.

Holt, J.M. (2019). Patient experience in primary care: A systematic review of CG–CAHPS surveys. Journal of Patient Experience, 6(2), 93–102.

Martino, S.C., Elliott, M.N., Cleary, P.D., Kanouse, D.E., Brown, J.A., Spritzer, K.L., Hays, R.D. (2009). Psychometric properties of an instrument to assess Medicare beneficiaries' prescription drug plan experiences. Health Care Financing Review, 30(3), 41–53.

plans with narrow networks or closed panels or providers who are not accepting new patients have less positive experiences or receive lower quality care in the responses to existing questions on the survey. If care is worse in some MA contracts because of these aspects of how care is provided, the survey functions as intended by identifying and reporting these differences to beneficiaries, contracts, and CMS.

The statistical reliability of the CAHPS measures is high, so that higher star categories correspond to meaningfully better performance. Generally, reliabilities of 0.7 or more are considered high for a quality measure (Price, Elliott, Zaslavsky, et al., 2014). The reliability of Medicare CAHPS measures ranges from 0.76 to 0.92. Contracts may further increase the reliability of their own scores by requesting sample sizes greater than the required minimum.

While the star category bands may appear to be narrow, the reliability of CAHPS measures meet or exceed standards for quality measurement (Adams 2009 [26]), so that higher star categories correspond to meaningfully better performance. While the CAHPS scoring using linear means may make between-plan differences appear to be compressed, the high contract-level reliability establishes excellent ability to differentiate plan performance. Based on the peer-reviewed measurement and quality-measurement literature, experts in measurement generally agree that reliability greater than 0.70 indicates acceptable reliability; reliabilities of 0.80 or greater are preferable for higher-stakes applications (Adams et al. 2010, Elliott et al. 2010; Nunnally & Bernstein, 1994; Roland et al. 2009; Safran et al., 2006).[27]

The differences between CMS's Medicare CAHPS implementation and others largely reflect CMS's use of additional survey items, case-mix adjustment, and reliability and statistical significance criteria to improve the validity, reliability, and accuracy of Medicare CAHPS scores and stars (*https://www.ma-pdpcahps.org/globalassets/ma-pdp/scoring-and-star-ratings/2019-analysis-of-reported-measures.pdf*); several of these beneficial features are not included in other CAHPS implementations. For example, the CMS Medicare CAHPS Getting Appointments and Care Quickly composite includes a highly-reliable item that is not present in alternate versions. The use of percentile cutoffs, combined with reliability and statistical significance testing, reduces the effects of chance and results in reliable, valid star assignment for CAHPS measures. This methodology, combined with highly-reliable underlying scores, ensures that changes in cut points reflect changes in contract performance rather than chance. These changes in cut points ensure that CAHPS Star Ratings continue to accurately differentiate contract performance.

Patient experience is an inherently important dimension of healthcare quality. It is also the case that the preponderance of evidence shows that better patient experience is associated with better patient adherence to recommended treatment, better clinical processes, better hospital patient safety culture, better clinical outcomes, reduced unnecessary healthcare use, and fewer inpatient complications (Anhang Price et al., 2014; Anhang Price et al., 2015).

Medicare CAHPS case-mix adjustment, which is informed by 20 years of research, accounts for factors such as age, health status, and dual eligibility and ensures that contract scores are not influenced by patient-level factors beyond their control. This adjustment ensures that contract-level scores fairly represent all contracts. Analyses of nonresponse in CAHPS data (Elliott et al. 2005; Elliott et al. 2009) have shown little or no evidence of nonresponse bias in the presence of CAHPS case-mix adjustment.

Medicare CAHPS survey vendors have access to beneficiary-level data and are permitted to conduct analyses with these data that do not risk disclosing the identity of respondents to plan sponsors, including restrictions on reporting cell sizes smaller than 11. These restrictions are necessary to ensure the confidentiality and validity of beneficiary responses to the Medicare CAHPS survey.

The collection and processing of CAHPS data undergo a rigorous quality assurance process that includes dual program coding, use of test data sets, team review of products, investigation of outliers, and comparisons to historic results. This quality assurance process is as rigorous as that followed for the production of other quality measures.

Comment: A couple of commenters suggested different updates to the content of the CAHPS survey. A commenter recommended that the Agency for Healthcare Research and Quality (AHRQ) and CMS consider expanding the survey to include questions on accuracy of provider directories and ease of accessing the information. Another commenter noted that questions on the CAHPS survey are not consistent across different lines of business.

Response: The Medicare CAHPS Survey was updated in 2016 to incorporate AHRQ's 5.0 updates to the CAHPS Health Plan Survey. CMS uses the most current version of the CAHPS Health Plan Survey as it is the national standard for measuring and reporting on the experiences of consumers with their health plan, and the only assessment of patient experiences with health plans endorsed by the National Quality Forum. In May 2019, AHRQ published a request for information inviting public comment to inform potential revisions to the Health Plan Survey (84 FR 21340). CMS will give careful consideration to any updates to the CAHPS Health Plan Survey that AHRQ may provide in the future. Additional testing and development to refine CAHPS items in areas such as care coordination is ongoing. With regard to adding questions around provider directories and ease of accessing plan information, specific measures of information seeking, such as experience with written health plan materials, have been explored in the context of CAHPS but have not resulted in reliable measures due to too few plan members reporting experience in the survey samples. CMS is exploring alternate ways of improving the accuracy of plan directories. Differences in CAHPS composite items across lines of business, such as in the Getting Appointments and Care Quickly composite, in some cases reflect additional items that Medicare CAHPS includes to maximize the reliability and validity of the CAHPS measures.

Comment: A commenter supported the increase in the weight for administrative access measures but

[26] *https://www.rand.org/pubs/technical_reports/TR653.html.*

[27] Adams, J.L., Mehrotra, A., Thomas, J.W., & McGlynn, E.A. (2010). Physician cost profiling—reliability and risk of misclassification. New England Journal of Medicine, 362(11), 1014–1021.

Elliott, M.N., Lehrman, W.G., Goldstein, E., Hambarsoomian, K., Beckett, M.K., & Giordano, L.A. (2010). Do hospitals rank differently on HCAHPS for different patient subgroups? Medical Care Research and Review, 67(1), 56–73.

Nunnally, J.C., & Bernstein, I.H. (1994). Psychometric theory (3rd ed.). New York: McGraw-Hill.

Roland, M., Elliott, M., Lyratzopoulos, G., Barbiere, J., Parker, R.A., Smith, P., . . . & Campbell, J. (2009). Reliability of patient responses in pay for performance schemes: Analysis of national General Practitioner Patient Survey data in England. British Medical Journal, 339, b3851.

Safran, D.G., Karp, M., Coltin, K., Chang, H., Li, A., Ogren, J., et al. (2006). Measuring patients' experiences with individual primary care physicians: Results of a statewide demonstration project. Journal of General Internal Medicine, 21, 13–21.

suggested keeping the CAHPS measures at their current weight because the administrative measures already take into account member experience. Another commenter said they would support an increase in access measures because plans have a direct impact on the outcome of these measures and can analyze, pinpoint root causes, and take action to avoid adverse outcomes.

Response: We appreciate these comments. CMS wants to ensure that the experiences of beneficiaries getting needed care, getting appointments and care quickly, care coordination, and ratings of health care quality, for example, are also emphasized with this weight change. MA plans are responsible for providing all of the Part A and B benefits and providing a managed care alternative to the traditional FFS Medicare program. In some cases, the MA plans provide additional (supplemental) benefits. One of the advantages of MA is the MA plan is responsible for coordinating the care among the enrollee's health care providers. Since the primary purpose of the health plan is to ensure their enrollees get needed health care services, patient experience and access measures that focus on whether the enrollee is getting needed care are critical in evaluating whether a plan is fulfilling its fundamental requirements.

Comment: A couple of commenters opposed the weight increase for access measures but also asked for clarification and requested a methodology change to the Call Center measures. A commenter requested CMS consider publishing Call Center results in HPMS on the same frequency as the Part C and Part D Timeliness Study (quarterly) to allow plan sponsors to better align internal testing/monitoring against CMS third-party testing. A commenter asked for clarification on the definition of the ''Call Center,'' noting it is unclear if this encompasses the Star Ratings measure for prospective members or if this is in reference to the member customer service call center.

Response: While we appreciate feedback on the usefulness of the Accuracy and Accessibility Study results and the request for publication of those results quarterly, we cannot do this because of the timing of the study. The Timeliness Study is conducted quarterly, and CMS publishes the results quarterly; conversely the Accuracy and Accessibility Study is conducted once a year, between February and May, and CMS publishes the results once a year, as soon as they are available in August. For purposes of the Star Ratings measure, the prospective customer service call center results are included in the measure calculation. The measure specification has not changed from prior years.

Comment: A few commenters opposed the current appeals measures and, consequently, did not believe the higher weight was prudent. One noted that these measures are distorted because beneficiaries may be unaware of the extent to which they are or are not receiving the proper benefits. The commenter recommended CMS conduct a survey of providers on how efficiently and accurately MA plans make organizational determinations and appeals. A commenter expressed concern regarding increasing the weight for appeals measures citing what they believe are fundamental flaws in these measures. They stated both the plan and Independent Review Entity (IRE) have difficulty reaching sound decisions in the 72 hour timeframe and argued the IRE demonstrates the same lack of medical expertise or misunderstanding of coverage guidelines as the MA plan; the commenter recommended providing more meaningful measures such as independent audits of the MA plans' initial determinations, the frequency with which physicians appeal MA plans initial determinations, the timeliness of initial determinations (using a much shorter standard than 72 hours), and other measures they say capture the patient and provider experience more accurately. A commenter stated health plans should be held accountable for their administrative responsibilities and insurance functions through compliance standards and plan monitoring, not Star Ratings.

Response: CMS clarifies that both Part C appeals measures assess the timeliness of appeals sent to the IRE and how often the IRE agrees with the plan's decisions. The purpose of these measures is not to directly assess the enrollees' comprehension of all of their plan benefits. CMS acknowledges the comments for new measurement suggestions for the Part C appeals process and is actively evaluating these suggestions for future measure development. However, CMS does not agree that there are fundamental flaws in the current Part C Appeals measures. The purpose of the appeals measures is to ensure appeals that are denied are processed in a timely manner and to assess if the denial by the health plan was consistent with the benefit or coverage requirements. CMS reminds plans that they can access timeliness and compliance data in real time at *www.medicareappeal.com* and bring to the attention of the IRE any data discrepancies. CMS disagrees that both the plan and IRE have difficulty making sound decisions in the 72-hour time frame and both lack the medical expertise or misunderstand the coverage guidelines. CMS notes only expedited reconsiderations must be sent to the IRE within 72 hours for Part C appeals (see § 422.590). In these cases this timeframe is required to avoid endangering the life or health of the enrollee or the enrollee's ability to regain or maintain maximum function; thus, a de novo review of an adverse organization determination must be processed quickly. Examples of cases that should be expedited include pre-service skilled nursing facility cases, pre-service acute inpatient care cases and cases in which a physician indicates that applying the standard timeframe for making a determination could seriously affect the life or health of the enrollee or the enrollee's ability to regain maximum function. Medicare health plans have an obligation to determine if an appeal should be expedited, including responding to an enrollee or provider request for expedited determination. We also remind plans that in expedited and standard service appeals, IRE may extend the decision timeframe by up to 14 calendar days if it is in the enrollee's interest.

Please remember if a plan fails to provide the appellant with a reconsidered determination within the required timeframes, this failure constitutes an affirmation of its adverse organization determination, and the plan must submit the case file to the IRE for review. Plans and sponsors must continue to have procedures in place for requesting and obtaining information necessary for making timely and appropriate decisions. The IRE's decision is based on the information gathered during its review process and the IRE must issue a decision within the same appeals timeframe as the plan. Please refer to 42 CFR 426.600(d). Therefore, the timeframes for the plan and the IRE are aligned.

In response to the recommendation that plans be held accountable for their administrative responsibilities and insurance functions through compliance standards and plan monitoring instead of Star Ratings, we assure commenters that this also happens. The Star Ratings measures only focus on two aspects of the appeals processes. Program audits provide a more comprehensive review of a sponsoring organization's compliance with the terms of its contract with CMS, including access to medical services and other enrollee protections required by Medicare. For more information about the program audit process, please see *https://www.cms.gov/files/document/2020-*

program-audit-process-overview.pdf. The purpose of the Star Ratings system is to measure quality of a health and drug plan and to provide information to help beneficiaries make more informed choices. The appeals measures are such indices of quality.

Comment: A few commenters focused their comments on the Complaints about the Health and Drug Plan measures. A commenter said they support a modest increase in weight for these measures because plans are generally able to analyze the root cause of the complaint and implement strategies to address beneficiary concerns. A few commenters noted that complaints not within the plans' control and complaints resulting from CMS policy decisions should be excluded.

Response: CMS thanks the commenter for their support of a modest increase in the weight of the complaints measure. Although a few commenters noted that complaints not within the plans' control and complaints resulting from CMS policy decisions should be excluded, CMS expects plans to be integral in assisting beneficiaries and ensuring their access to care is not disrupted, regardless if they directly created the issue at question, or not. CMS expects health plans and Part D sponsors will assist their enrollees in situations such as these, and help them understand how to correct issues, even if the underlying cause of complaints is not the sponsors' fault. Sponsors have an important responsibility for providing continued access to services. The fact that CMS received a complaint indicates the sponsor has not helped service their enrollee, as Medicare instructs beneficiaries to seek resolution first through their sponsors. If sponsors take the opportunity to assist their enrollees proactively, they will avoid having complaints recorded in the Complaints Tracking Module (CTM). CMS issued guidance in the HPMS memo dated May 10, 2019, Complaints Tracking Module (CTM) File Layout and Updated Standard Operating Procedures, which describes the Plan Request process for plans to submit requests to change incorrect contract assignments, change issue designation (that is, from Plan Issue level to CMS Issue), and change category/subcategory. The memo states that, for matters that are delegated to CMS for handling and/or final resolution, plans are to submit a CMS Issue Change Request and it lists examples of applicable situations. In the SOP Appendix A, CMS lists the subcategories and notes which subcategories are excluded from plan performance metrics.

Comment: A few commenters focused their comments on the disenrollment measure, Members Choosing to Leave the Plan, stating that the measure is flawed and misrepresents some changes in enrollment as dissatisfaction. They suggest CMS consider excluding members who switch plans but stay with the same parent organization, as it may actually suggest a high level of satisfaction with the parent organization. A commenter stated the measure is extremely volatile and can be impacted by many factors beyond a member's experience with their health plan, including job loss/movement, changes in individual finances, provider changing plans, relocations and changes in member needs.

Response: CMS appreciates these comments, but disagrees that the current specification for this measure is flawed. This measure reflects voluntary movements from one contract to another. For example, if a change in the provider network results in a beneficiary changing contracts, this reflects a decision by the beneficiary that the current contract is no longer providing the care or access to services that they want. Similarly, if the health status of the enrollee changes, and the current plan is not meeting the enrollee's changing health needs, this may result in a voluntary disenrollment and should be reflected in this measure.

This measure is a contract-level measure focused on quality at that level; therefore, disenrollments are considered voluntary even when a member enrolls into a different contract under the same parent organization. The member is changing from one contract to another for a reason and this should be reflected in this measure. If we were to change the measure specification to consider disenrollments as no longer voluntary when a member enrolls into another contract under the same parent organization, this change would be advantageous to larger parent organizations that have multiple contracts.

There are only 4 disenrollment codes used in this measure (11—Voluntary Disenrollment through plan, 13—Disenrollment because of enrollment in another Plan, 14—Retroactive and 99—Other (not supplied by beneficiary)). We agree that there are reasons for disenrollment that should not be counted against the plan. For example, enrollment changes because of a contract service area reduction, a PBP termination, LIS reassignments, passive enrollment of the enrollee into a Demonstration (MMP), and changes in residence out of the service area are not counted in the measure.

Comment: Some commenters supported the weight increase, indicating they appreciate CMS adding further emphasis on the voice of the patient. Some argued that better patient experience has been shown to improve patient compliance with medical advice.

Response: CMS appreciates the commenters' support of our proposal.

Comment: Several commenters expressed concern about implementing a weighting change during the COVID–19 pandemic because of the current uncertainty how the public health emergency will impact care delivery and patient experiences going forward. One noted this weight change would not give health plans adequate time to adjust for the volatility and inconsistency of CAHPS responses and difficulties in measurement during this time. A couple of commenters noted that depending on the state of the pandemic, additional weight afforded to the current patient experience and complaints measures will not accurately capture plan performance during this public health emergency and crisis. Another commenter noted patient experience data during this period may not be particularly accurate or useful as a measure of overall performance of Medicare Advantage or individual plans due to how the pandemic may impact how beneficiaries may respond to these types of surveys.

Response: The changes to the weighting of patient experience/complaints and access measures apply to the 2021 measurement year, not the 2020 measurement year when the pandemic first started. CMS agrees that there is a lot of uncertainty about how COVID–19 will impact the healthcare system and quality measurement and recognizes the challenges placed on the healthcare system and Part C and D plans; however, plans have until the 2021 measurement year to adjust their processes to account for the impact of COVID–19 on Star Ratings measures. One thing that is certain for plans is how much they focus on addressing their members' needs during the time of a pandemic. We believe that given the uncertainty during such times, it is even more important that plans be proactive, anticipate enrollees' needs, and work with them in a customized way to mitigate any challenges that enrollees might face in a pandemic environment. Therefore, it is important to move forward with these Star Ratings changes to further emphasize the importance of patient experience/complaints and access measures at this time. We reiterate that patient experience is an inherently important dimension of

healthcare quality and associated with better health outcomes and improved care delivery. This is critical information to help beneficiaries make more informed choices.

Comment: Some commenters noted that different areas of the country are experiencing different limitations of health care resources related to COVID–19, some of which may require redeployment of resources, so differences in CAHPS and HOS survey scores may be neither meaningful nor appropriate to compare plan performance. They request that CMS re-evaluate these measures after the COVID–19 crisis is resolved. Several commenters noted their concern about the long-term impact of the public health crisis on respondents' physical and mental health, and their perception of the health care system and health plans.

Response: CMS recognizes the challenges that COVID–19 has placed on the healthcare system and quality measurement. We understand the concern that it may impact how beneficiaries respond to CAHPS surveys and, consequently, the CAHPS measure scores. To that end, we believe that this would be a great opportunity for plans to focus even more on supporting their enrollees, being proactive and anticipating enrollees' needs, and working with them in a customized way to mitigate any challenges that enrollees might face in a pandemic environment. We are continuing to monitor whether additional Star Ratings adjustments need to be proposed for future years.

Comment: Several commenters stated the weight increase should not proceed at this time due to widespread restricted access to providers due to concern about capacity and public safety as a result of COVID–19, and the unknown duration of such restrictions. For example, beneficiaries may not be able to assess their experience with in-person encounters, and responses may be biased by exigencies secondary to COVID–19. One notes the proposed CAHPS weight changes for the 2021 measurement period provide little time for health plans to adjust for the volatility and consistency of CAHPS responses and difficulties in measurement.

Response: Again, we believe that this would be the ideal time for plans to take the opportunity to focus even more on supporting their enrollees, being proactive and anticipating enrollees' needs, and working with them in a customized way to mitigate any challenges that enrollees might face in a pandemic environment, particularly challenges in accessing services. As previously stated, these changes are for the 2021 measurement period so plans have time to adjust to the impacts of COVID–19. Even in a pandemic environment, increasing the weight for experience measures will encourage plans to focus on an enrollee's experience with the plan (for example, plan communication, plan innovation, mitigation of access issues). CMS will continue to monitor the impact of the public health emergency on quality measurement. For CAHPS measures, widespread changes in industry performance should be reflected in the cut points.

Summary of Regulatory Changes

After consideration of the comments and for the reasons indicated in the proposed rule and in the responses to comments, we are finalizing the provisions regarding the weight increase for patient experience/complaints and access measures as proposed at §§ 422.166(e)(1)(iii) and (iv) and 423.186(e)(1)(iii) and (iv).

In the proposed rule, we stated that if both Tukey outlier deletion and increasing the weight of patient experience/complaints measures and access measures were adopted the net savings for the Medicare Trust Fund would be $368.1 million for 2024, increasing to $999.4 million for 2030. We are finalizing the use of Tukey outer fence outlier deletion as proposed but to begin one year later, with the 2024 Star Ratings, and are finalizing the proposal to increase the weights of the patient experience and complaints measures and the access measures to 4 for the 2023 Star Ratings. Based on the combination of these final policies, we project the net cost to the Medicare Trust Fund would be $345.1 million for 2024, increasing to a net savings of $999.4 million for 2030. There is a net cost for 2024 since the increase in weight for patient experience/complaints measures and access measures results in an overall increase in the highest ratings for MA contracts, while in future years with the addition of the Tukey outlier deletion there is an overall decrease in the highest ratings for MA contracts.

5. Reclassification of the Statin Use in Patients With Diabetes (SUPD) Measure (§§ 422.164(d)(2), 423.184(d)(2)

Currently, the SUPD measure specifications require two diabetes medication fills to meet the denominator while only a single fill of a statin therapy is required to meet the numerator criteria. Recently, the Pharmacy Quality Alliance (PQA), the measure steward, has clarified SUPD as a process measure in a Frequently Asked Question (FAQ) (the FAQ can be found at *https://www.pqaalliance.org/measures-overview#supd*), therefore CMS no longer believes that the intermediate outcome measure classification for the SUPD measure is appropriate. We proposed to modify the classification of the SUPD measure from an intermediate outcome measure to a process measure, starting with the 2023 Star Ratings, based on data from the 2021 measurement period.

We received the following comments related to our proposal, and our responses follow:

Comment: The majority of commenters supported modifying the SUPD measure classification from an intermediate outcome to a process measure, changing the weight from 3 to 1. Commenters noted that outcomes are not measured in SUPD since it only requires a single fill of a statin medication. They agreed that SUPD is a process measure that is based on an important procedural intervention but does not capture a therapeutic outcome since SUPD does not monitor the medication adherence of a statin over a course of treatment. In addition, commenters noted that classifying SUPD as a process measure is consistent and aligns with the Part C Statin Therapy for Patients with Cardiovascular Disease measure.

Response: CMS appreciates the commenters' support of this proposal. It is consistent with the clarification from the measure steward, the Pharmacy Quality Alliance (PQA), in 2019 that SUPD is a process measure based on the National Quality Forum's (NQF) criteria.

Comment: A few commenters that support CMS's proposal to modify the SUPD measure category to a process measure also noted that CMS should exercise caution when creating additional measures in the Star Ratings program or changing measure categorizations. Commenters were concerned that measure weights are being changed too rapidly. One commenter also expressed concerns with selecting the SUPD measure and recommends that CMS consider replacing SUPD with the Healthcare Effectiveness Data and Information Set (HEDIS) measure Statin Therapy for Patients with Diabetes (SPD).

Response: CMS thanks the commenters for this feedback. CMS carefully evaluates all of the measures incorporated in the Star Ratings. CMS will continue to monitor each of the measures included in the Star Ratings as well as future measures incorporated into the Star Ratings. CMS also carefully evaluates the weights of each measure.

The weights are based on measure type. Typically, CMS aligns the measure specifications with the measure steward. The Statin Therapy for Patients with Cardiovascular Disease (SPC) is already included in the Part C Star Ratings while the SUPD measure is included for Part D. CMS first discussed the HEDIS SPD and SPC measures, and the PQA SUPD measure in the 2016 Call Letter. As stated in the 2017 Call Letter, the SPD measure overlapped with the SUPD measure. Therefore, CMS added only one of the HEDIS measures (the Part C SPC measure) to the 2017 display page as well as the Part D SUPD measure after consideration of stakeholder feedback through the Call Letter process. CMS gained experience with calculating and reporting the measures and added SPC and SUPD to the Star Ratings as announced in the 2019 Call Letter.

Comment: Commenters provided feedback on the timeline proposed for reclassifying SUPD starting with the 2023 Star Ratings (using 2021 data). Some noted that SUPD is a process measure that has not changed in terms of specifications to warrant retaining SUPD as an intermediate outcome measure for the 2021 and 2022 Star Ratings. Additionally, commenters were concerned that retaining the classification as an intermediate outcome with a weight of 3, rather than immediately reclassifying SUPD as a process measure with a weight of 1, could lead to confusion, and is inconsistent with the guidance of expert measure developers, which could lead to instability for the Star Ratings. However, there were a few commenters who supported CMS's proposed timeline as it would take into consideration plan efforts and coordination needed to account for the SUPD measure reclassification.

Response: Reclassifying SUPD as a process measure (including its weight), is a substantive change that must be proposed and finalized through rulemaking as required by § 423.184(d)(2). In the April 2018 final rule, CMS finalized the weight of 3 for SUPD for the 2021 and 2022 Star Ratings. In the February 2020 proposed rule, CMS proposed to reclassify SUPD as a process measure with a weight of 1 for future years, starting with the 2023 Star Ratings. This timeline and approach is consistent with the April 2018 final rule which outlined that a key tenet of the Star Ratings program is to make changes prior to the measurement year and to give sponsors enough lead time, in order to ensure greater transparency and stability for the Star Ratings program for plan sponsors.

Comment: A few commenters opposed reclassifying SUPD to a process measure or changing the weight of 3 to 1. Commenters noted that statin use for diabetic patients is an important and valuable intervention; thus, SUPD should remain classified as an intermediate outcome measure. Additionally, commenters were concerned with reclassifying SUPD and lowering the weight in the absence of outcomes-focused measures within the Star Ratings that address appropriate care for diabetes and cardiovascular care, given the strong correlation between the two conditions.

Response: CMS agrees that SUPD is an important measure that is included in the Star Ratings. Per NQF's definition of process measures, CMS agrees that prescribing a statin is a step in providing good care, rather than an outcome of such care. Furthermore, the measure steward, PQA, has classified SUPD as a process measure based on NQF's definition. As such, CMS proposed to reclassify SUPD as a process measure with a weight of 1 to align with the industry definitions.

Comment: Several commenters gave specific feedback regarding exclusion criteria related to SUPD, such as beneficiaries predisposed to statin intolerance or history of rhabdomyolysis. Commenters were concerned that only using prescription claims limited the types of exclusions included in SUPD. In addition, a few commenters noted this quality measure does not reflect or capture achievable outcomes related to reversing chronic disease or decreasing cardiovascular morbidity and mortality.

Response: We thank the commenters for the feedback, but these comments are out of scope for this rule since the comments do not reference the reclassification of the SUPD measure and the subsequent change to the measure weight. CMS will share the measure specification comments with the measure steward, PQA, about the additional populations that were recommended for exclusion, the concerns with using prescription claims and exclusions, and to consider future measures on outcomes related to reversing chronic disease.

Comment: A commenter was concerned with the current COVID–19 public health emergency and how it could impact the accuracy of the measure.

Response: Thank you for this feedback. CMS will continue to monitor the impact of the public health emergency on the SUPD measure.

After considering the comments we received and for the reasons outlined in the proposed rule and our responses to the comments, we are finalizing the proposal without modification. Starting with the 2023 Stars Rating, the SUPD measure will be reclassified as a process measure with a weight of 1. This change will be reflected in the Medicare Part C & D Star Ratings Technical Notes for the 2023 Star Ratings, which are based on the 2021 measurement period.

C. Medical Loss Ratio (MLR) (§§ 422.2420, 422.2440, and 423.2440)

In the February 18, 2020 proposed rule (85 FR 9008), we proposed certain modifications to the medical loss ratio (MLR) regulations for the Medicare Part C and Part D programs. Briefly, we proposed to amend § 422.2420(b)(2)(i) to allow MA organizations to include in the MLR numerator as ''incurred claims'' all amounts paid for covered services, including amounts paid to individuals or entities that do not meet the definition of ''provider'' as defined at § 422.2. We also proposed to codify the definitions of partial, full, and non-credibility and credibility factors that we published in the May 2013 Medicare MLR final rule (78 FR 31295 through 31296). Finally, for MA medical savings account (MSA) contracts receiving a credibility adjustment, we proposed to apply a deductible-based adjustment to the MLR calculation in order to recognize that the variability of claims experience is greater under health insurance policies with higher deductibles than under policies with lower deductibles.

1. Background

An MLR is expressed as a percentage, generally representing the percentage of revenue used for patient care rather than for such other items as administrative expenses or profit. The proposed rule provided background on the Part C and Part D medical loss ratio (MLR) requirements, including the statutory and regulatory authority. The Part C statute, at section 1857(e)(4) of the Act, expressly imposes a minimum medical loss ratio requirement for MA plans. Because section 1860D–12(b)(3)(D) of the Act incorporates by reference the requirements of section 1857(e) of the Act, these MLR requirements also apply to the Medicare Part D program. In the May 2013 Medicare MLR final rule, which codified the MLR requirements for Part C MA organizations and Part D sponsors (including organizations offering cost plans that offer the Part D benefit) in the regulations at 42 CFR part 422, subpart X, and part 423, subpart X. In the April 2018 final rule (83 FR 16440), we changed certain aspects of

the MLR calculation and revised the reporting requirements.

For contracts for 2014 and later, MA organizations and Part D sponsors are required to report their MLRs and are subject to financial and other sanctions for a failure to meet the statutory requirement that they have an MLR of at least 85 percent (see §§ 422.2410 and 423.2410). The statute imposes several levels of sanctions for failure to meet the 85 percent minimum MLR requirement, including remittance of funds to CMS, a prohibition on enrolling new members, and ultimately contract termination. The minimum MLR requirement creates incentives for MA organizations and Part D sponsors to reduce administrative costs, such as marketing costs, profits, and other uses of the funds earned by plan sponsors, and helps to ensure that taxpayers and enrolled beneficiaries receive value from Medicare health and drug plans.

2. Regulatory Changes to Incurred Claims (§ 422.2420)

Section 422.2420(a) of the regulations sets forth a high-level definition of the MLR as the ratio of the numerator, defined in paragraph (b), to the denominator, defined in paragraph (c). In general, MA costs are in the numerator and revenues are in the denominator. Section 422.2420(b)(1) identifies the three components of the MLR numerator for MA contracts that are not MSA contracts: (1) Incurred claims (as defined in paragraphs (b)(2) through (4)); (2) the amount of the reduction, if any, in the Part B premium for all MA plan enrollees under the contract for the contract year; and (3) expenditures under the contract for activities that improve health care quality, which are described in detail at § 422.2430. For MA MSA contracts, the three components of the MLR numerator are (1) incurred claims (as defined in paragraphs (b)(2) through (4)); (2) expenditures under the contract for activities that improve health care quality; and (3) the amount of the deposit into the Medicare savings account for MSA enrollees. We proposed to revise the regulation text regarding the incurred claims portion of the numerator.

Under current § 422.2420(b)(2)(i), incurred claims include direct claims that the MA organization pays to providers (including under capitation contracts) for covered services (described at paragraph (a)(2) of that section) that are provided to all enrollees under the contract. Section 422.2 defines a ''provider'' for purposes of the MA regulations as any individual or entity that is engaged in the delivery of health care services in a State and is licensed or certified by the State to engage in that activity in the state, or to deliver those services if such licensing or certification is required by State law and regulation. Per § 422.2420(a)(2), ''covered services'' are the benefits defined at § 422.100(c): basic benefits, mandatory supplemental benefits, and optional supplemental benefits.

As explained in greater detail in section II.A. of this final rule and sections II.A. and VI.F. of the proposed rule, we proposed revisions to the regulations at § 422.100 in order to codify subregulatory guidance and statutory changes that have expanded the types of supplemental benefits that MA plans may include in their plan benefit packages (PBPs). The proposed amendment to § 422.100(c)(2) would codify our longstanding interpretation of the statute to require a supplemental benefit to be an item or service (1) that is primarily health related; (2) for which the MA organization incurs a non-zero direct medical cost; and (3) that is not covered by Medicare Parts A, B, or D. In the 2019 Call Letter, issued on April 2, 2018, we announced that we had reinterpreted the scope of what would be ''primarily health related'' in order to meet this criterion to be a supplemental benefit. Under this reinterpretation, to be considered ''primarily health related,'' a supplemental benefit must diagnose, prevent, or treat an illness or injury, compensate for physical impairments, act to ameliorate the functional or psychological impact of injuries or health conditions, or reduce avoidable emergency and healthcare utilization; we explained in the contract year 2019 Call Letter how this means the benefit must focus directly on an enrollee's health care needs and must be medically appropriate and recommended by a licensed medical professional as part of a health care plan, but it need not be directly provided by one. As part of proposed § 422.100(c)(2), to account for the types of supplemental benefits that may be offered under the policy changes addressed in section II.A. of this final rule and sections II.A. and VI.F. of the proposed rule, we also proposed specific provisions to address permissible supplemental benefits that are not primarily health related and for which the non-zero direct cost incurred must be a non-administrative direct cost (if it is not a medical cost).

In § 422.102(f), as finalized in section II.A. of this final rule, we are codifying regulation text implementing amendments made by the BBA of 2018 to section 1852(a)(3) of the Act to expand the types of supplemental benefits that may be offered to chronically ill enrollees, starting in contract year 2020. Under paragraph (D) of section 1852(a)(3) of the Act, as added by the BBA of 2018, MA organizations may provide special supplemental benefits for the chronically ill (SSBCI) that are not primarily health related to chronically ill enrollees, as long as the item or service has the reasonable expectation to improve or maintain the chronically ill enrollee's health or overall function.

As explained in the proposed rule, under current § 422.2420(b)(2)(i) of the MA MLR regulations, incurred claims in the MLR numerator include direct claims paid *to providers* for covered services furnished to all enrollees under an MA contract. The amendment to section 1852(a)(3)(D) of the Act has expanded the types of supplemental benefits that can be ''covered services'' under an MA plan. The amendments to implement that change at § 422.102(f) and the continuation of our policy for establishing what it means for a benefit to be primarily health related, both, mean that permissible supplemental benefits might include items and services that would not typically be furnished by an individual or entity that is a ''provider'' as defined at § 422.2. A provider, as defined in § 422.2, is an individual or entity engaged in the delivery of health care services and who is licensed or certified by the State to engage in that activity in the State. To ensure that amounts that an MA organization pays for covered services to individuals or entities that are not health care providers are included in incurred claims under current § 422.2420(b)(2)(i), we proposed to amend the regulation to remove the specification that incurred claims are payments to providers for covered services.

The proposed rule explained that, if incurred claims do not include amounts an MA organization pays to individuals or entities that are not providers for supplemental benefits, including SSBCI, these expenditures could still potentially be included in the MLR numerator as expenditures related to quality improvement activities (QIAs). To be considered a QIA under § 422.2430, a benefit must be an activity that falls into one or more of the categories listed in paragraph (a)(2) of that section, and it must be designed for the purposes listed in paragraph (a)(3): (1) To improve health quality; (2) to increase the likelihood of desired health outcomes in ways that are capable of being objectively measured and of producing verifiable results; (3) to be directed toward individual enrollees,

specific groups of enrollees, or other populations as long as enrollees do not incur additional costs for population-based activities; and (4) to be grounded in evidence-based medicine, widely accepted best clinical practice, or criteria issued by recognized professional medical associations, accreditation bodies, government agencies or other nationally recognized health care quality organizations. As explained in the proposed rule, although we believe that supplemental benefits that meet the expanded ''primarily health related'' standard at proposed § 422.100(c)(2)(ii)(A) and non-primarily health related SSBCI described at § 422.102(f) could potentially qualify as QIAs under § 422.2430, whether a particular benefit met all of the requirements of that regulation would need to be determined on a case-by-case basis. With our proposed amendments to § 422.2420(b)(2)(i), this case-by-case determination would no longer be necessary for services that are covered under the plan benefit package offered by an MA plan pursuant to the statute and regulations governing the MA program; all amounts paid for covered services would be included in the incurred claims portion of the MLR numerator.

As explained in the proposed rule, we believe that including in the MLR numerator amounts MA organizations spend on supplemental benefits that meet the ''primarily health related standard'' at proposed § 422.100(c)(2)(ii)(A) and on non-primarily health related SSBCI under § 422.102(f), as amended in this final rule, is consistent with the purpose of the MA MLR requirement. As explained in the May 2013 Medicare MLR final rule adopting the MLR regulations (78 FR 31284), the MLR requirement creates an incentive for MA organizations to reduce administrative costs such as marketing costs, profits, and other uses of plan revenues, and to help ensure that taxpayers and enrolled beneficiaries receive value from Medicare health plans.

In order to ensure that the MLR numerator includes amounts MA organizations spend on supplemental benefits that are ''primarily health related'' under our current guidance and on non-primarily health related SSBCI under § 422.102(f), as adopted in this final rule, we proposed the following modifications to the regulation at § 422.2420(b)(2)(i):

- Remove the specification that incurred claims are direct claims that an MA organization pays *to providers* for covered services provided to all enrollees under the contract.
- Remove the specification that incurred claims include payments under capitation contracts *with physicians.*
- Replace the phrase ''direct claims,'' which customarily refers to billing invoices providers submit to payers for reimbursement, with the general term ''amounts.''

As amended under our proposal, § 422.2420(b)(2)(i) would include in incurred claims all amounts that an MA organization pays (including under capitation contracts) for covered services, regardless of whether the recipient of the payment is a provider as defined in § 422.2. Including in incurred claims amounts spent on these expanded supplemental benefits, as proposed, avoids creating uncertainty over whether payments for such covered services could otherwise be included in the MLR numerator (for example, as QIA-related expenditures), and it is consistent with our determination in the May 2013 Medicare MLR final rule (78 FR 31289) that incurred claims should reflect the benefit design under the contract.

We received 27 comments on the proposed amendments to § 422.2420(b)(2)(i). The following is a summary of the comments we received on the proposal and our responses:

Comment: The majority of commenters supported the proposal. Many commenters believed that including in the MLR numerator as incurred claims all payments for covered services would provide greater certainty and reduce plan burden by eliminating the need to assess whether individual benefits meet the criteria to qualify as QIAs under § 422.2430. A number of commenters believed that the proposed change would encourage the expansion of supplemental benefits to address social barriers to care and MA enrollees' other health needs. A few commenters commended us for recognizing the role played by individuals and entities that are not providers in implementing the expanded supplemental benefit flexibility. A couple of commenters noted that they agreed with our view that including in incurred claims amounts spent on these expanded supplemental benefits is consistent with our prior determination that incurred claims should reflect the benefit design under the contract.

Response: We thank the commenters for their support. We reiterate that under our proposal and this final rule, only amounts expended by the MA organization for covered services, which must meet the standards of the MA program for coverage, can be included in the MLR numerator as incurred claims.

Comment: A commenter supported the proposal but requested that we clarify that the incurred claims portion of the MLR numerator will include capitated payments by MA organizations to clinical risk-bearing entities (for example, Independent Practice Associations (IPAs), Physician Hospital Organizations (PHOs), and Accountable Care Organizations (ACOs)) that include amounts for both medical and administrative services, provided the arrangement satisfies a four-factor test that was originally set forth in a guidance document [28] related to the MLR rules that apply to issuers of employer group and individual market private insurance (hereinafter referred to as the ''commercial MLR rules''), and later incorporated into our annual MLR Data Form Filing Instructions for MA organizations and Part D sponsors. The commenter expressed concern that, if the four-factor test does not remain in place, all capitated payments to providers would need to be divided between medical services and delegated administrative services, and then aggregated up to the plan level to determine the amount to be excluded from the MLR as administrative costs.

Response: The amendment to § 422.2420(b)(2)(i), as proposed and finalized, includes in incurred claims all amounts that an MA organization pays (including under capitation contracts) for covered services, regardless of whether the recipient of the payment is a provider as defined in § 422.2. This revision removes the specification that the recipient of a payment for a covered service must be a provider (or a physician, in the case of capitated payments) to be included in incurred claims. The proposed change would not, if finalized, exclude from the incurred claims portion of the MLR numerator any payments that could be included in the numerator as incurred claims under the current MLR rules. However, this amendment also does not authorize inclusion in the numerator of costs that are excluded from incurred claims, such as administrative expenses addressed in § 422.2420(b)(4).

The four-factor test referenced by the commenter has been incorporated into our annual MLR Data Form Filing Instructions (formerly the MLR Report Filing Instructions) (OMB control no.

[28] CCIIO Technical Guidance (CCIIO 2012—001): Questions and Answers Regarding the Medical Loss Ratio Interim Final Rule. February 12, 2012.

0938–1232) (CMS–10476) for each contract year since contract year 2014. The instructions specify that amounts paid by an MA organization or Part D sponsor to clinical risk-bearing entities can be included in the MLR numerator as incurred claims if the following criteria are met:

(1) The entity contracts with an issuer to deliver, provide, or arrange for the delivery and provision of clinical services to the issuer's enrollees but the entity is not the issuer with respect to those services;

(2) The entity contractually bears financial and utilization risk for the delivery, provision, or arrangement of specific clinical services to enrollees;

(3) The entity delivers, provides, or arranges for the delivery and provision of clinical services through a system of integrated care delivery that, as appropriate, provides for the coordination of care and sharing of clinical information, and which includes programs such as provider performance reviews, tracking clinical outcomes, communicating evidence-based guidelines to the entity's clinical providers, and other, similar care delivery efforts; and

(4) Functions other than clinical services that are included in the payment (capitated or fee-for-service) must be reasonably related or incident to the clinical services, and must be performed on behalf of the entity or the entity's providers.

Payments to risk-bearing entities that include payments for administrative functions performed on behalf of the entity's member providers are incurred claims for purposes of § 422.2420 if all four factors outlined above are met.[29] However, to the extent that administrative functions are performed on behalf of the MA organization or Part D sponsor, that portion of the organization's or sponsor's payment that is attributable to administrative functions may not be included in incurred claims. This is the case regardless of whether payment is made according to a separate, fee-for-service payment schedule or as part of a global, capitated fee payment for all services provided.[30] We will continue to use this four-factor test to determine whether an MA organization can include payments to clinical risk-bearing entities.

Comment: A commenter expressed concern that the proposed changes to the definition of ''incurred claims'' could be interpreted as sufficiently broad to permit MA plans and PDPs to include in the MLR numerator costs associated with pharmacy benefit manager (PBM) services due to the nexus between those services and beneficiary access to covered drugs. The commenter was concerned in particular that the proposed change would allow MA organizations and Part D sponsors to include costs for implementing utilization management tools and strategies in the MLR numerator as incurred claims.

Response: We appreciate the commenter's concerns. Amending § 422.2420(b)(2)(i) as proposed to include in incurred claims amounts paid for covered services, regardless of whether the payment is made to a provider, does not allow MA organizations or Part D sponsors to include in the MLR numerator amounts that are identified as non-claims costs and excluded from incurred claims under our current rules. These non-claims costs that continue to be excluded from the MLR numerator include amounts paid to third party vendors for network development, administrative fees, claims processing, and utilization management (§ 422.2420(b)(4)). We note, however, that our current rules permit a clinical-risk bearing entity's costs related to utilization management and other administrative services to be included in incurred claims if all four factors outlined in the previous response are met. In addition, consistent with CCIIO's Technical Guidance,[31] our MLR Data Form Filing Instructions specify that when a third party vendor, through its own employees,[32] provides clinical services directly to enrollees, the entire portion of the amount the issuer pays to the third party vendor that is attributable to the third party vendor's direct provision of clinical services should be considered incurred claims, even if such amount includes reimbursement for administrative costs directly related to the vendor's direct provision of clinical services.[33]

Comment: A commenter opposed the proposal because they believed that including all payments for covered services in the incurred claims portion of the MLR numerator would be an unnecessary and inappropriate deviation from the commercial MLR rules, which only include payments to non-providers in the MLR numerator if they meet the requirements for QIA-related expenditures. The commenter expressed approval for the approach we took in the May 2013 Medicare MLR final rule, which was to use the commercial MLR rules as a reference point for developing the MLR rules for Medicare Advantage and Part D (hereinafter referred to as the ''Medicare MLR rules'') and to only depart from the commercial rules to extent necessary and appropriate given the Medicare context (78 FR 31285, 31290). The commenter stated the proposed rule did not identify any reason that the Medicare context makes it necessary and appropriate to depart from the requirement in the commercial MLR rules that incurred claims be paid to providers for covered services. The commenter asserted that the Medicare context does not meaningfully differ from the commercial context with respect to the benefits at issue.

Response: We respectfully disagree with the commenter. We continue to believe that it is important that we align the Medicare MLR rules with the commercial MLR rules in order to limit the burden on organizations that participate in both markets, and to make commercial and Medicare MLRs as comparable as possible for comparison and evaluation purposes. However, as stated in the February 2013 Medicare Program; Medical Loss Ratio Requirements for the Medicare Advantage and the Medicare Prescription Drug Benefit Programs Proposed Rule (78 FR 12428 through 12429) (hereinafter referred to as the ''February 2013 Medicare MLR proposed rule''), we also recognize that the commercial MLR rules may need to be revised in order to fit unique

[29] For example, a bundled payment to an Independent Practice Association (IPA) or similar entity for providing clinical services to enrollees which includes: The IPA processing claims payments to its member providers and submitting claims reports to issuers on behalf of its providers; performing provider credentialing to determine a provider's acceptability into the IPA network; and developing a network for its providers' benefit, can be included in incurred claims.

[30] For example, payment for processing claims in order to issue explanations of benefits (EOBs) to enrollees and handling any stage of enrollee appeals cannot be included in incurred claims. Payments for non-clinical services for which the contract between the clinical risk-bearing entity, such as an IPA, and the MA organization or Part D sponsor contains a ''clawback'' provision are not considered incurred claims for MLR reporting purposes.

[31] *See, for example,* the May 13, 2011 CCIIO Technical Guidance (CCIIO 2011–002), Q&A #12, available at: *https://www.cms.gov/CCIIO/Resources/Files/Downloads/mlr-guidance-20110513.pdf.*

[32] The term ''through its own employees'' does not include a third party vendor's contracted network of providers because such network providers are not considered employees of the third party vendor.

[33] The MLR Data Form Filing Instructions include the example of a Part D sponsor that contracts with a pharmacy benefit manager (PBM) to provide clinical services directly to enrollees through a mail order pharmacy. The instructions explain that the sponsor's payments to the PBM for mail order pharmacy services provided directly by the PBM's employees, including administrative costs related to the PBM's direct provision of such mail order pharmacy services, would be included in the sponsor's incurred claims.

characteristics of the MA and Part D programs. We believe that it is appropriate that we depart from the commercial MLR rules and expand the meaning of ''incurred claims'' to include covered services furnished by individuals and entities that are not providers, as proposed. The amendment to section 1852(a)(3)(D) of the Act by the BBA of 2018 to expand the types of supplemental benefits that can be ''covered services'' under an MA plan and the implementation of that change at § 422.102(f), as well as CMS' reinterpretation of what it means for a supplemental benefit offered by an MA plan to be primarily health related, mean that permissible supplemental benefits might include items and services that would not be furnished by a ''provider'' as defined at § 422.2. As we explained in the contract year 2019 Call Letter, a benefit is primarily health related if it diagnoses, prevents, or treats an illness or injury, compensates for physical impairments, acts to ameliorate the functional or psychological impact of injuries or health conditions, or reduces avoidable emergency and healthcare utilization; and while we indicated that supplemental benefits must be medically appropriate and recommended by a licensed provider, we acknowledged that they might not be directly provided by a health care professional. Because SSBCI are only required to have a reasonable expectation of maintaining or improving the health or overall function of the chronically ill enrollee and are not required to be primarily health related, we believe those benefits can be provided by someone who is not a health care professional. We are concerned that uncertainty about whether payments for these benefits can be included in the MLR numerator may make MA organizations less inclined to include them in their plan offerings. We believe that it is contrary to Congress' intent in amending section 1852(a)(2)(D) of the Act, and that it undermines CMS' efforts to provide MA organizations with additional flexibility to meet beneficiaries' health needs through supplemental benefits, if the MLR fails to adapt to changes in the permissible benefit design and ultimately deters MA organizations from offering those benefits. In addition, we note that section 2718 of the Public Health Service Act specifies that commercial MLRs shall reflect the percentage of total premium revenue spent ''on reimbursement for clinical services provided to enrollees,'' QIAs, and non-claims costs (which are excluded from the MLR numerator). By contrast, section 1857(e)(4) of the Act, which sets forth the minimum MLR requirement for the MA program, does not require that the portion of the MLR numerator consisting of non-QIA expenditures should be for ''clinical services'' or otherwise specify how the Secretary should calculate Medicare MLRs. Although the commercial and Medicare MLR requirements were both created by the Affordable Care Act of 2010, the statute gives the Secretary greater flexibility in determining how to integrate an MLR requirement into the Medicare program. We continue to use this flexibility to revise the calculation of the Medicare MLR as appropriate based on the unique characteristic of the MA and Part D programs, and we believe that amendment here is such an appropriate change.

Comment: A commenter believed that the proposed change was both unnecessary and unlikely to be effective as a means of encouraging MA organizations to expand their supplemental benefit offerings. The commenter cited data showing that MA organizations had been increasing their supplemental benefit offerings in recent years, which the commenter attributed to previous rule changes. The commenter recommended that instead of adjusting the MLR calculation to encourage the expansion of coverage of supplemental benefits, we should address the barriers to providing supplemental benefits that have been identified by MA organizations—specifically, upfront costs, trade-offs among benefits, return on investment, and provider availability. The commenter cautioned that the proposal may have unintended, negative impacts on non-supplemental benefit coverage, but the commenter did not specify what it meant by non-supplemental benefit coverage or what those negative impacts might be.

Response: We thank the commenter for their feedback and recommendations. As indicated in our response to other comments, we proposed to revise the meaning of ''incurred claims'' to include payments for covered services furnished by individuals or entities that are not providers as defined at § 422.2 in order to avoid creating uncertainty about whether expenditures for supplemental benefits can be included in the MLR numerator, which might deter MA organizations from offering those benefits. Although the purpose of our proposal was not to give MA organizations an incentive to offer expanded supplemental benefits, as noted above, we did receive numerous comments, some of which were submitted by MA organizations, which expressed support for the proposed change because the commenters believed it would encourage plans to offer expanded supplemental benefits. Our efforts to change how supplemental benefits are accounted for in the MLR numerator do not preclude us from pursuing other opportunities that are appropriate for CMS to take to promote the expansion of supplemental benefits.

Comment: A commenter requested that we clarify in final rulemaking the review and enforcement actions we undertake to ensure that QIA is not abused at the expense of MA enrollees. Another commenter requested that we closely examine all MA activities that are currently categorized as QIA to ensure that their utilization improves quality.

Response: At present, we do not actively collect information on MA organizations' QIA expenditures. As a result of change to the MLR reporting requirements finalized in the April 2018 final rule (83 FR 16674), MA organizations are not required to include in their annual MLR submissions information on their QIA expenditures. We have the authority under § 422.2480 to conduct selected audit reviews of the data reported under § 422.2460, which includes the capability to request detailed data regarding the QIA expenditures included in the Medicare MLR, in order to determine that the MLR and remittance amounts were calculated and reported accurately, and that sanctions were appropriately applied. MA organizations are required to attest to the accuracy of the MLR data submitted. In addition, we note that MA organizations and Part D sponsors are required to submit and attest to the data that details their spending on enrollee health care services as part of their annual bids.

Comment: Several commenters requested that we expand our proposal to include in incurred claims all expenditures related to combating COVID–19.

Response: The commenters did not provide specific information on the types of expenditures they wish to make that they believe would not already be included in the MLR numerator as incurred claims under our proposal. Without more detailed information, we are unable to determine whether including the expenditures that the commenters are contemplating in incurred claims would in fact necessitate a modification to our proposal, or whether there is logical outgrowth to make such a modification

or whether it is consistent with our overall policies on the Medicare MLR.

Comment: We received several recommendations for additional changes to the MLR requirements that are outside the scope of this final rule. A commenter recommended that we delay implementation of the MLR enrollment sanctions for contracts that fail to meet the MLR requirement for three consecutive contract years; that we develop a fixed quality improvement (QI) rate that could be added to the MLR numerator, similar to what is permitted under the commercial MLR regulations (45 CFR 158.221(b)(8)); that we provide guidance to plan sponsors concerning corrections of prior MLR submissions when errors are found that impact remittance calculations and that we develop a process to correct such data; and that we not apply the MLR requirements to standalone Part D plans. A commenter recommended that we mandate in the final rule that Part D sponsors must utilize a system to apply direct and indirect remuneration (DIR) fees at the point of sale as a means of improving the accuracy of the reported MLRs.

Response: We thank the commenters for their recommendations and will consider whether they are appropriate to address through future rule-making or other guidance.

After considering the comments we received and for the reasons outlined in the proposed rule and our responses to the comments, we are finalizing the proposal without modification.

3. Codifying Current Definitions of Partial, Full, and Non-Credibility and Credibility Factors (§§ 422.2440 and 423.2440)

The regulations at §§ 422.2440 and 423.2440 provide for the application of a credibility adjustment to the medical loss ratios (MLRs) of certain MA and Part D contracts with relatively low enrollment. A credibility adjustment is a method to address the impact of claims variability on the experience of smaller contracts by adjusting the MLR upward. As discussed in the February 2013 Medicare MLR proposed rule (78 FR 12438), for contracts with fewer members, random variations in the claims experience of enrollees could cause a contract's reported MLR to be considerably below or above the statutory requirement in any particular year, even though the MA organization or Part D sponsor estimated in good faith that the combination of the projected revenues and projected claims would produce an MLR that meets the statutory 85 percent minimum MLR requirement. The MLR credibility adjustments address the effect of this random variation by increasing the MLR of smaller contracts, thereby reducing the probability that such contracts will fail to meet the minimum MLR requirement simply because of random claims variability.

Whether a contract receives a credibility adjustment depends on the extent to which the contract has credible experience. A contract with credible experience is one that covers a sufficient number of beneficiaries for its experience to be statistically valid. A contract with fully credible experience has sufficient data to expect that the statistical variation in the reported MLR is within a reasonably small margin of error and will not receive a credibility adjustment under §§ 422.2440(b) and 423.2440(b). A contract has non-credible experience if it has so few beneficiaries that it lacks valid data to determine whether the contract meets the MLR requirement. Under §§ 422.2440(c) and 423.2440(c), a contract with non-credible experience is not subject to sanctions for failure to meet the 85 percent MLR requirement. A contract has partially credible experience if it exceeds the enrollment threshold for non-credible experience but does not have a sufficient number of enrollees for its experience to be fully credible. For contracts with partially credible experience, a credibility adjustment adds additional percentage points to the MLR in recognition of the statistical unreliability of the underlying data.

In the May 2013 Medicare MLR final rule (78 FR 31295 through 31296), CMS published the definitions of partial, full, and non-credibility and the credibility factors for partially credible MA and Part D contracts for contract year 2014. The factors appeared in that final rule in Tables 1A (finalized here as Table 1 to § 422.2440) and 1B to (finalized here as Table 1 to § 423.2440). Consistent with that final rule and regulations at §§ 422.2440 and 423.2440, for contract years 2015 through 2020, we finalized through the annual Advance Notice and Rate Announcement process the continued use of these definitions and credibility factors.

As explained in the proposed rule, we believe that the definitions of partial, full, and non-credibility and the credibility factors published in the May 2013 Medicare MLR final rule continue to appropriately address the effect of random claims variability on the MLRs of low enrollment MA and Part D contracts. However, we believe that it is more consistent with the policy and principles articulated in Executive Order 13892 on Promoting the Rule of Law Through Transparency and Fairness in Civil Administrative Enforcement and Adjudication (October 9, 2019) that we define and publish the definitions of partial, full, and non-credibility and the credibility factors in the **Federal Register**, and that we codify these definitions and factors in the Code of Federal Regulations, as opposed to defining and publishing these terms and factors through the annual Advance Notice and Rate Announcement process. Therefore, we proposed to amend our regulations at §§ 422.2440 and 423.2440 to codify the definitions of partial, full, and non-credibility and the credibility factors that we published in the May 2013 Medicare MLR final rule (78 FR 31296).

We proposed to amend paragraph (d) of §§ 422.2440 and 423.2440 by removing the current text (which states that CMS will define and publish definitions of partial, full, and non-credibility and the credibility factors through the annual Advance Notice and Rate Announcement process) and adding new paragraphs (d)(1) through (3) to specify ranges for the number of member months at which a contract's experience is, respectively, partially credible, fully credible, or non-credible. We proposed that the number of member months at which a contract's experience is defined as partially credible, fully credible, or non-credible be the same as the values that were used define each of those terms in the May 2013 Medicare MLR final rule. Thus, for MA contracts, we proposed that a contract is partially credible if it has at least 2,400 member months and fewer than or equal to 180,000 member months, fully credible if it has more than 180,000 member months, and non-credible if it has fewer than 2,400 member months. For Part D contracts, we proposed that a contract is partially credible if it has at least 4,800 member months and fewer than or equal to 360,000 member months, fully credible if it has more than 360,000 member months, and non-credible if it has fewer than 4,800 member months. We proposed to amend §§ 422.2440 and 423.2440 by removing from paragraphs (a) and (b) of both sections the text which indicates that CMS determines whether a contract's experience is partially credible or fully credible, respectively, and by adding at paragraphs (a), (b), and (c) of both sections new language specifying that partially credible experience is defined at (d)(1), fully credible experience is defined at (d)(2), and non-credible experience is defined at (d)(3).

At § 422.2440, we proposed to add new paragraph (e) to address the credibility adjustment for partially

credible contracts. We proposed at paragraph (e)(1) that, for partially credible MA contracts other than MSA contracts, the credibility adjustment is the base credibility factor determined under proposed paragraph (f). At new paragraph (f), we proposed to specify that the base credibility factor for a partially credible MA contract is determined based on the number of member months and the factors in Table 1 to § 422.2440. New paragraph (f) also states the rules for using Table 1 to § 422.2440 to identify the base credibility factor: (i) When the number of member months for a partially credible MA contract exactly matches the amount in the ''Member months'' column in Table 1 to § 422.2440, the value associated with that number of member months is the base credibility factor; and (ii) the base credibility factor for a number of member months between the values shown in Table 1 to § 422.2440 is determined by linear interpolation.

At § 423.2440, we proposed to add new paragraph (e), which provides that, for partially credible Part D contracts, the applicable credibility adjustment is determined based on the number of member months and the factors in Table 1 to § 423.2440. New paragraph (e) states the rules for using Table 1 to § 423.2440 to identify the base credibility factor: (1) When the number of member months used to determine credibility exactly matches a member month category listed in Table 1 to § 423.2440, the value associated with that number of member months is the credibility adjustment; and (2) the credibility adjustment for a number of member months between the values shown in Table 1 to § 423.2440 is determined by linear interpolation.

We received no comments on this proposal and are finalizing this provision without modification for the reasons outlined in the proposed rule.

4. Deductible Factor for MA Medical Savings Account (MSA) Contracts (§ 422.2440)

We proposed to include in the MLR calculation an additional adjustment factor for MA medical savings account (MSA) contracts that receive an MLR credibility adjustment. Specifically, we proposed that the credibility adjustment for partially credible MA MSA contracts will be calculated by multiplying the applicable base credibility factor in Table 1 to § 422.2440 by a ''deductible factor.'' This additional adjustment for MA MSAs is intended to recognize that the variability of claims experience is greater under health insurance policies with higher deductibles than under policies with lower deductibles, with high cost or outlier claims representing a larger portion of the overall claims experience of plans with high deductibles. As a result, a contract with a high average deductible is more likely to report a low MLR than is a contract with the same number of enrollees but with a low average deductible. As under the commercial MLR rules, the proposed deductible-based adjustment would only apply to contracts that receive a credibility adjustment due to low enrollment. We believe that a contract with experience that is fully credible has sufficient data to expect that the statistical variation in the reported MLR is within a reasonably small margin of error, regardless of the deductible level.

In the February 2013 Medicare MLR proposed rule (78 FR 12428), we explained that we used the commercial MLR rules as a reference point for developing the Medicare MLR rules. We sought to align the commercial and Medicare MLR rules in order to limit the burden on organizations that participate in both markets, and to make commercial and Medicare MLRs as comparable as possible for comparison and evaluation purposes, including by Medicare beneficiaries. However, we recognized that some areas of the commercial MLR rules would need to be revised to fit the unique characteristics of the MA and Part D programs. One way in which the Medicare MLR rules currently deviate from the commercial rules is the omission of a deductible-based adjustment to the Medicare MLR calculation. The rationale given in the February 2013 Medicare MLR proposed rule for omitting a deductible factor from the Medicare MLR calculation was that Medicare deductibles were more confined than deductibles in the commercial market, and that we believed that the limited range of Medicare cost sharing did not prompt the need for such an adjustment (78 FR 12439).

As explained in the proposed rule, although we continue to believe that deductibles for most MA and Part D contracts are too low to necessitate the adoption of a deductible factor for all contracts, we now recognize that the February 2013 Medicare MLR proposed rule's rationale for excluding a deductible factor from the Medicare MLR calculation did not adequately take into account the specific characteristics of MA MSA plans, which tend to have much higher deductibles than other MA plan types. For contract year 2020, the average deductible is $454 for MA plans (excluding MA MSAs) and $6,000 for MA MSAs. The proposed rule noted that, under the commercial MLR regulations at 45 CFR part 158, a deductible factor applies to the credibility adjustment of issuers of employer group and private health insurance plans that have an average deductible of $2,500 or higher. For contract year 2020, all MA MSAs have deductibles in excess of $2,500. These significantly higher deductibles in MSA plans cause MA MSA contracts to have more variability in their claims experience relative to MA contracts with the same number of enrollees but lower deductibles. In light of this information, we believe that it is clear that our policy of excluding a deductible factor for MA MSA contracts should be revisited.

Further, to the extent that this variability in claims experience and its potential impact on the MLR calculation has deterred MA organizations from offering an MSA product, the proposed addition of a deductible factor to the MLR calculation for MA MSAs would serve to encourage the offering of MA MSA plans by eliminating the current inconsistency in how the commercial and Medicare MLR rules take into account the greater variability of claims experience under health insurance policies with high deductibles. The proposed rule noted that our proposal to add a deductible factor to the MLR calculation for MA MSA contracts aligns with the directive in Executive Order 13890 on Protecting and Improving Medicare for Our Nation's Seniors (October 3, 2019) for the Secretary to take actions that ''encourage innovative MA benefit structures and plan designs, *including through changes in regulations and guidance that reduce barriers to obtaining Medicare Medical Savings Accounts . . . .*'' (emphasis added). The proposed rule also noted that, for many Medicare beneficiaries, the greatest barrier to enrolling in an MA MSA has been the lack of MA MSA plans in the beneficiary's area of residence. For contract year 2020, MA MSA plans are only available in 27 states and the District of Columbia. The omission of a deductible-based adjustment from the current Medicare MLR regulations could contribute to the limited availability of MA MSAs for Medicare beneficiaries because the greater variability in the MLR for contracts with high average deductibles—and the resulting higher risk of a potential remittance to CMS or sanctions under § 422.2410—could dissuade MA organizations from offering plans of this type. We noted in the proposed rule our belief that finalizing a deductible factor for MA

MSAs would make it less likely that MA organizations would be deterred from offering MA MSA plans out of concern that the MA MSA contract would be at risk of failing to meet the MLR requirement due to random variations in claims experience.

We proposed to adopt the same deductible factors that apply under the commercial MLR regulations at 45 CFR part 158. As noted in the December 1, 2010 Health Insurance Issuers Implementing Medical Loss Ratio (MLR) Requirements Under the Patient Protection and Affordable Care Act Interim Final Rule (75 FR 74881 through 74882), the commercial deductible factors were based on an actuarial analysis of anticipated claims experience in the commercial market by actuarial consultants to the National Association of Insurance Commissioners (NAIC). We explained in the proposed rule that we would prefer to use Medicare data to develop the deductible factors that apply to MA MSAs, and that we intend to assess the feasibility of using Medicare data for this purpose. We noted in the proposed rule and continue to believe that the commercial deductible factors are suitable for adjusting MSA MLRs in the absence of Medicare-specific deductible factors because the commercial factors are designed to take into account the variability in claims experience resulting from similarly high deductibles. We proposed to apply the commercial deductible factors in the MLR calculation for MA MSAs. We solicited comment on whether and how Medicare data should be used to evaluate whether the difference in variability between MLRs for MSA plans and non-MSA plans necessitates the use of Medicare-specific deductible factors, as well as how Medicare data could be used to develop Medicare-specific deductible factors. We also solicited comment on whether and how the proposed deductible factors should be adjusted to account for any unique features of the Medicare MLR rules (for example, the inclusion of the MA MSA deposit amount in the Medicare MLR numerator and denominator), or to reflect any differences between the commercial and Medicare MLR rules (such as the commercial rules' lower minimum MLR requirement for small group and individual health insurance plans (80 percent, compared to the Medicare rules' 85 percent MLR requirement for all contracts)). We solicited comment on potential consequences of the application of a deductible factor to the MLR calculation for MA MSA contracts, such as impacts on benefits for enrollees in MSA plans.

We proposed new § 422.2440(e)(2) to specify that the credibility adjustment for an MA MSA contract would be the base credibility factor determined under new paragraph (f), multiplied by the deductible factor determined under new paragraph (g). At new paragraph (g), we proposed to specify that the applicable deductible factor for an MA MSA contract would be based on the enrollment-weighted average deductible for all MSA plans under the contract, where the deductible for each plan under the contract is weighted by the plan's portion of the total number of member months for all plans under the contract during the contract year for which the MLR is being calculated. (We note that all MA plans under an MA MSA contract must be MSA plans, and MSA plans may only be offered under MSA contracts.) When the weighted average deductible for a contract exactly matches the amount in the ''Weighted average deductible'' column in Table 2 to § 422.2440, the value associated with that weighted average deductible is the deductible factor. The deductible factor for a weighted average deductible between the values shown in Table 2 to § 422.2440 is determined by linear interpolation.

We received 5 comments on the proposal to add a deductible factor to the MLR calculation for MA MSAs. The following is a summary of the comments we received on the proposal and our responses:

Comment: A commenter supported the proposal. The commenter expressed hope that adding a deductible factor to the MLR calculation for MA MSA contracts would lead to the greater availability of MA MSA products in the marketplace, which the commenter believed would be an attractive option for many consumers.

Response: We thank the commenter for their support.

Comment: A commenter stated that they do not support policies that single out high-deductible health plans for preferential MLR treatment for the purpose of encouraging beneficiaries to enroll in such plans.

Response: We appreciate the commenter's objection to MLR policies that favor certain plan types over others. However, we disagree with the commenter's characterization of the proposed application of a deductible factor to the MLR calculation for certain MSA contracts as a form of preferential treatment. As explained in the proposed rule and summarized here, we believe an additional adjustment to the MLR calculation for MSA contracts is appropriate because the variability of claims experience is greater under health insurance policies with higher deductibles than under policies with lower deductibles, with high cost or outlier claims representing a larger portion of the overall claims experience of plans with high deductibles. This is the case because high-deductible health plan enrollees' medical expenses must exceed a higher threshold before the plan begins to incur claims costs that can be included in the MLR numerator. As a result, a contract with a high average deductible is more likely to report a low MLR than is a contract with the same number of enrollees but a low average deductible. The deductible factor, which functions as a multiplier on the credibility adjustment factor, is calibrated so that the probability that a contract will fail to meet the MLR requirement is the same for all contracts that receive a credibility adjustment, regardless of the deductible level. Because the deductible factor is intended to mitigate the increased likelihood that a contract with a high deductible will fail to meet the MLR requirement due to random variations in claims experience, we believe that its application to the Medicare MLR calculation for MSA contracts serves to level the playing field for all MA contract types. We believe that the absence of a deductible factor from the current regulations unduly penalizes MSA contracts and that adding a deductible factor removes this potential deterrent to the offering of MSAs.

Comment: Three commenters opposed the proposal because they objected to CMS giving MA organizations an incentive to enroll beneficiaries in high deductible health plans such as MSAs. A commenter expressed concern that beneficiaries may enroll in these plans due to their low premiums and tax benefits, without realizing that they could be responsible for thousands of dollars of pre-deductible costs should they need significant medical attention. Another commenter warned that Medicare beneficiaries have limited incomes and frequently experience chronic conditions, the proliferation of high-deductible MSAs among this vulnerable population could have catastrophic effects on beneficiary health, as enrollees forego care to avoid paying high out-of-pocket costs. A couple of commenters cited research which suggests that although high deductible plans reduce costs, this may be attributable to a decrease in utilization of necessary medical services or to high

deductible plans enrolling younger, healthier members.

Response: We appreciate the commenters' concerns. Expanding access to MSAs so that Medicare beneficiaries who see the advantages in enrolling in a high-deductible plan have the option of doing so is a priority of the Trump administration. As discussed in the proposed rule, the proposal to add a deductible factor to the MLR calculation for MA MSA contracts aligns with the directive in Executive Order 13890 on Protecting and Improving Medicare for Our Nation's Seniors (October 3, 2019) for the Secretary to take actions that ''encourage innovative MA benefit structures and plan designs, *including through changes in regulations and guidance that reduce barriers to obtaining Medicare Medical Savings Accounts . . . .*'' (emphasis added).

We note that the research cited by the commenters is mostly based on the experience of enrollees in high-deductible health plans operating outside of the Medicare context. We believe that the widespread availability of zero premium MA plans makes it less likely that Medicare beneficiaries will enroll in high deductible plans due to the low premiums and tax benefits without adequately considering their potential out of pocket liability. In addition, there are protections to ensure that MSA enrollees have information that enables them to assess the coverage provided by MSA plans. Section 1852(c)(1)(B) of the Act and § 422.111(b)(2)(ii) require that MSA plans disclose, in clear, accurate, and standardized form to each enrollee at the time of enrollment and at least annually thereafter, a comparison of the benefits under the plan with benefits under other MA plans.

After consideration of the public comments we received and for the reasons outlined in the proposed rule and our responses to comments, we are finalizing the proposal without modification.

V. Codifying Existing Part C and D Program Policy

A. Medicare Advantage (MA) and Cost Plan Network Adequacy (§§ 417.416 and 422.116)

Section 1852(d)(1)(A) of the Act establishes that an organization offering an MA plan may select the providers from whom the benefits under the plan are provided so long as the organization makes such benefits available and accessible with reasonable promptness to each individual electing the plan within the plan service area. This is generally implemented at § 422.112(a), which provides that a coordinated care plan must maintain a network of appropriate providers that is sufficient to provide adequate access to covered services to meet the needs of the population served. In the April 15, 2010, Medicare Program; Policy and Technical Changes to the Medicare Advantage and the Medicare Prescription Drug Benefit Program Final Rule (75 FR 19691), CMS added criteria at § 422.112(a)(10) for determining whether an MA plan network is adequate and meets the statutory standard by codifying that MA plans must have networks that are consistent with the prevailing community pattern of health care delivery in the service area. The regulation provides that CMS will consider factors that make up the community patterns of health care, which CMS will use as a benchmark in evaluating MA plan networks, and lists certain examples of those factors in § 422.112(a)(10)(i) through (v). CMS explained in the October 22, 2009, Medicare Program; Policy and Technical Changes to the Medicare Advantage and the Medicare Prescription Drug Benefit Programs Proposed Rule (74 FR 54644) that it would develop an automated system for reviewing network adequacy based on the elements that define community patterns of health care delivery and that we would define through subregulatory guidance how CMS would operationalize these factors.

Since that time, CMS has routinely provided subregulatory guidance to MA organizations that defines how CMS measures and assesses network adequacy.[34] We built the Network Management Module (NMM) in HPMS to facilitate automated reviews of plan networks and to annually transmit information to MA plans about provider/facility specialty types that are subject to maximum time and distance standards, minimum number requirements, and other critical information needed for the network adequacy reviews. The NMM also gave existing MA organizations and new applicants to the MA program the opportunity to routinely test their networks against our standards. Currently, we require that organizations contract with a sufficient number of specified providers/facilities to ensure that 90 percent of the beneficiaries have access to at least one provider/facility of each specialty type within the published maximum time and distance standards. We update and refine the data and information that feed into network adequacy measures and perform analyses as needed. It is important that CMS ensure that MA organizations maintain an adequate network of contracted providers that are capable of providing medically necessary covered services to beneficiaries, both to ensure compliance with section 1851(d) of the Act and to protect beneficiaries. The network adequacy rules protect beneficiaries by ensuring that most, it not all, of the beneficiaries enrolled in a plan have access to providers within a reasonable time and distance from where the beneficiaries reside.

In this final rule, we are codifying existing network adequacy standards to provide MA organizations with a greater understanding of how CMS measures and assesses network adequacy by adding a new regulation at § 422.116. Specifically, we are codifying in § 422.116 the list of provider and facility specialty types subject to network adequacy reviews, county type designations and ratios, maximum time and distance standards, minimum number requirements, and exceptions. The regulation also addresses CMS's annual publishing of the Provider Supply file and Health Service Delivery (HSD) reference file to release updated numbers and maximums for these standards in subsequent years. The final regulation reflects modifications from our current network adequacy policy to further account for access needs in all counties, including rural counties, and to take into account the impact of telehealth providers in contracted networks. Section 1876(c)(4) of the Act imposes similar requirements for cost plans offered under section 1876 of the Act to make Medicare-covered services available and accessible to each enrollee with reasonable promptness when medically necessary. Under this authority, we are also amending § 417.416(e) to require 1876 cost organizations to also comply with the network adequacy standards described in § 422.116. A summary of our proposal follows.

1. General Provisions

We proposed in § 422.116(a) that each network-based MA plan demonstrate that it has an adequate contracted provider network that is sufficient to provide access to medically necessary covered services consistent with standards in section 1851(d) of the Act, the regulations at §§ 422.112(a) and 422.114(a), and the rules in new § 422.116. We also proposed that when required by CMS, an MA organization

[34] *See* ''Medicare Advantage and Section 1876 Cost Plan Network Adequacy Guidance'' *https://www.cms.gov/Medicare/Medicare-Advantage/MedicareAdvantageApps/index.*

must attest that it has an adequate network for access and availability of a specific provider or facility type that CMS does not independently evaluate in a given year. We explained that we would require such attestation in the MA organization's application or contract for a given year, but we might require the attestation when performing other network adequacy reviews, such as when there is a significant change in the MA plan's provider network.

We cross-referenced § 422.114(a)(3)(ii) to identify the network-based plan types that would be subject to these network adequacy requirements. Network-based MA plans include all coordinated care plans in § 422.4(a)(1), network-based MA private-fee-for-service (PFFS) plans in § 422.4(a)(3), and 1876 cost organizations. Generally, network-based MA medical savings account (MSA) plans are considered coordinated care plans in accordance with § 422.4(a)(1)(iii)(D), which includes ''other network plans'' as a type of coordinated care plan. However, since MSA plans do not require contracted networks, we proposed to exclude MSA plans from the requirements in § 422.116. By cross-referencing § 422.114(a)(3)(ii), we carved out an MA regional plan that meets access requirements substantially through deemed contracting, so local and regional PFFS plans operating in CMS defined network areas must meet CMS network adequacy requirements at § 422.116.

We proposed, at paragraph (a)(2), to codify the general rule underlying § 422.116 that an MA plan must meet maximum time and distance standards and contract with a specified minimum number of each provider and facility specialty type, with each contract provider type within maximum time and distance of at least one beneficiary (in our MA Medicare Sample Census) in order to count toward the minimum number. The location of a contracted provider specialty or facility is not required to be within the county or state boundaries to be considered within the time and distance standards. The minimum number criteria and the time and distance criteria vary by the county type. We proposed to establish the specific provider and facility types; county types; specific time and distance standards by county designation; and specific minimum provider number requirements in paragraphs (b), (c), (d) and (e), respectively, of § 422.116. Regardless of whether CMS evaluates a plan's network against the access and adequacy standards in a given year, a plan's network must meet these standards and will be held to full compliance with the standards. At paragraphs (a)(3) through (4), we proposed to codify additional general rules about the network adequacy requirements in this section. At paragraph (a)(3), we proposed general rules for which provider types are not counted in evaluating network adequacy. In paragraph (a)(4), we proposed to codify certain administrative practices we have instituted over the past several years. Specifically, we proposed to annually update and make available Health Service Delivery (HSD) reference files in advance of our review of plan networks. These HSD files contain the minimum provider and facility number requirements, minimum provider ratios, and the minimum time and distance standards. We also proposed that we would annually update and make available a Provider Supply file that identifies available providers and facilities with office locations and specialty types. The Provider Supply file is updated annually based on information from the Integrated Data Repository (IDR), which has comprehensive claims data, as well as information from public sources. We may also update the Provider Supply file based on its findings from validation of provider information.

2. Provider and Facility Specialty Types

We proposed to codify at § 422.116(b) the list of provider and facility specialty types that have been subject to CMS network adequacy standards in the past, as not all specialty types are included in network adequacy reviews. We identified and proposed to codify the 27 provider specialty types and 14 facility specialty types that are currently used in the evaluation of network adequacy in each service area. We identified these provider and facility specialty types as critical to providing services based on review of Medicare FFS) utilization patterns, utilization of provider/facility specialty types in Medicare FFS and managed care programs, and the clinical needs of Medicare beneficiaries. We proposed to codify at § 422.116(a)(3) existing policy on the provider and facility types that are not counted in evaluating network adequacy: Specialized, long-term care, and pediatric/children's hospitals and providers and facilities contracted with the organization only for its commercial, Medicaid, or other non-MA plans. In paragraph (a)(3), we also proposed that hospital-based dialysis may count in network adequacy criteria for the facility type of Outpatient Dialysis. We clarified that primary care providers, the first provider specialty in our proposed list in paragraph (b)(1), are measured as a single specialty by combining provider specialty codes (001–006) in the HSD reference file.

Section 2005 of the SUPPORT Act establishes a new Medicare Part B benefit for Opioid Use Disorder treatment services furnished by Opioid Treatment Programs (OTPs) on or after January 1, 2020. OTPs provide medication-assisted treatment for people diagnosed with an Opioid Use Disorder and must be certified by the Substance Abuse and Mental Health Services Administration (SAMHSA) and accredited by an independent, SAMHSA-approved accrediting body. We did not propose to include OTPs as a facility type in § 422.116(b)(2) and explained it was due to the newness of the benefit and that we may consider adding OTPs to the facility type list in future proposals. However, we reminded MA organizations that they are required to pay for medically necessary care from certified OTPs.

We proposed at § 422.116(b)(3) that CMS may remove a specialty or facility type from the network adequacy evaluation for a particular year by not including the type in the annual publication of the HSD reference file. For example, in the past CMS removed oral surgery as a provider specialty type from the HSD reference file, and replaced home health and durable medical equipment with an attestation in its application about the plan's network ensuring access to providers of these types. We proposed at § 422.116(a)(1) to require an MA plan to submit an attestation when required by CMS. We explained that we would require an MA organization to complete an attestation that it has an adequate network that provides the required access to and availability of provider specialty or facility types even where we do not evaluate access ourselves. Network adequacy criteria are measured for each individual specialty type and do not roll up into an aggregate score. Therefore, the removal of a specialty type from the network review will not affect the outcome of an MA plan's network review and use of an attestation in lieu of evaluation will permit us some necessary flexibility. In light of the lack of change to the list we have used over the past several years, we did not propose any means for CMS to add new provider specialty or facility types to the network adequacy evaluation without additional rulemaking.

3. County Type Designations

We proposed at § 422.116(c) to codify our current policy regarding county designations. Network adequacy is

assessed at the county level, and counties are classified into five county type designations: Large Metro, Metro, Micro, Rural, or CEAC (Counties with Extreme Access Considerations). These metrics provide the means by which the various network adequacy criteria are differentiated to represent large geographic variations across the United States and its territories. They are based on the population size and the population density of each county.

We proposed to codify at § 422.116(c) the five county type designations using population size and density parameters that were identified in Table 6 in the proposed rule (85 FR 9094). Under our proposal, a county must meet both the population and density parameters for inclusion in a given county type designation and we explained that the proposed parameters are consistent with those we have used in conducting network adequacy reviews in prior years. We explained that we based the parameters on approaches used by the United States Census Bureau in its classification of ''urbanized areas'' and ''urban clusters,'' and by the Office of Management and Budget (OMB) in its classification of ''metropolitan'' and ''micropolitan.'' To calculate population density at the county level, we divided the latest county-level population [35] estimate by the land area [36] for that county. We also stated that our county designation methodology was designed specifically for MA network adequacy and may not be appropriate for other purposes.

4. Maximum Time and Distance Standards and Customization

We proposed in § 422.116(a)(2) that network adequacy is measured using both maximum time and distance standards and minimum number requirements that vary by county type. In § 422.116(d), we proposed that CMS determines maximum time and distance standards by county type and specialty type and publishes these standards annually in the HSD Reference file. Maximum time and distance standards are set by county designation, referred to as the ''base'' time and distance standards, or by a process referred to as ''customization.'' We proposed to codify the base time and distance standards by county designation that are in current practice with recent network reviews and included the standards in Table 7 of the proposed rule (85 FR 9095) as well as in the proposed regulation text as Table 1 to paragraph (d)(2). We also explained in greater detail how the specific time and distance standards we proposed for each provider and facility type and county designation were developed and refer readers to the proposed rule for that discussion (85 FR 9097).

As explained in the proposed rule, we have added flexibility in recent years to expand the time (in minutes) and distance (in miles) standards beyond the base standards in cases where, due to a shortage of supply of providers or facilities, it is not possible to meet the base time and distance standards. We proposed to codify this flexibility and the process for using it at § 422.116(d)(3) and refer to it as ''customization.'' To customize distance standards, we use software to map provider location data from the Provider Supply file against the population distribution data in CMS's MA Medicare Sample Census.[37] For each specialty and county where there are insufficient providers within the base distance standard, we use mapping results to identify the distance at which 90 percent of the population would have access to at least one provider or facility in the applicable specialty type. The resulting distance is then rounded up to the next multiple of five (51.2 miles would be rounded up to 55 miles), and a multiplier specific to the county designation is applied to determine the analogous maximum time criterion. We requested comment on our customization methodology and whether we should adjust factors in the distance calculation to achieve outcomes that are more equitable.

Customization of base criteria may be triggered based on information received through exception requests from plans, or from other sources, such as certificates of need (CON) from state departments of health. However, we proposed that CMS may only use customization to increase time and distance standards from the base standards, and may not reduce time and distance standards below the base standards. We solicited comment from the industry on other sources of information that CMS should consider and how it would work within the structure of our network adequacy standards.

Historically, we have required that at least 90 percent of the beneficiaries residing in a particular county have access to at least one provider/facility of each specialty type within the published maximum time and distance standards for that county. In an effort to encourage more MA offerings in rural areas, we proposed to reduce this percentage to 85 percent in Micro, Rural, and CEAC counties. In these generally ''rural'' counties, there is evidence of a lower supply of physicians, particularly specialists, compared to urban areas.[38] In order to account for this shortage, two state Medicaid programs that utilize network adequacy criteria have adjusted percentages in rural counties to require that standards be met for less than 100 percent of enrollees. New Jersey allows an 85 percent coverage requirement for primary care in ''non-urban counties'' but 90 percent in urban counties.[39] Tennessee's Medicaid managed care program takes a slightly different approach, requiring that 60 percent of enrollees have access within 60 miles and 100 percent within 90 miles.[40] Additionally, the Part D program has a 90 percent retail pharmacy network coverage requirement in urban and suburban areas that drops to 70 percent for rural areas.[41] Further, our data indicates that existing failures in MA plans' meeting the time and distance standards frequently occur at the range between 80 to 89 percent of beneficiaries. As a result, we proposed to adopt a similar change in our MA network adequacy approach to account for access challenges in Micro, Rural,

[35] United States Census Bureau. American Factfinder. Annual Estimates of the Resident Population: April 1, 2010 to July 1, 2018: 2018 Population Estimates. Retrieved from: *https://factfinder.census.gov/faces/tableservices/jsf/pages/productview.xhtml?pid=PEP_2017_PEPANNRES&src=pt.*

[36] United States Census Bureau. American Factfinder. Population, Housing Units, Area, and Density: 2010—United States—County by State; and for Puerto Rico: 2010 Census Summary File 1. Retrieved from: *https://factfinder.census.gov/faces/tableservices/jsf/pages/productview.xhtml?pid=DEC_10_SF1_GCTPH1.US05PR&prodType=table.*

[37] CMS built the MA Medicare Sample Census, which derives from information maintained by CMS on the residence of Medicare beneficiaries. CMS built the Sample Census to be an adequate representative sample of Medicare beneficiaries in each applicable county. This file is only available to CMS and is only utilized for the purposes of measuring network adequacy.

[38] Department of Health and Human Services, National Advisory Committee on Rural Health and Human Services (2018) ''Rural Health Insurance Market Challenges: Policy Brief and Recommendations.'' Retrieved April 3, 2019, from: *https://www.hrsa.gov/sites/default/files/hrsa/advisory-committees/rural/publications/2018-Rural-Health-Insurance-Market-Challenges.pdf.*

[39] State of New Jersey Dept. of Human Services. ''Contract Between State of New Jersey Department of Human Services Division of Medical Assistance and Health Services and _____, Contractor'' Sec. 4.8.8 ''Provider Network Requirements'' Retrieved April 5, 2019, from: *https://www.state.nj.us/humanservices/dmahs/info/resources/care/hmo-contract.pdf.*

[40] State of Tennessee, Department of Finance and Administration, Division of Health Care Finance and Administration, Division of TennCare (2019) ''Statewide Contract with Amendment 9—January 1, 2019'' Attachment IV. Retrieved April 3, 2019, from: *https://www.tn.gov/content/dam/tn/tenncare/documents/MCOStatewideContract.pdf.*

[41] Section 423.120(a)(1.).

and CEAC counties; at § 422.116(d)(4)(i) we proposed that at least 85 percent of the beneficiaries have access to at least one provider/facility of each specialty type within the published time and distance standards in Micro, Rural, and CEAC counties. We estimated that approximately 14 percent of contracts (96 contracts) operating in these county designations will benefit from the reduced percentage and will no longer need to submit an exception request. We proposed to codify the existing policy of using a 90 percent threshold for Large Metro and Metro counties in § 422.116(d)(4)(ii). We noted that this specific proposal did not include a change from current policy requirements for a minimum number of provider specialties and facilities and that we proposed, at paragraph (e), that MA plans would still be required to maintain contracts with a minimum number of providers in each county.

We also proposed to give an MA plan a 10-percentage point credit towards the percentage of beneficiaries residing within the applicable time and distance standards for certain provider specialty types when the plan contracts with telehealth providers for those specified specialty types. For example, in a rural county where an MA plan must have 85 percent of beneficiaries residing within applicable time and distance standards, the MA plan would receive an additional 10 percentage points towards the 85 percent requirement should they contract with applicable telehealth providers under § 422.135. We explained that this is not currently part of the network adequacy evaluation, but we believed it is appropriate in light of the expanding coverage in the MA program of additional telehealth benefits. In the April 2019 final rule, we adopted § 422.135 to implement the option for MA plans to offer additional telehealth benefits as part of their coverage of basic benefits under section 1852(m) of the Act, as amended by section 50323 of the BBA of 2018. In that rulemaking, we solicited feedback from the industry concerning the impact, if any, that telehealth should have on network adequacy policies. We received approximately 35 responses from stakeholders in managed care, provider, advocacy, and government sectors. While health plans clearly favored taking into account telehealth access while evaluating network adequacy, providers had more concerns that telehealth services could be used to replace, rather than supplement, in-person healthcare delivery. A commenter stated that it is imperative that beneficiaries continue to have the choice to access services in-person not only as a matter of preference, but to ensure those that do not have access to the required technologies are not left without care. Section 1852(m)(4) of the Act and the regulation at § 422.135(c)(1) require that an enrollee in an MA plan offering additional telehealth benefits must retain the choice of receiving health care services in person rather than through electronic exchange (that is, as telehealth). With that in mind, and emphasizing the importance of maintaining an in-person network, we did not propose any changes to how we currently calculate minimum provider requirements and MA plans would still contract with a minimum number of providers for each specialty type. We explained that we believed this is imperative for MA plans to be able to provide in-person care when needed or when preferred by the beneficiary and that contracting with telehealth providers as a supplement to an existing in-person contracted network would give enrollees more choices in how they receive health care. Further, we explained that it is important and appropriate to account for contracted telehealth providers in evaluating network adequacy consistent with reflecting how MA plans supplement, but do not replace, their in-person networks with telehealth providers. We proposed, at § 422.116(d)(5) to provide a 10-percentage point credit towards the percentage of beneficiaries residing within time and distance standards for specific provider specialty types by county when the MA plan includes one or more telehealth providers that provide additional telehealth benefits, as defined in § 422.135, in its contracted network. Since additional telehealth benefits described at § 422.135 only apply to MA plans, cost plans would not be eligible for this 10-percentage point credit under proposed § 417.416(e)(3).

We explained that a 10-percentage point credit is an appropriate amount that proportionately supplements a plan's percentage score because telehealth providers add value to a contracted provider network, but should not have the same level of significance or value as an in-person provider. Additionally, we noted how information from prior network adequacy reviews show that many failures in meeting time and distance standards occur in this 80 to 89 percent range. Therefore, we stated, a 10-percentage point credit is significant enough to have an impact on MA plans and encourage the use of telehealth, while being proportionate to the role that telehealth providers have in a contracted network. Further, we proposed to apply this telehealth credit only to five specific provider specialty types: Dermatology, psychiatry, neurology, otolaryngology and cardiology. We explained that this limited approach would allow CMS to monitor the effectiveness of the credit, while also allowing us to determine whether there may be access or quality of care impacts. As we discussed in the April 2019 final rule, additional telehealth benefits are monitored by CMS through account management activities, complaint tracking and reporting, and auditing activities. These oversight operations will alert CMS to any issues with access to care and CMS may require MA organizations to address these matters if they arise.

We explained how we identified the five provider types for this proposal. CMS considered previous input from industry stakeholders, publicly available studies, and analyses of Medicare claims data for telehealth services in determining applicable provider specialty types. We considered not only the potential that telehealth has within a specialty type, but also the observed access challenges for provider specialty types over the years of our network adequacy reviews. In our experience, most MA plans do not have challenges meeting time and distance standards for primary care as compared to non-primary care provider specialty types. We also stated that it is critical to quality health care that Medicare beneficiaries have a primary care provider that they can visit in person and within a suitable time and distance. Therefore, despite the potential and prevalence of telehealth for furnishing primary care services, we did not believe that it was necessary to take telehealth access into account when measuring and setting minimum standards for access to primary care providers. We solicited comments on the provider specialty types we proposed to be eligible for the telehealth credit and whether CMS should expand or limit this credit to a different set of provider specialties.

In the proposed rule, we explained that we had received comments from providers and physician groups about the limitations of current network adequacy policies on dialysis treatment when performed in a hospital, at home, or in an outpatient facility. Some research suggested that home-based dialysis may offer advantages over in-center hemodialysis, including patient convenience, reduction in costs associated with dialysis, and potentially improved patient quality of life and blood pressure control with greater

survival and fewer hospitalizations.[42] We acknowledged in the proposed rule that there is more than one way to access medically necessary dialysis care and stated that we wanted plans to exercise all of their options to best meet a beneficiary's health care needs. We solicited comment on: (1) Whether CMS should remove outpatient dialysis from the list of facility types for which MA plans need to meet time and distance standards; (2) allowing plans to attest to providing medically necessary dialysis services in its contract application (as is current practice for DME, home health, and transplant services) instead of requiring each MA plan to meet time and distance standards for providers of these services; (3) allowing exceptions to time and distance standards if a plan is instead covering home dialysis for all enrollees who need these services; and (4) customizing time and distance standards for all dialysis facilities.

Additionally, we explained that CMS had received comments concerning patterns of provider consolidation and its impact on higher costs for patients. We received feedback from stakeholders that providers in concentrated areas may leverage network adequacy requirements in order to negotiate prices well above Medicare FFS rates. We solicited comment on existing problems and behavior in non-rural, consolidated provider markets and recommendations that we could take to encourage more competition in these markets.

We also proposed a policy to incorporate consideration of Certificate of Need (''CON'') laws into our network evaluations, as a modification from our current policy after a brief summary of the topic. President Trump's Executive Order 13890 on Protecting and Improving Medicare for Our Nation's Seniors (October 3, 2019) calls for adjustments to network adequacy requirements to account for the competitiveness of state health care markets, including taking into account whether states maintain CON laws or other anticompetitive restrictions. Many states began adopting CON laws in the 1960s and 1970s in part to promote resource savings and to prevent investments that could raise hospital costs.[43] A number of studies have found no evidence that CON programs have led to resource savings, and in some instances, may raise health care costs. In one study published in 2013, researchers studied whether states that dropped CON programs experienced changes in costs or reimbursements from coronary artery bypass graft surgery or percutaneous coronary interventions.[44] In this study, the cost savings from removing the CON requirements slightly exceeded the total fixed costs of new facilities that entered after deregulation. Another study published in 2016 concluded that there is no evidence that CON requirements limit health care price inflation and little evidence that they reduce health care spending.[45] It further concluded that CON laws are associated with higher per unit costs and higher total healthcare spending. Most relevant here, other studies suggest that the removal of these laws that serve as a barrier to entry into the market lead to greater access to providers and a redistribution of health care services to higher quality providers, improving the overall quality of health outcomes.[46]

After listing this research, we stated that it pointed out that CON laws restrict the supply and competition for healthcare services and increases costs and that CON laws adversely affect access in states and counties where they are in effect, including for MA organizations that operate in those areas. CMS pays MA organizations a capitated amount in each county for the provision of Medicare benefits based on the expected costs to provide benefits. When MA organizations must pay more for benefits, as the research demonstrates happens when there are fewer providers or facilities with which to contract, that reduces the access to benefits offered by MA organizations. In order to take into account the adverse effects that CON laws have on access, we proposed in § 422.116(d)(6) to provide that MA organizations may receive a 10-percentage point credit towards the percentage of beneficiaries residing within published time and distance standards for affected provider and facility types in states that have CON laws, or other state imposed anticompetitive restrictions, that limit the number of providers or facilities in a county or state. In the proposed rule, we explained that, where appropriate, CMS may instead address network adequacy by customizing base time and distance standards in states with CON laws. We explained that the proposal was justified based on the studies cited that have shown that CON laws adversely affect competition and free market entry in states and that our network adequacy policy thus should provide for us to consider this factor when evaluating the adequacy of an MA organization's contracted network.

We proposed to make this credit equal to and in addition to, if applicable, the proposed telehealth credit (10 percentage points) for reasons similar to those for the telehealth credit policy: Information from prior network adequacy reviews show that many failures in meeting time and distance standards occur in the 80 to 89 percent range. We explained that, under our proposal, CMS could elect to grant this credit instead of customizing time and distance standards depending on a number of factors, like the speed of implementing customized standards, operational and timing constraints, and the amount of work required to calculate customized time and distance standards. We solicited comment on additional criteria or factors we should consider when deciding whether to apply the 10-percentage point credit or customize time and distance standards in the impacted states or counties. Additionally, we solicited comment about what other actions CMS could take in markets with state CON laws.

We also considered whether there are circumstances where a more limited application of network adequacy flexibility might be more appropriate. We solicited comment as to how and under what circumstances we should refrain from applying the 10 percentage point credit, should mitigate the size of this credit, or other actions we might undertake to apply this flexibility in a more limited manner.

5. Minimum Number Standards

We proposed to codify the current policy that MA plans must contract with a specified minimum number of each provider and facility specialty type in § 422.116(e). The MA plan must have a minimum number of in-person providers and facilities in each county for each specialty type specified in paragraph (b). We explained the general rules at § 422.116(e)(1) that the provider or facility must be within the maximum time and distance of at least one beneficiary in order to count towards the minimum number requirement and cannot be a telehealth-only provider. We also proposed to codify the

[42] Comparative Effectiveness of Home-Based Kidney Dialysis Versus In-Center or Other Outpatient Kidney Dialysis Locations—A Systematic Review [internet]: *https://www.ncbi.nlm.nih.gov/books/NBK344417/.*

[43] Daniel Sherman, ''The Effect of State Certificate-of-Need Laws on Hospital Costs: An Economic Policy Analysis,'' *Federal Trade Commission,* January 1988.

[44] Vivian Ho, Meei-Hsiang Ku-Goto, ''State Deregulation and Medicare Costs for Acute Cardiac Care,'' *Med Care Res Rev.,* April 2013.

[45] Matthew D. Mitchell, ''Do Certificate-of-Need Laws Limit Spending?'' *Mercatus Working Paper,* Mercatus Center at George Mason University, Arlington, VA, September 2016.

[46] David M. Cutler, Robert S. Huckman, and Jonathan T. Kolstad, ''Input Constraints and the Efficiency of Entry: Lessons from Cardiac Surgery,'' *American Economic Journal: Economic Policy,* February 2010.

methodology for establishing the minimum number requirements for specific contracted provider and facility specialty types per county. We explained that CMS would use this methodology each year to determine and publish the updated minimum provider standards on an annual basis and that certain standards for the minimum number of providers are updated annually to account for changes in the Medicare population, MA market penetration, and county designations. Our proposal required the provider/facility to be within the maximum time and distance of at least one beneficiary in order to count towards the minimum number requirements. We noted that the location of a contracted provider specialty or facility is not required to be within the county or state boundaries to be considered within the time and distance standards.

We proposed to codify at § 422.116(e)(2)(iii), our existing practice that all facilities, except for acute inpatient hospitals facilities, have a minimum number requirement of one. We limited the methodology for establishing and changing the required minimum number standard to acute inpatient hospitals and other non-facility provider specialties. We proposed the methodology at § 422.116(e)(3): CMS determines the minimum number requirement for all provider specialty types and Acute Inpatient Hospitals by multiplying the ''minimum ratio'' by the ''number of beneficiaries required to cover,'' dividing the resulting product by 1,000, and rounding up to the next whole number. The steps and components of the methodology were proposed in paragraphs (e)(3)(i) and (ii) and explained in the preamble of the proposed rule.

The Minimum Ratio is the number of providers required per 1,000 beneficiaries, and for Acute Inpatient Hospitals, the number of beds per 1,000 beneficiaries. We stated that CMS had established minimum ratios in 2011 using a number of data sources, including, Medicare fee-for-service claims data, American Medical Association (AMA) and American Osteopathic Association (AOA) physician workforce data, U.S. Census population data, National Ambulatory Medical Care Survey data, AMA data on physician productivity, and published literature. We proposed to codify those minimum ratios in the regulation at § 422.116(e)(3)(i) and reproduced it in the preamble as Table 13. (85 FR 9101)

We stated that the Number of Beneficiaries Required to Cover is also calculated by CMS based on an established methodology. The Number of Beneficiaries Required to Cover is the minimum population that an MA plan's network should be able to serve and represents the potential number of beneficiaries an organization may serve within a county. We proposed at § 422.116(e)(3)(ii)(A) that the Number of Beneficiaries Required to Cover is calculated by multiplying the ''95th Percentile Base Population Ratio'' times the total number of Medicare beneficiaries residing in a county. We explained that CMS uses its MA State/County Penetration data to calculate the total number of Medicare beneficiaries residing in a county. For counties with lower populations, and particularly for specialties with lower minimum ratios, the minimum number is usually one.

We proposed to continue the current policy of calculating the 95th Percentile Base Population Ratio annually for each county type. We explained in the proposed rule that CMS has previously allowed MA organizations to provide their expected enrollment and then define their networks based on that number, but had later developed and implemented a more objective means to measure network adequacy for all MA plans consistently. Based on our position that the 95th Percentile Base Population Ratio is a fair and consistent enrollment estimate that can be applied to new and current plans, we proposed to codify its continued use. While it varies over time as MA market penetration and plan enrollment changes across markets, the 95th Percentile Base Population Ratio currently ranges between 0.073 and 0.145 depending on county type, indicating that MA plans are expected to have networks at least sufficient to cover between 7.3 percent (Large Metro) and 14.5 percent (CEAC) of the Medicare beneficiaries in the county. This ratio represents the proportion of Medicare beneficiaries enrolled in the 95th percentile MA plan (that is, 95 percent of plans have enrollment lower than this level). We explained in the proposed rule how to calculate the 95th Percentile Base Population Ratio. We use the List of PFFS Network Counties [47] to exclude PFFS plans in non-networked counties [48] from the calculation at the county type level. We use the MA State/County Penetration data [49] to determine the number of eligible Medicare beneficiaries in each county, and our Monthly MA Enrollment data [50] to determine enrollment at the contract ID and county level, including only enrollment in RPPO, LPPO, HMO, HMO/POS, healthcare prepayment plans under section 1833 of the Act, and network PFFS plan types. We calculate penetration at the contract ID and county level by dividing the number of enrollees for a given contract ID and county by the number of eligible beneficiaries in that county. Finally, we group counties by county designation to determine the 95th percentile of penetration among MA plans for each county type. We proposed to codify the methodology for calculating the 95th Percentile Base Population Ratio at § 422.116(e)(3)(ii)(B).

6. Exceptions

Finally, we also proposed to codify in paragraph (f) a process by which an MA plan may request and receive an exception from the network adequacy standards in § 422.116. Under our current policy, CMS conducts network adequacy reviews through an automated process, but also allows for exceptions to that process when failures are detected in the submitted network. We proposed to codify the exceptions process, the basis upon which an MA plan may request an exception, and the factors that CMS may consider when evaluating an MA organization's request for an exception to the standards in § 422.116. We proposed that an MA organization may request an exception when two criteria are met: (1) Certain providers or facilities are not available for the MA organization to meet the network adequacy criteria as shown in the Provider Supply file for the year for a given county and specialty type, and (2) the MA organization has contracted with other providers and facilities that may be located beyond the limits in the time and distance criteria, but are currently available and accessible to most enrollees, consistent with the local pattern of care. For example, certain providers/facilities may not be available for contracting when the provider has moved or retired, or when the provider/facility does not contract with any

[47] CMS. PFFS Plan Network Requirements. Retrieved from: *https://www.cms.gov/Medicare/Health-Plans/PrivateFeeforServicePlans/NetworkRequirements.html.*

[48] Non-networked counties in this context means there are not at least two networked plans operating in that county.

[49] CMS. MA State/County Penetration. Retrieved from: *http://www.cms.gov/Research-Statistics-Data-and-Systems/Statistics-Trends-and-Reports/MCRAdvPartDEnrolData/MA-State-County-Penetration.html.*

[50] CMS. Monthly MA Enrollment by State/County/Contract. Retrieved from: *https://www.cms.gov/Research-Statistics-Data-and-Systems/Statistics-Trends-and-Reports/MCRAdvPartDEnrolData/Monthly-MA-Enrollment-by-State-County-Contract.html.*

organizations or exclusively with another organization. We proposed that we would implement and interpret the regulation such that the MA plan would have to contract with telehealth providers, mobile providers, or providers outside the time and distance standards, but accessible to most enrollees (or consistent with the local pattern of care), in order for the MA plan to request an exception by CMS. In evaluating exception requests, CMS proposed that it would consider: (i) Whether the current access to providers and facilities is different from the HSD reference and Provider Supply files for the year; (ii) whether there are other factors present, in accordance with § 422.112(a)(10)(v), that demonstrate that network access is consistent with or better than the original Medicare pattern of care; and (iii) whether approval of the exception is in the best interests of beneficiaries. These three criteria were proposed to be codified at paragraph (f)(2)(i), (ii) and (iii).

Currently, CMS collects information for purposes of testing an MA organization's network adequacy using the PRA-approved collection titled, ''Triennial Network Adequacy Review for Medicare Advantage Organizations and 1876 Cost Plans, CMS–10636, OMB 0938–1346.'' [51] CMS relies on this collection of information to evaluate whether an MA organization maintains a network of appropriate providers and facilities that is sufficient to provide adequate access to covered services based on the needs of the population served. In the PRA package, CMS explained that organizations must comply with the current CMS network adequacy criteria posted in the HSD reference file on CMS's website and updated annually. We proposed to codify the standards in order to formalize the use of criteria posted in the HSD reference file by codifying and explaining the standards and, where necessary, the formulas used to calculate network adequacy standards (that is, provider/facility types, maximum time and distance standards, minimum provider/facility numbers). We proposed that CMS would continue to use the HSD reference file as a means to communicate these standards to MA organizations and that we anticipated that there would be no updates or changes required to the approved collection of information for CMS to assess network adequacy. We stated in the proposed rule how the codified provisions would not impose any new or revised information collection requirements (that is, reporting, recordkeeping, or third-party disclosure requirements) or burden. We confirm here that these provisions are not subject to the PRA.

We thank commenters for their input to help inform our final rule on network adequacy policies. We received the following comments on this proposal, and our response follows:

Comment: A number of commenters gave feedback regarding the provider and facility specialty type lists in § 422.116(b). Some commenters suggested that CMS add provider specialty types for physical therapist, occupational therapist, transplant providers, psychologists, clinical social workers, nurse specialists, emergency physicians, and optometry. A few commenters suggested that CMS add transplant centers and inpatient rehabilitation hospitals and units to the list of facility specialty types.

Response: We appreciate the many viewpoints and recommendations on this subject. The regulation at § 422.112(a) require that MA organizations must ensure that all covered services are available and accessible under the plan. Further, MA organizations must maintain a network of providers to provide adequate access to covered services and must make arrangements for care outside the plan provider network, at in-network cost-sharing, when network providers are unavailable. As a result of this critical protection, we do not require that all provider and facility specialties be subject to network adequacy standards. In past network adequacy reviews, we have not evaluated every possible provider type that may provide a Medicare covered benefit in our network reviews. We also have not evaluated provider subspecialties, especially those that are extremely specialized in nature. We ensure access to all Medicare covered services through monitoring and investigating complaints in the CMS Complaint Tracking Module. We identify which provider and facility specialty types are critical and necessary to evaluate separately based on a review of Medicare FFS utilization patterns, utilization of provider/facility specialty types in Medicare FFS, specialties in other managed care programs, and the clinical needs of Medicare beneficiaries. For example, we consider the utilization rate of specific provider types in order to determine if it justifies the effort of developing specific standards, collecting data from plans, and analyzing the information. Therefore, we proposed to codify network adequacy standards for the 27 provider specialty types and 14 facility specialty types that are currently used in the evaluation of network adequacy in each service area and have well-established base time and distance standard associated with them. We emphasize that MA enrollees are entitled to access to all medically necessary services from Medicare participating providers and facilities whether or not the provider or facility type is subject to specific network adequacy standards under § 422.116.

Comment: In response to our identification of other options we were considering regarding outpatient dialysis centers, many commenters supported removing outpatient dialysis from the list of facility specialty types, and instead, requiring an attestation in its contract application. These commenters explained that this change would drive patient-centered innovation in dialysis treatment, encourage competition, and bring down high reimbursement costs for dialysis treatment. They also pointed out that this change would be consistent with how CMS monitors and ensures beneficiary access to durable medical equipment, home health care, and transplant services. Commenters suggested that the use of an attestation would ensure patient protection while also giving plans the flexibility they need to expand the delivery of innovative solutions to beneficiaries with End Stage Renal Disease (ESRD) requiring dialysis treatment. A few commenters that supported the removal of outpatient dialysis also suggested that providing exceptions for plans covering home dialysis for all beneficiaries who need such services or customizing time and distance standards for dialysis facilities would also improve the proposal.

On the other hand, many commenters recommended that CMS finalize its proposal and maintain maximum time and distance standards for outpatient dialysis centers without change. These commenters raised concerns that the removal of outpatient dialysis as a facility type would result in the discrimination of ESRD patients by MA plans because the network design would discourage patients with ESRD from enrolling. A few commenters believed that the removal of outpatient dialysis centers from the list of facility and specialty types for which we would use specific standards would conflict with the intent of the 21st Century Cures Act, which allows ESRD patients to enroll in MA plans in 2021. Some commenters raised access to care concerns and pointed out barriers to home dialysis,

[51] *https://www.cms.gov/Regulations-and-Guidance/Legislation/PaperworkReductionActof1995/PRA-Listing-Items/CMS-10636.*

such as housing insecurity and a lack of caregiver support, and others explained the need to have both home dialysis and in-center dialysis options of care and to leave the treatment choice in the hands of the patient. Lastly, a couple commenters did not believe that CMS provided adequate notice in the proposed rule to make any changes to outpatient dialysis in the final rule.

Response: In our proposal, we explained that we believed that there is more than one way to access medically necessary dialysis care and we sought to improve our network adequacy standards as they relate to measuring and setting minimum standards for access to dialysis services. We do not agree with commenters that the removal of outpatient dialysis facilities will result in network designs that discriminate against or discourage ESRD beneficiaries from enrolling in MA plans. Regardless of whether a facility or provider specialty type is subject to network adequacy standards, MA organizations are required in § 422.112(a)(3) to arrange for health care services outside of the plan provider network when network providers are unavailable or inadequate to meet an enrollee's medical needs. Section 422.112(a)(10) requires MA plans to ensure access and availability to covered services consistent with the prevailing community pattern of health care delivery in the areas served by the network. The factors making up community patterns of health care delivery that CMS considers when evaluating an MA plan network—and which continue to apply regardless whether a specific time and distance or minimum number requirement is established pursuant to § 422.116 for a provider specialty or facility type—are at § 422.112(a)(10). For example, for any provider or facility types that are not included in network adequacy standards at § 422.116, CMS may consider the number and geographical distribution of eligible health care providers available to potentially contract with an MA organization to furnish plan covered services within the service area when deciding if MA plans meet access and availability requirements. Additionally, we may consider the prevailing market conditions in the service area of the MA plan and, more specifically, the number and distribution of health care providers contracting with other health care plans (both commercial and Medicare) operating in the service area of the plan. Therefore, if network providers are incapable of meeting the enrollee's medical needs because the burden of travel to the in-network dialysis center is inconsistent with the prevailing community pattern of health care delivery in the area, the MA plan must arrange for care outside of the network and at in-network cost-sharing in order to meet the MA plan's obligation under the MA program rules to furnish covered services. The network adequacy maximum time and distance standards proposed at § 422.116 are one way that we quantify prevailing patterns of health care delivery in areas, but it is not the only way to evaluate a network, as § 422.112(a)(10) provides. Most importantly, it does not mean that MA organizations do not need to maintain an adequate contracted network of contracted providers simply because a provider or facility type is not included in the network adequacy standards at § 422.116. MA organizations must maintain a network of contracted providers that is sufficient to provide adequate access to covered services to meet the needs of the population served and is consistent with the prevailing community pattern of health care delivery in the areas where the network is being offered. This critical beneficiary protection ensures that MA enrollees have similar reasonable access to providers and facilities as beneficiaries in FFS Medicare. Therefore, we believe that MA plans will continue to provide adequate access to dialysis providers. We disagree with commenters that believe that the removal of outpatient dialysis from the list being finalized in § 422.116 of facility types that are separately evaluated on time and distance and minimum number standards would necessarily lead to discrimination against ESRD patients or would conflict with the intent of the 21st Century Cures Act. The 21st Century Cures Act removed the prohibition against beneficiaries with ESRD from enrolling in an MA plan effective for plan years beginning on or after January 1, 2021. MA organizations must abide by all existing legal and regulatory anti-discrimination requirements, which include prohibitions on discrimination on the basis of health status, for any beneficiaries with ESRD enrolling in an MA plan.

For CMS performance data collected for Part C Star Ratings, CMS surveys beneficiaries on the ease of getting needed care and seeing specialists, as well as getting appointments and care quickly, through the Consumer Assessment of Healthcare Providers and Systems (CAHPS) survey questions. MA organizations are incentivized by CMS Star Ratings policies to maintain high-star ratings by scoring well on these types of survey measures. Further, if beneficiaries believe that an MA organization is discriminating against them, complaints may be submitted into the Complaint Tracking Module (CTM). We monitor and investigate complaints related to access concerns and work with regional office caseworkers to resolve any issues with the MA organizations. We would take compliance or enforcement actions against an MA organization for failing to provide adequate access to medically necessary services, as warranted.

Also, we do not believe that the removal of outpatient dialysis as a facility type would cause access to care concerns. As we pointed out, MA organizations must maintain a contracted network that is sufficient to provide adequate access to covered services, and this includes the ability for enrollees to receive care in-person at an outpatient dialysis facility. We agree with commenters that this change will drive patient-centered treatment in dialysis services, which is at the heart of our intent in considering this change in policy. While we proposed to codify maximum time and distance standards for the facility type outpatient dialysis, we also solicited comments about four options to improve measuring and setting standards for access to dialysis services because we wanted MA plans to use more than one treatment modality to address access to dialysis services: (1) Removing outpatient dialysis from the list of facility types with specific evaluation standards; (2) allowing plans to attest to providing medically necessary dialysis services in its contract application (as is current practice for DME, home health, and transplant services); (3) allowing exceptions to time and distance standards if a plan is instead covering home dialysis for all enrollees who need these services; and (4) customizing time and distance standards for all dialysis facilities. We believe that by eliminating the outpatient dialysis facility type from the list in § 422.116(b)(2), MA organizations have the freedom to enhance their networks by contracting with dialysis providers that offer dialysis treatment through home-based modalities. These home based modalities give enrollees flexibility and control over their lives so that enrollees can choose the treatments that best meet their needs. We agree with commenters and understand that beneficiaries undergoing dialysis treatment often face changes in circumstances that may warrant movement from one modality to another. We believe this further

supports our intent to encourage MA organizations to establish networks that provide the most advanced and available treatment options to Medicare beneficiaries.

We also agree with commenters that the removal of outpatient dialysis from the list of facilities for which there are specific time and distance and minimum provider standards could encourage greater competition in dialysis treatment and treatment modalities, which will eventually lead to lower costs for Medicare beneficiaries without resulting in the denial of, or access to, lesser care. The removal of outpatient dialysis as a facility type from our network adequacy standards allows all dialysis treatments to be treated equally, which will encourage MA organizations to contract with facilities that offer different forms of dialysis treatments, rather than just dialysis at an outpatient facility. We believe this increased competition among treatment modalities could drive down plan and patient costs for dialysis services. We do not believe that creating exceptions related to home dialysis or customizing time and distance standards will bring about the same level of change that CMS is seeking. CMS will continue to oversee the provision of dialysis services through its monitoring efforts to ensure that MA beneficiaries have access to medically necessary care that meets their needs. We routinely monitor access to care complaints and impose compliance or enforcement actions, when necessary, to hold MA organizations accountable for the provision of all medically necessary covered services.

Lastly, a few commenters did not believe that CMS provided adequate notice and sufficient detail in the proposed rule for the alternative that we are finalizing here. We disagree and believe that our proposal and continued consideration of other options for outpatient dialysis were clear in the proposed rule. We received numerous comments discussing the four options we identified in the proposed rule (85 FR 9099), as well as the proposal to include outpatient dialysis as a facility type with maximum time and distance standards. The comments, as we have previously discussed, weighed these options and clearly discussed the benefits and drawbacks on the merits of the issues presented, indicating to us that our consideration of other options for outpatient dialysis was understood by commenters. We thank commenters for all of their input in helping to inform us as we considered a final policy concerning outpatient dialysis.

In this final rule, we are removing outpatient dialysis as a facility specialty type at § 422.116(b)(2) that is subject to network adequacy standards. Under our authority in § 422.116(a)(1), we intend to require that MA organizations submit an attestation that it has as an adequate network that provides the required access and availability to dialysis services, including outpatient facilities. We are finalizing the 27 provider specialty types and the other 13 facility types (that is, the types other than outpatient dialysis facilities) in § 422.116(b) as proposed.

Comment: A few comments questioned our proposal at § 422.116(b)(3) specifying that CMS may remove a provider or facility type from the network adequacy evaluation for a particular year by not including the type in the annual publication of the HSD reference file. A few commenters recommended that both additions and removals of provider and facility types be subject to notice and comment rulemaking.

Response: The HSD reference file is built annually by applying the rules in § 422.116. We reiterate the importance of the beneficiary protection at § 422.112(a), that even if a provider or facility specialty type is not subject to network adequacy standards, that access to providers at in-network cost-sharing must be provided by the MA organization. We proposed the ability to remove specialty types in the HSD reference file to account for circumstances where it may not be necessary to evaluate the number and accessibility of each of the 27 specialty and 13 facility types in a particular year. Additionally, as we described in our proposal, § 422.116(a) will permit us to require an MA plan to complete an attestation that it has an adequate network that provides the required access to and availability of provider or facility specialty types even where we do not evaluate access ourselves. Since network adequacy criteria are measured for each individual specialty type and do not roll up into an aggregate score, the removal of a specialty type from the network review will not affect the outcome of an MA plan's network review and, as discussed throughout this section of this final rule, we believe that there are adequate protections available to ensure that enrollee access to services is not compromised. We are finalizing § 422.116(b)(3) to allow CMS to remove a provider or facility type from the network adequacy evaluation for a particular year by not including the type in the annual publication of the HSD reference file.

Comment: Most commenters supported the proposed base time and distance standards. There were a few commenters that suggested that CMS consider alternative approaches to codifying a uniformly applied time and distance standard. A commenter suggested that CMS allow for the use of a combination of qualitative and quantitative standards. Others commenters suggested measures of provider availability (for example, percentage accepting new patients, timeliness of appointment availability), performance on access-related quality and patient experience measures, and degree of physical co-location of services.

Response: We appreciate the recommendations and, because we are always looking for new ways of improving the network adequacy reviews, will take them into consideration for potential future policy development. Our network adequacy methodology, as proposed and as finalized here, aims to objectively evaluate the networks of various types of coordinated care plans across a national landscape that includes urban, suburban, and rural regions. We believe that using quantitative methods that account for some degree of variance across these different regions provides a fair and reasonable evaluation that we can efficiently test against hundreds of MA plans annually. Therefore, we are finalizing base time and distance standards that vary by county type designation and take into account the nature of the provider or facility supply in the health care marketplace. Further, the customization process, which we are finalizing as proposed at paragraph § 422.116(d)(3), allows us to adjust the base time and distance standards, when needed, to take into account the unique characteristics of specific regions, such as geographic landscape, which may alter the pattern of care in a county. We also proposed an exceptions process at § 422.116(f), which allows us to also consider qualitative characteristics that may serve as the rationale for a valid exception when an MA network fails to meet time and distance standards. We have continued to hone and improve our network adequacy methodology since 2011 and believe our objective and transparent approach allows for the proper balance of quantitative and qualitative measures that allows CMS to quickly and efficiently measure the adequacy of hundreds of MA networks in a given year. We also note that some of the performance measures (for example, patient experience and access-related quality measures) suggested are

already included in CMS's MA plan Star Ratings system, which is used to measure how well plans perform in several categories, including quality of care and customer service. We do not believe it is necessary to duplicate those as part of network evaluations.

Therefore, we are finalizing the general rules for network adequacy proposed at § 422.116(a), with the exception of § 422.116(a)(3)(ii), which will not be finalized to align with how we are not finalizing specific standards for Outpatient Dialysis facilities. Also, we are finalizing the county type designations at § 422.116(c) and the maximum time and distance standards at § 422.116(d) as proposed, with the exception of the maximum time and distance standards for the Outpatient Dialysis facility type for reasons previously discussed.

Comment: A number of commenters supported the proposed base time and distance standards at § 422.116(d). A few commenters recommended changes to the proposed base time and distance standards in specific county type designations or due to the plan type. Some commenters recommended that Institutional Special Needs Plans (I–SNPs) should have reduced network adequacy standards for specific provider or facility types like podiatry, primary care, diagnostic radiology, physical therapy, occupational therapy, and speech therapy, or should be excepted altogether from the measures. Others recommended that we reduce time and distance standards for occupational therapy and dermatology in all county types, and for primary care and psychiatry in non-metro county types.

Response: We conduct network adequacy reviews at the contract level, meaning we evaluate the adequacy of the MA organization's network across all of their plan types (for example, HMOs, PPOs, SNPs); we do not singularly evaluate the network of a specific plan benefit package. We believe that conducting network reviews at the contract level allows us to consider the broadest availability of contracted providers and facilities for an MA organization while also providing administrative efficiency for CMS to evaluate fewer HSD network submissions. Therefore, our network methodology does not change base time and distance standards based on the plan type being reviewed, such as an I–SNP. We also do not believe that it would be necessary to change our network adequacy standards based on the plan types that we review. For example, while I–SNPs may be unique in that beneficiaries may receive a number of health care services from a single institution, there are also I–SNP institutionalized-equivalent beneficiaries that reside at home. Further, these beneficiaries may still need to travel to another facility to receive specialized care or the specialty providers will need to travel to deliver the care. As a result, we believe that even for plans like I–SNPs, it is important that MA organizations maintain a contracted network that can deliver medically necessary care and is compliant with our network adequacy standards.

We have honed and improved its base time and distance standards for each specific provider and facility type in each county designation over a period of nine years. For example, we updated maximum time and distance standards when the new county designation methodology was implemented (that is, moving from classifying counties based on metropolitan statistical areas to the current county designations) and have adjusted some standards based on a significant change in supply. We proposed base time and distance standards that we believe represent a fair expectation for health care patterns of delivery in the five county types based on many years of data and network evaluation. Additionally, the customization process, as proposed and finalized, allows us to adjust standards at the county and provider/facility type level where needed to take into account factors like utilization or supply patterns that indicate the base time and distance standards are not reflective of prevailing patterns of community health care delivery. Therefore, we are not making any changes to our base time and distance standards in the final rule and are finalizing these standards as proposed.

Comment: A number of commenters supported the minimum provider number requirements at § 422.116(e). Commenters supported CMS's policy that there be at least one contracted provider or facility specialty type within required time and distance standards that is accessible to Medicare beneficiaries. A commenter recommended that CMS use the same minimum provider ratio in the calculation of the minimum provider number requirement in all county types.

Response: We thank commenters for their support of this policy. As we described in our proposed rule, CMS established minimum ratios in 2011 using a number of data sources, including, Medicare fee-for-service claims data, American Medical Association (AMA) and American Osteopathic Association (AOA) physician workforce data, U.S. Census population data, National Ambulatory Medical Care Survey data, AMA data on physician productivity, and published literature. We proposed Minimum Ratios for each provider and county type at § 422.116(e)(3)(i). The Minimum Ratio is the number of providers required per 1,000 beneficiaries. As the overall population and population density widely varies between large metro and rural county types, so does the rate of health care utilization in these areas. Health care utilization patterns are higher in metro areas, and therefore, our proposed Minimum Ratios are slightly higher in metro county types. In accordance with our current rules at § 422.112(a)(10), we considered the prevailing patterns of community health care delivery, such as whether the service area is comprised of rural or urban areas, when developing the Minimum Ratios. We are finalizing the minimum number requirements as proposed in § 422.116(e).

Comment: Many commenters supported our proposed customization process at § 422.116(d)(3). In particular, commenters supported that CMS may only use customization to increase time and distance standards from the base standards. A commenter suggested that CMS allow health plans to provide feedback on county time and distance standard changes to ensure appropriate customization is consistent year after year. Other commenters suggested that geographic barriers like rivers, mountains, and oceans should trigger customization, in addition to supply shortages.

Response: We appreciate commenters' support of our customization process. We agree with commenters that geographic barriers that play a significant role in utilization patterns are triggering events that may result in the customization of time and distance standards by CMS. We clarify here, and in additional regulation text being finalized at § 422.116(d)(3), that when necessary due to utilization or supply patterns, CMS may set maximum time and distance standards for specific provider or facility types for specific counties by customization. We stated in the proposed rule that customization of base criteria may be triggered based on provider or facility supply shortages, information received through exception requests from plans, or from other sources, such as restrictions or limitations caused by state certificate of need (CON) laws. When information from these sources shows that utilization or supply patterns indicate the base time and distance standards are not reflective of prevailing patterns of community health care delivery, CMS

may customize the maximum time and distance standards. In the past, CMS has only customized maximum time and distance standards by increasing them above the base time and distance standard and will continue this policy by finalizing § 422.116(d)(iv). We solicited comment in the proposed rule about other sources of information that we should consider as part of the customization analysis, but we do not believe that it is necessary or appropriate to limit the source or type of information that could be used to trigger the customization analysis. By codifying a standard to guide when we will use customization without limiting the information that would indicate that utilization or supply standards make it necessary to use customized, instead of the base, time and distance standards, we are ensuring that the network adequacy evaluations appropriately reflect access and availability of health care for each area.

Customization of base time and distance standards occurs narrowly and is very specific to the provider or facility specialty type and county where the triggering event occurs. Further, MA organizations will not be subject to reductions in the time and distance standard below the base standards at § 422.116(d)(2); CMS will only be increasing from the base standards through customization to take into account the information and utilization and supply standards that trigger the need for customization and make it easier for MA organizations to comply with network adequacy standards. As such and because the regulation describes the standards governing the customization process, we do not believe an opportunity for prior review and comment on customized time and distance standards before implementation is the best course of action. As we mentioned, we consider information from exception requests to help inform our customization of time and distance standards. Should an MA organization continue to fail to meet customized time and distance standards, the organization may submit an exception request and provide further information about why its network cannot meet the standard. CMS will take that information under consideration for the current network review and may make additional adjustments to the customized time and distance standards in the following year. We believe this is the most efficient means of receiving MA organization input on customized standards as circumstances in counties change year over year. Therefore, we are finalizing the customization process at § 422.116(d)(3), with an addition to clarify that CMS may set maximum time and distance standards for provider or facility types for specific counties when necessary due to utilization or supply patterns.

Comment: We received numerous comments expressing support for the reduction in the percentage of beneficiaries residing within maximum time and distance standards in Micro, Rural, and CEAC counties from 90 percent to 85 percent. Some commenters described this as a reasonable adjustment in light of the limited availability of some providers in rural areas. They explained that this proposal could increase access to MA plans for beneficiaries residing in rural areas by bringing competition and better health care choices to beneficiaries. Other commenters that were supportive of the proposal also requested that CMS make this reduction applicable to all five county type designations, rather than limiting it to Micro, Rural, and CEAC counties. A few commenters suggested that we further reduce the percentage down to 80 percent.

We also received some comments that expressed opposition to this reduction. Some commenters expressed concern that reducing the threshold requirement may result in the unintended consequence of leaving some rural communities without appropriate access to essential services because it would reduce the incentives for MA plans to contract with specialists.

Response: We thank commenters for their viewpoints on our proposal to reduce the percentage of beneficiaries residing within maximum time and distance to 85 percent at § 422.116(d)(4)(i). We agree that a reduction is necessary in rural counties (Micro, Rural, and CEAC) due to the limited availability of providers and the lower population density in those areas. CMS considers the number and geographical distribution of eligible providers available to potentially contract with an MA organization when evaluating a network based on community patterns of care under § 422.112. The beneficiary population is typically less dense per square mile than in metro counties so we believe having a reduced threshold will make the standards more consistent with the community patterns of care in rural areas. As a result, we agree with commenters that this adjustment may increase access to MA plans for beneficiaries residing in rural areas. We do not believe that this reduction will result in leaving some rural communities without appropriate access to essential services. Our minimum number requirements proposed at § 422.116(e) require that an MA plan contract with at least one provider within maximum time and distance standards of a beneficiary in the area. Further, CMS rules at § 422.112(a) require that MA organizations must ensure that all covered services are available and accessible under the plan, regardless of how many providers or facilities are contracted with the MA organization. MA organizations must make arrangements for care outside the plan provider network, at in-network cost-sharing, when network providers are unavailable or the network is insufficient. Therefore, beneficiaries in these rural communities will continue to have access to specialty providers and facilities because MA organizations are still required to contract with at least one or must pay for health care services rendered at non-contracted Medicare participating providers at the Medicare FFS rate.

We proposed a modest reduction of 5 percent and limited this reduction to only Micro, Rural, and CEAC counties. We believe this to be an appropriate adjustment based on our data that shows that existing failures in MA plans' meeting the time and distance standards frequently occur at the range between 80 to 89 percent of beneficiaries. We understand that some commenters would like CMS to see an increased reduction or expand this reduction to all county types, however, we believe that the approach we are finalizing will allow us to observe the impacts of this policy change on MA plans and health care providers; we may consider further adjustments to the percentage as needed. Additionally, as this policy change was also intended to drive more MA plan access in rural areas, we do not believe it is necessary or appropriate at this time to apply this reduction to the access standard for metro counties. We are finalizing the reduction in the percentage of beneficiaries residing within maximum time and distance to 85 percent for Micro, Rural, and CEAC counties at § 422.116(d)(4)(i).

Comment: We received numerous comments about the 10-percentage point telehealth credit towards the percentage of beneficiaries residing within published time and distance standards for applicable provider specialty types proposed at § 422.116(d)(5). Most commenters were very supportive and appreciated CMS' support of telehealth goals and thought that CMS's proposal would incentivize MA organizations to contract with providers that have adopted telehealth technology. A few

commenters were opposed to this ''telehealth credit'' and felt that telehealth should be implemented into network adequacy in a way that does not diminish access to in-person care. These commenters believed that allowing a telehealth credit would make it too easy for MA organizations to comply with a standard that is set for in-person access to a provider. Also, opposing commenters believed that this policy may unintentionally encourage plans to use telehealth services as substitutes for existing in-person services, even in areas where provider availability and beneficiary access are strong.

Response: We appreciate commenters support for this proposal as well as the concerns that were raised by the commenters that opposed it. We believe the telehealth credit that we proposed upholds maximum time and distance standards for the applicable provider specialty types and provides a modest incentive for MA organizations to supplement their networks with providers that can furnish additional telehealth benefits. Our proposal does not decrease the maximum time and distance standards that must be maintained for compliance with our network adequacy measures for the applicable provider types; it allows for a reduced portion of the beneficiary population to be within those maximum time and distance standards. For example, in Metro counties, MA organizations would still need to ensure that they contract with in-person providers that are within maximum time and distance standards of at least 80 percent of the beneficiary population even after the credit is applied. We believe it is important and appropriate to account for contracted telehealth providers in evaluating network adequacy consistent with reflecting how MA plans supplement, but do not replace, in-person networks with telehealth providers. The rules at § 422.135(c) for providing additional telehealth benefits require that the MA organizations furnish in-person access to the specified Part B service at the election of the enrollee. This protection preserves the beneficiary's right to choose when they would prefer to have medically necessary care provided in-person rather than through electronic exchange (that is, through electronic information and telecommunications technology). Further, our telehealth credit proposal does not count telehealth-only providers as equal to providers that deliver in-person care. We limited the impact that supplementing a network with telehealth providers could have on the network adequacy standards by offering a 10-percentage point credit, while maintaining the maximum time and distance standards required for the applicable provider types. We believe this approach appropriately incentivizes MA organizations to contract with providers that offer additional telehealth benefits and maintains standards that ensure that in-person providers are within a reasonable time and distance for most beneficiaries.

Comment: Some commenters suggested that CMS modify the telehealth credit by increasing the credit to as high as a 20-percentage point credit.

Response: Our proposal attempted to strike the proper balance between incentivizing MA organizations to contract with providers that offer additional telehealth benefits while also maintaining adequate access to in-person care for the same provider specialties. Therefore, we proposed a 10-percentage point credit towards the percentage of beneficiaries residing within maximum time and distance standards. We believe a 10-percentage point credit is an appropriate amount that proportionately supplements a plan's percentage threshold because telehealth providers add value to a contracted provider network, but should not have the same level of significance or value as an in-person provider. Additionally, information from prior network adequacy reviews show that many failures in meeting time and distance standards occur in this 80 to 89 percent range. We believe an increase to a 20-percentage point credit would be too significant at this time. We plan to observe the frequency and impact of this telehealth credit in network adequacy reviews and will consider adjusting this percentage in the future as needed.

Comment: A few commenters recommended that CMS add to the applicable provider list of dermatology, psychiatry, cardiology, neurology, and otolaryngology proposed at § 422.116(d)(5) by also including the provider types of ophthalmology, allergy and immunology, nephrology, primary care, gynecology, endocrinology, infectious diseases, or making all provider types applicable for the telehealth credit. Commenters encouraged CMS to expand the list of specialty providers to account for advances in medical technology and promote beneficiary choice in how to receive medical services.

Response: We appreciate commenters' suggestions on expanding the list of applicable provider types for this telehealth credit. As we explained in the previous comment response, we believe the telehealth credit amount is properly balanced to maintain adequate access to in-person care while also incentivizing MA organizations to contract with telehealth providers. We note that in the proposed rule, we did not believe it was necessary to take telehealth into account for primary care providers. 85 FR 9099. However, the use of and access to primary care doctors via telehealth, as well as other provider specialties highlighted by commenters (whose comments referred to circumstances outside the Public Health Emergency), has been critically important in delivering medical care to Medicare beneficiaries during the during the COVID–19 pandemic Public Health Emergency. Based on our experience during this emergency, we observed how important it is to have policies that encourage the widespread availability of telehealth services at all times. Additionally, President Trump's Executive Order 13890 on Protecting and Improving Medicare for Our Nation's Seniors (October 3, 2019) called for enhanced access to health outcomes made possible through telehealth services or other innovative technologies as a way to secure and improve Medicare. In light of the COVID–19 pandemic and this Executive Order, we now believe that we should expand the list of specialty provider types finalized at § 422.116(d)(5) and there is no reason to restrict this credit to only provider types that are the most apt to provide telehealth services or for which we have seen potential for failing to meet the specific time and distance standards. New medical technologies and treatments are rapidly evolving across various providers and we would like to broaden the scope of eligible providers to account for these developments by implementing recommendations from commenters on the provider types in § 422.116(b)(1) that should be eligible for the telehealth credit. However, we also do not believe that it is appropriate to make this credit available to all provider types at this time. Therefore, based on the comments received, we are adding the following provider types to the list finalized at § 422.116(d)(5): Ophthalmology, Allergy and Immunology, Nephrology, Primary Care, Gynecology/OB/GYN, Endocrinology, and Infectious Diseases.

Comment: A few commenters recommended that we modify CMS's proposal at § 422.116(d)(5) to include 1876 cost plan telehealth providers that provide telehealth services through supplemental benefits.

Response: Our proposal at § 422.116(d)(5) limited the credit to

providers that provide additional telehealth benefits, as defined in § 422.135, in its contracted networks. As we pointed out in the proposed rule, additional telehealth benefits described at § 422.135 only apply to MA plans. For that reason, our proposal did not extend the 10-percentage point credit to cost plans. We believe this is appropriate because of the protections and rules that exist for additional telehealth benefits that that require access to in-person care at the election of the enrollee. Telehealth services offered through supplemental benefits are not subject to these rules and may be too limited in scope to warrant a credit for network adequacy. Therefore, we are finalizing this telehealth credit as proposed at § 422.116(d)(5).

Comment: We received numerous comments in support of our proposal at § 422.116(d)(6) that MA organizations may receive a 10-percentage point credit towards the percentage of beneficiaries residing within published time and distance standards for affected provider and facility types in states that have CON laws, or other state imposed anticompetitive restrictions, that limit the number of providers or facilities in a county or state. Some commenters expressed agreement with our discussion in the proposed rule that CON laws have a negative impact on network adequacy, reduce competition, result in higher prices and lower patient access. Other commenters opposed the ''CON law credit'' and disagreed with our viewpoint on the impact that CON laws. Opposing commenters suggested that CON laws are not a significant barrier to providers in underserved areas and help assure that there is not an overabundance of specialized facilities that need to treat patients in order to remain in business, which causes an overutilization of services. These commenters were concerned that a 10-percentage point credit may hinder enrollee access to providers. We received some comments seeking clarification on the term ''other anticompetitive restrictions'' and the conditions under which the CON law credit will be available.

Response: We appreciate commenters' varying viewpoints on CON laws and their impact on network adequacy. We continue to believe that CON laws adversely affect competition and free market entry, and therefore, MA organizations must pay more for benefits when there is a limited supply of providers or facilities. We believe the 10-percentage point credit is an appropriate adjustment to make for MA organizations that contract with providers or facilities that are affected by CON laws in counties and states. As previously mentioned, prior network adequacy reviews show that many failures in meeting time and distance standards occur in the 80 to 89 percent range. Like the telehealth credit, this credit does not reduce the maximum time and distance criteria required for specific providers or facilities; it reduces the compliance threshold that MA organizations must meet in order to meet our network adequacy standards. Even when this credit applies, MA organizations must still contract providers and facilities where a majority of beneficiaries reside within maximum time and distance standards.

We proposed that MA organizations may receive a 10-percentage point credit towards the percentage of beneficiaries residing within published time and distance standards for affected provider and facility types in states that have CON laws, or *other state imposed anticompetitive restrictions,* that limit the number of providers or facilities in a county or state. We are implementing this network adequacy policy in furtherance of President Trump's Executive Order 13890 on Protecting and Improving Medicare for Our Nation's Seniors (October 3, 2019), which called for adjustments to network adequacy requirements to account for the competitiveness of state health care markets, including taking into account whether states maintain Certificate of Need (CON) laws or *other anticompetitive restrictions.* We clarify here that the term ''anticompetitive restrictions'' at § 422.116(d)(6) is meant to encompass state laws that restrict the provider or facility supply of specialty types listed at § 422.116(b), even if the state does not formally call them CON laws. For example, Wisconsin does not have a CON law, but has a limit on the maximum number of approved hospital beds .[52]

Additionally, we clarify that CMS will identify the states, counties and provider/facility specialty types where the CON law credit will be available for MA organizations. CMS has conducted comprehensive research on every state to determine whether the state uses CON laws or other anticompetitive restrictions and whether those laws affect the provider or facility types in our network adequacy standards at § 422.116(b). As we have described in regulation text, CMS may customize base time and distance standards in states with CON laws in lieu of allowing for the 10-percentage point credit. We clarify here and in regulation text at § 422.116(d)(6), that CMS may use customization when necessary due to utilization or supply patterns. Therefore, the 10-percentage point credit will not be allowable in counties where the specific provider or facility type maximum time and distance standards have already been customized. CMS will use the HPMS Network Management Module to identify the county and provider/facility combinations that are eligible for this 10-percentage point credit and MA organizations will need to submit a credit request for each provider or facility type they believe has been affected by the CON or anticompetitive laws.

Therefore, we are finalizing at § 422.116(d)(6) that in a state with CON laws, or other state imposed anti-competitive restrictions that limit the number of providers or facilities in the state or a county in the state, CMS will either award the MA organization a 10-percentage point credit towards the percentage of beneficiaries residing within published time and distance standards for affected providers and facilities in paragraph (b) of this section or, when necessary due to utilization or supply patterns, customize the base time and distance standards.

Comment: We received some comments about the cumulative effect of the telehealth and CON law credits on the percentage of beneficiaries residing within published time and distance standards. Some commenters questioned whether it was allowable to combine the two credits and others expressed concern with the effect of combining the two credits. Commenters were concerned that the combined change in the compliance percentage would likely have adverse impacts on provider access and choice.

Response: When discussing the CON law credit in the proposed rule, we stated that the CON law credit could be ''in addition to'' the telehealth credit, when applicable. We confirm that interpretation here and reiterate that both of these credits may be applied together to the percentage of beneficiaries residing within maximum time and distance standards at § 422.116(d)(4). We note that these credits do not reduce the actual maximum time and distance standards themselves, and that CMS still requires that MA organizations contract with providers where a majority of beneficiaries (that is, no less than 65 percent in rural counties, and 70 percent in non-rural counties, when both credits apply) reside within maximum time and distance standards for in-person access to care when

[52] *http://docs.legis.wisconsin.gov/statutes/statutes/150/VII/93.*

needed. Additionally, we reiterate that § 422.112(a) requires that MA organizations must ensure that all covered services are available and accessible under the plan and that MA organizations must maintain a network of providers to provide adequate access to covered services and must make arrangements for care outside the plan provider network, at in-network cost-sharing, when network providers are unavailable or the network is inadequate.

Comment: A few commenters recommended changes to our proposed exceptions process. Some commenters recommended that CMS shift from categorically treating an ''inability to contract'' as an invalid rationale for an exception and instead consider it a valid rationale relating to consolidated or concentrated provider markets. Others recommended that CMS consider exceptions based on documented provider activities that have resulted in anticompetitive practices impeding efforts to meet network adequacy standards. Another commenter suggested that where there may be repeated exception requests based on geographical barriers, CMS should consider granting permanent exceptions. Finally, a commenter requested that CMS revise its language in § 422.116(f) to expressly provide for exceptions for I–SNPs because they commonly furnish services in long-term care facilities.

Response: Under our proposal, an MA organization may request an exception when two criteria are met. First, certain providers or facilities are not available for the MA organization to meet the network adequacy criteria as shown in the Provider Supply file for the year for a given county and specialty type; second, the MA organization has contracted with other providers and facilities that may be located beyond the limits in the time and distance criteria but are currently available and accessible to most enrollees, consistent with the local pattern of care. We explained in the proposed rule the meaning of ''available'' by providing examples, such as when the provider has moved or retired, or when the provider/facility does not contract with any organizations or exclusively with another organization. (85 FR 9102–9103). However, we distinguish these examples from situations where an MA organization is unable to successfully negotiate and establish a contract with a provider or facility, which we refer to as the ''inability to contract.'' The non-interference provision at section 1854(a)(6) of the Act prohibits us from requiring any MA organization to contract with a particular hospital, physician, or other entity or individual to furnish items and services or require a particular price structure for payment under such a contract. As such, we cannot assume the role of arbitrating or judging the bona fides of contract negotiations between an MA organization and available providers or facilities. With respect to comments about ''documented provider activities that have resulted in anticompetitive practices,'' we believe that commenters are also referring to price negotiations between MA organizations and providers. We maintain that the ''inability to contract'' with an available provider or facility is not a valid justification for an exception at § 422.116(f). Therefore, we will generally not accept an organization's assertion that it cannot meet our network adequacy criteria because providers/facilities are not willing to contract with it.

With respect to comments about permanent exceptions for geographic barriers, we clarify here that we would not create a ''permanent'' exception, as this would unnecessarily burden the exception process. Instead, we would utilize our customization process to recalibrate maximum time and distance requirements in accordance with the local pattern of care. As mentioned in our discussion about customization, we use information received through exception requests to stay informed and determine which counties or provider/facility types require a permanent adjustment in maximum time and distance standards through customization to account for things such as geographic characteristics or changes in supply.

Finally, we reiterate here that we do not believe it is necessary to change network adequacy standards based on the plan types that we review. Beneficiaries may still need to travel to another facility to receive specialized care or the specialty providers may need to travel to deliver the care to the long-term care facility. As a result, we do not believe any specific exceptions are needed for I–SNPs.

We proposed to codify the three criteria that we consider when evaluating exception requests at paragraphs (f)(2)(i), (ii) and (iii); that CMS considers whether the current access to providers and facilities is different from the HSD reference and Provider Supply files for the year; there are other factors present, in accordance with § 422.112(a)(10)(v), that demonstrate that network access is consistent with or better than the original Medicare pattern of care; and approval of the exception is in the best interests of beneficiaries. We reiterate that all three criteria must be met for CMS to approve an exception. We are finalizing the exceptions process and these criteria at § 422.116(f) as proposed.

Comment: Some commenters, in connection with a proposal to revise § 422.502 to address how CMS would use an entity's past performance on an MA contract in evaluating applications for new plans or service area expansions, stated that CMS should be more specific about what is and is not a basis for denying applications in connection with network adequacy in order to minimize uncertainty and unpredictability for MA organizations. Commenters suggested that CMS should add other and more specific criteria for use in considering applications.

Response: Although we are not addressing in this final rule the proposal to revise § 422.502 to address our use of information about past performance in evaluating an application, we understand that our statement in the proposed rule about how we would require an entity applying for a new MA contract to provide an attestation about the adequacy of its network could be seen as touching on that topic. We will address our proposal about § 422.502 in a future final rule, but believe that additional clarity regarding attestations about meeting the network adequacy regulation and how they would be used in the context of applications for new MA contracts or service area expansions should be addressed as part of our network evaluation regulation.

We proposed specific regulation text (which we are finalizing) in § 422.116(a) that each network-based MA plan must demonstrate that it has an adequate contracted provider network. In addition, we proposed that when required by CMS, an MA organization must attest that it has an adequate network for access and availability of a specific provider or facility type that CMS does not independently evaluate in a given year (85 FR 9093). We explained that we anticipated requiring such attestation in the MA organization's application or contract for a given year but we might require the attestation when performing other network adequacy reviews, such as when there is a significant change in the MA plan's provider network.

Under our current network adequacy policy, as described in the PRA approved collection of information titled, ''Triennial Network Adequacy Review for Medicare Advantage Organizations and 1876 Cost Plans'' (CMS–10636) and referenced in our

proposed rule, we removed network reviews from the application process beginning in 2018 for contract year 2019. Therefore, failures detected during network reviews are no longer used as a basis to deny an MA application. In the proposed rule, we made clear that an attestation could be used in connection with applications. In light of the comments discussed above, and to address the intersection of our regulations regarding network adequacy and the bases for denying applications, we are finalizing regulatory text to explicitly provide that we do not require information other than an attestation regarding compliance with network adequacy requirements as part of the application for a new or expanding service area and will not deny such an application on the basis of such requirements. This provides greater clarity regarding how network adequacy and the application process intersect by codifying the current practice of relying on other mechanisms, such as our triennial reviews, to evaluate compliance with the specific network adequacy standards finalized in § 422.116 and to enforce those standards. The provision we are finalizing here at § 422.116(a)(1)(ii), however, does not prohibit CMS from considering or using information about an entity's failure to comply with a MA contract for purposes of an application denial when or if that compliance failure was associated with access to services or network adequacy evaluations and resulted in the imposition of an intermediate sanction or civil money penalty under to part 422 subpart O, with the exception of a sanction imposed under § 422.752(d). Therefore, we are finalizing regulatory text at § 422.116(a)(1)(ii) that CMS does not require information, other than an attestation, regarding compliance with § 422.116 as part of an application for a new or expanding service area and will not deny application on the basis of an evaluation of the applicant's network for the new or expanding service area.

After careful consideration of all comments received, and for the reasons set forth in the proposed rule and in our responses to the related comments summarized earlier, we are finalizing the proposed changes to §§ 417.416(e)(3) and 422.116 with the following modifications:

- We are finalizing regulatory text at § 422.116(a)(1)(ii) that CMS does not require information, other than an attestation, regarding compliance with § 422.116 as part of an application for a new or expanding service area and will not deny application on the basis of an evaluation of the applicant's network for the new or expanding service area. Accordingly, we are designating the text we proposed at paragraph (a)(1) as paragraph (a)(1)(i) in the final regulation.
- We are not finalizing § 422.116(a)(3)(ii), which clarified the definition of the facility type Outpatient Dialysis.
- We are not finalizing Outpatient Dialysis in the list of facility specialty types at § 422.116(b)(2) and are finalizing the list of other facility-types as proposed but with different numbering, accordingly.
- We are not finalizing the base maximum time and distance standards for Outpatient Dialysis for all county designations at § 422.116(d)(2).
- We are finalizing the customization process at § 422.116(d)(3) with a modification that describes what triggers customization by CMS.
- We are finalizing § 422.116(d)(5) as proposed with the addition of Ophthalmology, Allergy and Immunology, Nephrology, Primary Care, Gynecology/OB/GYN, Endocrinology, and Infectious Diseases provider specialty types to the list of provider types for which the telehealth credit is available.
- We are finalizing § 422.116(d)(6) with a modification that describes when CMS may use the customization process as it relates to Certificate of Need or other anticompetitive laws.

M. Special Election Periods (SEPs) for Exceptional Conditions (§§ 422.62, 422.68, 423.38, and 423.40)

1. Part C Special Election Periods (§ 422.62)

Section 1851(e)(4) of the Act establishes special election periods (SEPs) during which, if certain circumstances exist, an individual may request enrollment in a Medicare Advantage (MA) plan or discontinue the election of an MA plan and change his or her election to original Medicare or to a different MA plan. We have codified SEPs for the following circumstances specifically addressed in section 1851(e)(4) of the Act:

- SEP for Non-renewals or Termination.
- SEP for Changes in Residence.
- SEP for Contract Violation.

Section 1851(e)(4)(D) of the Act also grants the Secretary the authority to create SEPs for individuals who meet other exceptional conditions. This authority is codified at § 422.62(b)(4). CMS has historically included in regulation those SEPs that the statute explicitly authorizes and has established the SEPs for exceptional circumstances in our subregulatory guidance rather than through regulation.

We proposed to codify a number of SEPs that we have adopted and implemented through subregulatory guidance as exceptional circumstances SEPs. Consistent with § 422.68(c), we also proposed to revise § 422.68(d) to clarify that for SEPs that are described in § 422.62(b), elections are effective as of the first day of the first calendar month following the month in which the election is made, unless otherwise noted.

The proposed MA SEPs are summarized below. (Readers should refer to the proposed rule for more detail on these SEPs.):

SEP for Employer/Union Group Health Plan (EGHP) Elections. We proposed to revise § 422.62(b)(4) to codify a SEP for individuals making MA enrollment requests into or out of employer sponsored MA plans, for individuals to disenroll from an MA plan to take employer sponsored coverage of any kind, and for individuals disenrolling from employer sponsored coverage (including COBRA coverage) to elect an MA plan.

SEP for Individuals Who Disenroll in Connection with a CMS Sanction. At new § 422.62(b)(5), we proposed to codify the SEP for individuals enrolled in an MA plan offered by an MA organization that is sanctioned by CMS.

SEP for Individuals Enrolled in Cost Plans that are Non-renewing their Contracts. At new § 422.62(b)(6), we proposed to codify the SEP for individuals enrolled in cost plans that are non-renewing their contracts for the area in which the enrollee lives.

SEP for Individuals in the Program of All-inclusive Care for the Elderly (PACE). At new § 422.62(b)(7), we proposed to codify the SEP allowing an MA plan enrollee to disenroll from an MA plan at any time in order to enroll in PACE.

SEP for Individuals Who Terminated a Medigap Policy When They Enrolled For the First Time in an MA Plan and Who Are Still in a Trial Period. We proposed, at new § 422.62(b)(8), to codify the SEP for individuals who are eligible for guaranteed issue of a Medigap policy under section 1882(s)(3)(B)(v) of the Act upon disenrollment from the MA plan in which they are enrolled.

SEP for Individuals With ESRD Whose Medicare Entitlement Determination Was Made Retroactively. We proposed to codify at new § 422.62(b)(9) that individuals whose Medicare entitlement determination based on ESRD was made retroactively would have a SEP to prospectively elect an MA plan offered

by the MA organization, provided they met certain requirements.

SEP for Individuals Whose Medicare Entitlement Determination Was Made Retroactively. We proposed, at new § 422.62(b)(10), to codify a SEP for individuals whose Medicare entitlement determination was made retroactively.

SEP for Individuals Who Lose Special Needs Status. At new § 422.62(b)(11), we proposed to codify the SEP for individuals enrolled in an MA special needs plan (SNP) who are no longer eligible for the SNP because they no longer meet the applicable special needs status.

SEP for Individuals Who Belong to a Qualified SPAP or Who Lose SPAP Eligibility. At new § 422.62(b)(12), we proposed to codify a SEP for individuals who belong to a qualified State Pharmaceutical Assistance Program (SPAP) to make one election to enroll in an MA–PD plan each calendar year.

SEP for Enrollment Into a Chronic Care SNP and for Individuals Found Ineligible for a Chronic Care SNP. At new § 422.62(b)(13), we proposed to codify the SEP allowing individuals with severe or disabling chronic conditions to enroll in a Chronic Care SNP (C–SNP) designed to serve individuals with those conditions.

SEP for Disenrollment from Part D to Enroll in or Maintain Other Creditable Coverage. At new § 422.62(b)(14), we proposed to codify the SEP that provides an opportunity for individuals to disenroll from an MA–PD plan (only by electing Original Medicare or an MA-only plan) in order to enroll in or maintain other creditable drug coverage (such as TRICARE or VA coverage) as defined in § 423.56(b).

SEP to Enroll in an MA Plan with a Star Rating of 5 Stars. At new § 422.62(b)(15), we proposed to codify the SEP allowing an eligible individual to enroll in an MA plan with a Star Rating of 5 stars during the plan contract year in which that plan has the 5-star overall rating.

SEP for Non-U.S. Citizens who Become Lawfully Present. At new § 422.62(b)(16), we proposed to codify the SEP for non-U.S. citizens who become lawfully present in the United States.

SEP for Providing Individuals who Requested Materials in Accessible Formats Equal Time to Make Enrollment Decisions. We proposed to codify, at new § 422.62(b)(17), a SEP for situations where an MA organization or CMS was unable to provide required notices or information in an accessible format, as requested by an individual, within the same timeframe that it was able to provide the same information to individuals who did not request an accessible format.

SEP for Individuals Affected by a FEMA-Declared Weather-Related Emergency or Major Disaster. We proposed to codify, at new § 422.62(b)(18), the SEP for individuals affected by a weather-related emergency or major disaster who were unable to make an election during another valid election period.

SEP for Significant Change in Provider Network. At new § 422.62(b)(23), we proposed to codify the SEP that is available when CMS determines that mid-year changes to an MA plan's provider network are significant, based on the effect on, or potential to affect, current plan enrollees' continued access to covered benefits.

SEP for Individuals Enrolled in a Plan Placed in Receivership. We proposed to establish a new SEP, at new § 422.62(b)(24), for individuals enrolled in plans offered by MA organizations experiencing financial difficulties to such an extent that a state or territorial regulatory authority has placed the organization in receivership.

SEP for Individuals Enrolled in a Plan that has been Identified by CMS as a Consistent Poor Performer. We proposed to establish a new SEP, at new § 422.62(b)(25), for individuals who are enrolled in plans identified with the low performing icon (LPI) in accordance with § 422.166(h)(1)(ii).

SEP for Individuals Affected by a Federal Employee Error. At new § 422.62(b)(21), we proposed to codify a SEP for individuals whose enrollment or non-enrollment in an MA–PD plan is erroneous due to an action, inaction or error by a federal employee.

SEP for Other Exceptional Circumstances. Lastly, we proposed to retain the authority currently at § 422.62(b)(4) to create SEPs for individuals who meet other exceptional conditions established by CMS and move it to new § 422.62(b)(26).

Also based on the Secretary's authority to create SEPs for individuals who meet exceptional conditions, we proposed to codify the following SEPs currently outlined in subregulatory guidance that coordinate with Part D election periods:

SEP for Individuals Who Experience an Involuntary Loss of Creditable Prescription Drug Coverage. At new § 422.62(b)(19), we proposed to codify the SEP for individuals who experience an involuntary loss of creditable prescription drug coverage, including a reduction in the level of coverage so that it is no longer creditable but not including any such loss or reduction due to a failure to pay premiums.

SEP for Individuals Who Are Not Adequately Informed of a Loss of Creditable Prescription Drug Coverage. At new § 422.62(b)(20), we proposed to codify a SEP for individuals who are not adequately informed of a loss of creditable prescription drug coverage, or that they never had creditable coverage.

SEP for Individuals Eligible for an Additional Part D IEP. At new § 422.62(b)(22), we proposed to codify the SEP for an individual who is eligible for an additional Part D Initial Enrollment Period (IEP) to have an MA SEP to coordinate with the additional Part D IEP.

These proposed revisions would codify existing subregulatory guidance for SEPs that MA organizations have previously implemented and are currently following, except the SEP for Individuals Enrolled in a Plan Placed in Receivership and the SEP for Individuals Enrolled in a Plan that has been identified by CMS as a Consistent Poor Performer. We also proposed minor editorial changes in § 422.62(b) and (c), such as changing ''Original Medicare'' to ''original Medicare.''

In general, we received support for the proposed SEPs. We received specific comments on the following proposed SEPs. (Comments that apply to SEPs proposed for both MA and Part D will be addressed in this section and not repeated in the Part D SEP section.) The comments on those proposals and our responses follow:

SEP for Employer/Union Group Health Plan (EGHP) Elections

Comment: A commenter recommended that we revise the current description of this SEP, which is that it is available to individuals who have (or are enrolling in) an employer or union sponsored MA plan, and change it to indicate that it is available to individuals who have (or are enrolling in) an employer or union sponsored plan.

Response: We interpret this comment as a request to ensure that this SEP is available to individuals who have (or are enrolling in) an employer or union sponsored plan that is not an MA plan. As proposed, this SEP is available to individuals who are moving from employer or union coverage of any kind to an employer or union sponsored MA plan. In addition, the SEP is available to individuals who wish to disenroll from an MA plan to take employer or union sponsored coverage of any kind. As such, we believe the comment is addressed by the SEP, as proposed.

Comment: A commenter recommended that CMS codify the retroactive effective date guidelines related to this SEP, which are referenced in subregulatory guidance. Specifically, where there is a delay between the time in which the member completes the enrollment or disenrollment request with the EGHP and when it is ultimately received by the health plan, the current guidelines indicate that the effective date may be retroactive up to, but may not exceed, 90 days from the date the MA organization received the request from the employer or union group. The disenrollment effective date guidelines indicate up to 90 days' retroactive payment adjustment is possible in cases where the EGHP does not provide the plan with timely notification of a member's requested disenrollment.

Response: We did not propose to codify a provision for retroactive payment adjustment due to employer or union delays in providing the MA organization with timely notification of a member's requested disenrollment, and we decline to adopt such a provision at this time. It has been CMS' longstanding expectation that in the event an MA organization chooses to delegate to an employer or union the collection and initial processing of beneficiary enrollment and disenrollment requests, the MA organization's agreement with the employer or union would require the employer or union to meet enrollment and disenrollment processing timeliness requirements that ensure the timely submission of enrollment and disenrollment requests. As such, retroactivity is necessary when the employer or union fails to meet these processing timeliness requirements.

SEP for Individuals Who Terminated a Medigap Policy When They Enrolled For the First Time in an MA Plan and Who Are Still in a Trial Period

Comment: A commenter who expressed support for this proposal urged CMS to ensure that beneficiaries under age 65 with ESRD who have guaranteed issue rights under state laws and rules are aware of them.

Response: We appreciate the commenters' support and agree that education and outreach are essential for individuals to understand their enrollment options. We will continue to partner with existing stakeholders to ensure that clear and comprehensive information is provided to beneficiaries so they are able to make an informed coverage choice.

SEP for Individuals Affected by a Federal Employee Error

Comment: A commenter, citing some stakeholder concerns regarding the 2019 redesign of the Medicare Plan Finder (MPF) tool, requested that CMS articulate in regulatory language (either in the SEP for individuals affected by a federal employee error or a separate entry) that a SEP for exceptional circumstances may exist when there are errors in the MPF or other CMS-issued or managed information platforms that beneficiaries used when making their decisions.

Response: We appreciate the comment. As the MPF and other CMS-issued or managed information platforms are the responsibility of the federal government, a beneficiary who relied on erroneous information on these platforms would be eligible for this SEP. As a result, we do not see a need to revise the current regulatory text or establish a new, separate SEP.

SEP for Individuals Affected by a FEMA-Declared Weather-Related Emergency or Major Disaster

Comment: A number of commenters supported the proposal to codify this SEP and many of them recommended that it be expanded to address State-declared emergencies and public health emergencies such as COVID–19. A commenter questioned if the SEP would apply when FEMA provides fire management assistance. Commenters also requested that the end date should be revised so that the SEP is available to eligible individuals in cases where the emergency is declared with a retroactive effective date and/or lasts for more than 4 months.

Response: We appreciate the comments and agree that eligibility for this SEP should not be solely contingent upon a FEMA declaration. Based on these comments and consistent with our goal of providing an enrollment or disenrollment opportunity to an individual who missed an election period due to circumstances beyond his or her control, we will revise the proposed SEP to include any emergency declaration issued by a Federal, state, or local government entity in response to a disaster or other emergency. This would not include instances in which fire management assistance is provided by FEMA, as this occurs prior to the declaration of an emergency or major disaster as part of state and/or local government efforts to stop the spread of fire and mitigate fire risk to the built environment, and is not itself an emergency declaration. We also agree with the comment that the SEP end date should be revised so that the SEP is available to eligible individuals in cases where the emergency is declared with a retroactive effective date and/or lasts for more than four months. We believe that the SEP end date should be related to the end of the emergency period, not the start of the emergency period.

As such, in §§ 422.68(b)(18) and 423.38(c)(23) we will change the scope of the SEP so that it applies to FEMA-declared emergencies/disasters, as well as disaster or other emergency declarations issued by a federal, state or local government entity. It will be available in the geographic areas identified in the emergency/disaster declaration. We also specify in this paragraph that the SEP will—

- Start as of the date the declaration is made, the incident start date or, if different, the start date identified in the declaration, whichever is earlier; and
- End 2 full calendar months following the end date identified in the declaration or, if different, the date the end of the incident is announced, whichever is later. This 2-month period is consistent with other longstanding SEPs such as the SEP for Significant Change in Provider Network and the SEP for Individuals Whose Medicare Entitlement Determination Made Retroactively.

In finalizing the SEP with these revisions, we will retain the requirement that the individual was eligible for an election period at the time of the incident period and did not make an election during that election period because he or she was prevented from doing so due to the incident. We will refer to this SEP as the *SEP for Government Entity-Declared Disaster or Other Emergency*.

SEP for Individuals Enrolled in a Plan Placed in Receivership

Comment: A commenter stated that it is unclear how an MA organization might know if another MA organization is having financial problems during the enrollment period and, therefore, would not know if a beneficiary is eligible for this SEP.

Response: The SEP is available only to individuals enrolled in a plan offered by an organization that has actually been placed into receivership, which, in our experience, is always a well-publicized event in the impacted area, usually involving a high level of media attention. We believe that MA organizations offering plans in the area in which another MA organization has been placed into receivership will be aware of such an event through its normal course of business in the areas it serves. When a beneficiary requests

enrollment on the basis of their current plan being placed into receivership, the new plan can accept the beneficiary's verbal or written attestation as proof of their eligibility for this SEP.

Comment: Two commenters suggested that CMS allow MA plans and Part D sponsors to accept verbal beneficiary attestation as proof of eligibility for this SEP and not require additional proof of election eligibility. They believed that allowing verbal beneficiary attestation will expedite enrollment processing and may reduce enrollment denials. Additionally, they believed it would be consistent with current SEPs permitting verbal attestation for election period eligibility, such as the SEPs for Change in Residence, EGHP, etc.

Response: We did not propose that additional proof of eligibility for this SEP be required. Consistent with longstanding policy regarding eligibility for any SEP, an applicant's written or verbal attestation of SEP eligibility is sufficient.

SEP for Individuals Enrolled in a Plan That Has Been Identified by CMS as a Consistent Poor Performer

Comment: A commenter, who expressed support for this new SEP and the new SEP for Individuals Enrolled in a Plan Placed in Receivership, requested that if a beneficiary who is eligible for these new SEPs or any other SEP has an agent of record, that a pathway be created for the agent of record to make the plan change.

Response: Beneficiaries are not precluded from using an agent/broker or any other available means to enroll in a plan when the beneficiary qualifies for a SEP.

Comment: Another commenter who expressed support for this new SEP and the new SEP for Individuals Enrolled in a Plan Placed in Receivership stated that impacted beneficiaries should be able to make elections utilizing these new SEPs only through contacting CMS directly, adding that to include these two new SEPs on plan enrollment forms, enrollment websites and other enrollment mechanisms is an unnecessary burden. The commenter believed that adding two new SEPs would be confusing for beneficiaries, as there are already numerous SEPs for beneficiaries to understand. This commenter also stated that the two new SEPs should be available to beneficiaries only outside of the Annual Enrollment Period (AEP) and only until such time as CMS terminates its contract with the plan. The commenter stated that an MA parent organization would not be able to identify a plan that has been identified by CMS as a consistent poor performer or a plan that has been placed in receivership and requested that CMS not require plans to offer these two new SEPs until contract year 2022.

Response: We appreciate the comment and believe that any potential beneficiary confusion can be minimized by presenting these two new election opportunities to beneficiaries in a clear and accurate manner. We believe that it is important that the SEPs be available throughout the year, not just outside of the AEP, given the effective date implications. That is, if a beneficiary finds it necessary to change plans during October or November using one of these SEPs, their new coverage should be effective the next month and they should not have to wait until January 1 or later. We disagree with the commenter and do not believe that it is an unnecessary burden to mention these two SEPs in plan materials where other SEPs are listed, such as the Attestation of Eligibility for an Enrollment Period. Exclusion of the two new SEPs would result in beneficiaries not being fully aware of all potential election periods available to them. With regard to the comment that an MA parent organization would not be able to identify a plan that has been identified by CMS as a consistent poor performer, we note that since plans are able to accept a verbal or written attestation from the beneficiary that they are eligible for a SEP, plans are able to accept a verbal or written attestation regarding eligibility for the SEP for Individuals Enrolled in a Plan Placed in Receivership and the SEP for Individuals Enrolled in a Plan that has been Identified by CMS as a Consistent Poor Performer. In addition, plans are able to verify another organization's LPI status via the Medicare Plan Finder or the released Star Rating summary report. As a result, we do not see a reason to delay the offering of these two new SEPs until contract year 2022.

SEP for Significant Change in Provider Network

Comment: A commenter suggested that CMS revise this SEP so that it may be used when an individual plan enrollee's provider is terminated without cause, adding that while there is an existing SEP for significant change in an MA provider network, it is only triggered when a threshold of terminations is met. The commenter states that an individual may have joined a plan specifically because their provider contracts with it, or have developed a relationship with that provider they wish to maintain.

Response: We appreciate the comment. As stated in the proposed rule, CMS considers significant changes to provider networks to be those that go beyond individual or limited provider terminations that occur during the routine course of plan operations. CMS appreciates that an individual would want to maintain a relationship with an individual provider, however, an individual provider's termination from a plan would not disrupt or affect that enrollee's continued access to covered benefits. CMS continues to believe this SEP is best reserved for network changes that are significant and have the potential to affect the access of covered benefits for a large number of enrollees.

SEP for Individuals with ESRD Whose Medicare Entitlement Determination Was Made Retroactively

Comment: Two commenters supported the proposal to codify a SEP for individuals with ESRD whose Medicare entitlement determination was made retroactively because it would allow beneficiaries to enroll who were not able during the customary period, as well as ensure that beneficiaries may enroll into an MA plan if certain conditions are met prior to the MA ESRD enrollment rule taking effect in 2021. Both commenters recommended that educational outreach be made to individuals with ESRD.

Response: We appreciate the commenters' support and agree that education and outreach are essential for individuals to understand their enrollment options. We will continue to partner with existing stakeholders to ensure that clear and comprehensive information is provided to beneficiaries so they are able to make an informed coverage choice.

SEP for Other Exceptional Circumstances

Comment: A commenter expressed strong support for CMS' statement that it retains the ability to grant case-by-case exceptional circumstance SEPs, and that the list at § 422.62(b)(26) is not exhaustive. The commenter expressed concern that leaving the creation of new SEPs solely to rulemaking will mean that it will take longer to implement new, necessary SEPs should the need arise and will make the agency's response less nimble and may hinder its ability to quickly meet the needs of beneficiaries. The commenter urges CMS to reiterate, or otherwise educate, plan sponsors, 1–800–MEDICARE counselors and CMS staff that despite exceptional circumstance SEPs now being codified, that such discretion still exits.

Response: We appreciate the commenters' support and continue to believe that it is important to retain the discretion to establish SEPs on a case-by-case basis. As such, at newly redesignated § 422.62(b)(26) and newly redesignated § 423.38(c)(34), we are finalizing our proposal to codify a SEP for other exceptional circumstances, which are, as stated in the proposed rule, situations in which it is in the best interest of the beneficiary that she or he be provided an enrollment (or disenrollment) opportunity. To date, CMS has used the existing authority at §§ 422.62(b)(4) and 423.38(c)(8)(ii) to assist individuals whose unique situations are outside the parameters of the existing SEPs, in order to address an individual's exceptional circumstances related to new enrollments or enrollment/disenrollment from an MA or Part D plan. These SEPs, which we also refer to as enrollment exceptions, are utilized when the reason is not captured in an existing SEP or specific circumstances require an exception to the predefined criteria. Consistent with current practice, CMS will consider granting an enrollment exception when one or more of the following factors is present:

++ Extraordinary Circumstances—Circumstances beyond the beneficiary's control that prevented him or her from submitting a timely request to enroll or disenroll from a plan during a valid enrollment period. This is inclusive of, but not limited to, a serious medical emergency of the beneficiary or their authorized representative during an entire election period, a change in hospice status, or mailed enrollment forms returned as undeliverable on or after the last day of an enrollment period.

++ Erroneous Election—Situations in which a beneficiary provides a verbal or written allegation that his or her enrollment in a MA or Part D plan was based upon misleading or incorrect information provided by a plan representative or State Health Insurance Assistance Program (SHIP) counselor, including situations where a beneficiary states he or she was enrolled into a plan without his or her knowledge or consent, and requests cancellation of the enrollment or disenrollment from the plan.

++ Plan Accessibility—A SEP may be warranted to ensure beneficiary access to services and where without the approval of an enrollment exception, there could be adverse health consequences for the beneficiary. This is inclusive of, but not limited to, maintaining continuity of care for a chronic condition and preventing an interruption in treatment.

CMS will review supporting details and documentation to determine eligibility for the SEP for exceptional circumstances, which, as currently implemented, can be in response to an individual beneficiary's request for an exception to the current enrollment rules, as well as CMS' determination that an exception is warranted for a group of beneficiaries. The SEP would take effect once CMS makes its determination and the enrollee has been notified. The effective date for an enrollment or disenrollment election using an approved enrollment exception would be based on the beneficiary's circumstances and may either be prospective or retroactive.

In addition to proposing to codify SEPs established in sub-regulatory guidance, as well as proposing two new SEPs (related to plans placed into receivership or being identified as a consistent poor performer), we requested comments on other SEPs that should be considered for codification. In response to that request, we received the following feedback:

Comment: A commenter urged us to establish a SEP for individuals in MA or Part D plans who are impacted by significant changes in their plan benefits from one year to the next, for example, significantly higher premiums or reduced benefits. They believed that this was particularly important for individuals with standalone PDPs since they do not have the same option to change plans during the first three months of the year afforded to those who begin the year enrolled in an MA plan (pursuant to the MA OEP). The commenter stated that most people who are enrolled in a given plan tend to rely on that plan remaining more or less the same, and, as a consequence, many people do not carefully scrutinize their Annual Notice of Change (ANOC) or other plan documents describing annual changes.

Response: Every Fall, CMS conducts a robust educational campaign that urges beneficiaries to review their plan benefits and make changes if their plan no longer meets their needs or if there are other options that could lower their out-of-pocket expenses. The ANOC is an important resource that plans are required to send to members detailing how benefits will change in the next plan year. Ultimately, it is the beneficiary's responsibility to assess their own drug and healthcare needs and determine if there is a better plan for them. We appreciate the commenter's concern, but will not be finalizing the suggested SEP.

Comment: Two commenters recommended that we establish a SEP for beneficiaries who have been accepted for admission to, or have been admitted to, an extended neoplastic disease care hospital and a physician has noted that the individual has life expectancy of ninety days or less. The commenters stated that this was important because individuals who are diagnosed with advanced cancer are often at the end of their lives and should be able to disenroll from their MA plan to Original Medicare if the hospital where they choose to receive their care is outside of the plan's network. The commenters also noted that, as an alternative or an addition, CMS should determine extended neoplastic disease care hospitals to be ''institutions'' so that beneficiaries would be eligible for the Open Enrollment Period for Institutionalized Individuals (OEPI). The commenters noted that if this change was made, an additional revision should be made to waive the 90-day length of stay requirement.

Response: While we understand and are sympathetic to beneficiaries diagnosed with advanced cancer, we do not believe that the establishment of a new SEP is an appropriate remedy to this very specific situation. When establishing (and now codifying) SEPs, we look for broad scenarios where we believe it is imperative that beneficiaries have opportunities to join, change, or disenroll from plans. Beneficiaries who are not able to disenroll from their MA plan to return to Original Medicare still have access to Medicare Part A and Part B benefits. MA plans are required to cover all services covered by Original Medicare and if a member needs covered medical care that the providers in the plan's network cannot provide, the plan must cover care from an out-of-network provider.

The absence of neoplastic disease care hospitals from the list of facilities considered to be institutions is outside the scope of this proposal.

Comment: A commenter requested that we codify two SEPs that are in Chapter 2 of the Medicare Managed Care manual that were not included in the proposed SEPs in 42 CFR part 422: The SEP for Dual-Eligible Individuals and Other LIS Eligible Individuals and the SEP for CMS and State-Initiated Enrollments. Similarly, they also requested that we codify two SEPs in Chapter 3 of the Medicare Prescription Drug Benefit Manual that were not included in the proposed SEPs in 42 CFR part 423: The SEP for Full-Benefit Dual Individuals with Retroactive Uncovered Months and the SEP for Individuals Involuntarily Disenrolled

from an MA–PD plan due to loss of Part B.

Response: We appreciate the comments. The commenter requests that we codify in the Part C regulations the SEP for Dual-Eligible Individuals and Other LIS Eligible Individuals that is included in Chapter 2 of the Medicare Managed Care Manual. We disagree that this SEP should be codified as a Part C SEP, as it is included in the Part C enrollment guidance merely as a reiteration of an already existing Part D SEP at § 423.38(c)(4). To codify this in the Part C regulations would result in the establishment of additional election periods that we did not intend to establish. The basis for the existing SEP for Dual-Eligible Individuals and Other LIS Eligible Individuals is the fact that the beneficiary is (or has been) receiving the Part D low income subsidy, which is specific to Part D and why the SEP is codified in 42 CFR part 423 and not proposed as a SEP in part 422. Therefore, we decline to codify a SEP for Dual-Eligible Individuals and Other LIS Eligible Individuals in the Part C regulations.

The commenter also requests that we codify in the Part C regulations the SEP for CMS and State-Initiated Enrollments that is included in Chapter 2 of the Medicare Managed Care Manual. This SEP is based on § 422.60(g)(5), which states that individuals who are passively enrolled by CMS into an MA–PD plan are eligible for the Part D SEP described in § 423.38(c)(10). To codify a new Part C SEP would be redundant; therefore, we decline the commenter's request to do so.

The commenter also requests that we codify in the Part D regulations the SEP for Full-Benefit Dual Eligible Individuals with Retroactive Uncovered Months that is included in Chapter 3 of the Medicare Prescription Drug Benefit Manual. As described in guidance, this SEP addresses the scenario in which a Part D eligible individual needs prescription drug coverage through the Limited Income Newly Eligible Transition (LI NET) program prior to his or her enrollment in a Part D plan, either by submitting an application to a plan or by being auto-enrolled by CMS into a plan for a future date. Since the process for establishing retroactive drug coverage through LI NET is a CMS-directed process, and does not involve an individual taking action to request enrollment in a plan, we did not propose to codify this SEP, and we decline to do so in this final rule.

Lastly, the commenter requests that we codify in the Part D regulations the SEP for Individuals Involuntarily Disenrolled from an MA–PD plan due to loss of Part B that is included in Chapter 3 of the Medicare Prescription Drug Benefit Manual. As described in subregulatory guidance, individuals who are involuntarily disenrolled from an MA–PD plan due to loss of Part B but who continue to be entitled to Part A have a SEP to enroll in a PDP. The SEP begins when the individual is advised of the loss of Part B and continues for two additional months. We agree with the commenter that this SEP should be codified; the fact that it was not included in the proposed rule was an oversight. In response to this comment, we will codify at § 423.38(c)(33) the SEP for Individuals Involuntarily Disenrolled from an MA–PD plan due to loss of Part B.

In addition to comments received on specific SEPs and suggested SEPs, we also received the general comments discussed below.

Comment: A commenter recommended that CMS codify its guidance from Chapter 2 of the Medicare Managed Care Manual (MMCM), section 30.4, that an organization is not required to contact an applicant to confirm SEP eligibility if the enrollment request includes the applicant's attestation of SEP eligibility. The commenter stated that codifying this guidance would be particularly helpful in instances where the SEP is based on factual circumstances such as the beneficiary's former plan is placed in receivership or has been consistently poor performing, and the beneficiary attestation is the easiest source of the information.

Response: In codifying these SEPs, we focused on what the SEPs were and detailed the situations when they would be applicable. We did not include in the proposed rule the codification of subregulatory guidance regarding attestation of SEP eligibility. We believe that details concerning the operational processing of enrollment requests are better suited for sub-regulatory guidance where we are able to go into more detail and provide examples and context. As such, we are declining the commenter's recommendation to codify guidance related to beneficiary attestations.

Comment: A commenter urged CMS to also consider that some beneficiaries may experience financial or enrollment difficulties stemming from the COVID–19 disruption. Concerned that some beneficiaries who have temporarily lost their Part B coverage for non-payment of premium may miss their opportunity to enroll through the open enrollment that ended in March 2020 due to staffing disruptions at local social security offices.

Response: We are aware that given the ongoing COVID–19 pandemic, stakeholders are looking for flexibilities for all aspects of Medicare enrollment and entitlement. However, it appears that the commenter is providing feedback regarding Medicare Part B enrollment and associated rules in 42 CFR part 407. We did not include in the proposed rule any new or revised regulations regarding Part B enrollment periods or loss of Part B coverage for non-payment of premium. We thank the commenter for their insights, but decline to address or modify any Part B enrollment rules given that they are outside the scope of this rulemaking.

Comment: A commenter stated that CMS should clarify whether the effective date for certain SEPs should be the first of the month following when the request is made. The commenter referenced SEPs such as the SEP for Individuals Who Disenroll in Connection with a CMS Sanction, the SEP for Individuals in PACE or the SEP for Individuals Who Dropped a Medigap Policy When They Enrolled For the First Time in an MA Plan and Who are Still in a ''Trial Period.'' In addition, another commenter requested that we clarify the effective date for enrollment requests the organization receives from individuals eligible for the SEP for Individuals Whose Medicare Entitlement Determination Made Retroactively. As stated in the proposed rule, the effective date is the first day of the month following the MA organization's receipt of the election, but cannot be earlier than the first day of the month in which the notice of the Medicare entitlement determination is received by the individual. The commenter recommends that CMS permit retroactive enrollment based on when the beneficiary receives the notice of entitlement.

Response: We proposed to specify at §§ 422.68(d) and 423.40(c) that the effective date for elections made using SEPs described in §§ 422.62(b) and 423.38(c) is the first day of the calendar month following the month in which the election is made, unless otherwise noted. This applies to the SEP for Individuals Whose Medicare Entitlement Determination Made Retroactively as well, since it is not until an individual is notified of the Medicare entitlement determination that he or she, or an MA or Part D plan sponsor for that matter, would be aware of the determination and the Part A and/or Part B effective dates. We therefore disagree with the commenter that CMS should permit an enrollment to be retroactive to a date prior to when an individual received notification of

Medicare entitlement or prior to the date the individual requests enrollment in the plan.

After considering the public comments, we are finalizing all MA SEPs as proposed, with the exception of the *SEP for Individuals Affected by a FEMA-Declared Weather-Related Emergency or Major Disaster* at § 422.68(b)(18), which will be renamed the *SEP for Government Entity-Declared Disaster or Other Emergency.* This paragraph is being revised to change the scope of the SEP so that it applies to FEMA-declared emergencies, as well as emergency declarations issued by a federal, state or local government entity. We are also specifying in this paragraph that the SEP will—

- Start as of the date the declaration is made, the incident start date or, if different, the start date identified in the declaration, whichever is earlier; and
- End 2 full calendar months following the end date identified in the declaration or, if different, the date the end of the incident is announced, whichever is later.

In addition, we are adopting without modification the minor editorial changes in § 422.62(b) and (c) and the changes proposed at § 422.68 regarding effective dates of the SEPs.

2. Part D Special Election Periods (§ 423.38)

Section 1860D–1(b)(3) of the Act establishes special election periods (SEPs) during which, if certain circumstances exist, an individual may enroll in a stand-alone Part D prescription drug plan (PDP) or disenroll from a PDP and enroll in another PDP or in an MA plan that includes Part D benefits (MA–PD plan). We have codified SEPs for the following circumstances, which are explicitly discussed in the Act:

- SEP for Involuntary Loss of Creditable Prescription Drug Coverage.
- SEP for Individuals Not Adequately Informed about Creditable Prescription Drug Coverage.
- SEP for Enrollment/Non-enrollment in Part D due to an Error by a Federal Employee.
- SEP for Dual- and Other LIS-Eligible Individuals.
- SEP for MA–PD enrollee using the MA SEP65.

Section 1860D–1(b)(1)(B) of the Act directs us to adopt enrollment rules ''similar to (and coordinated with)'' those under Part C. Accordingly, in addition to those SEPs as previously described, we have applied certain SEPs established under the MA program to the Part D program. The SEPs from the MA program that have been codified for Part D include the following:

- SEP for Non-renewals or Terminations.
- SEP for Changes in Residence.
- SEPs for Contract Violation.

Section 1860D–1(b)(3)(C) of the Act also grants the Secretary the authority to create SEPs for individuals who meet other exceptional conditions, which is reflected at § 423.38(c)(8)(ii). Pursuant to this authority, we have previously codified SEPs for the following circumstances:

- SEP for Individuals Who Gain, Lose, or Have a Change in their Dual or LIS-Eligible Status.
- SEP for CMS and State-Initiated Enrollments.

CMS proposed to codify the following SEPs for exceptional circumstances, which are currently outlined in subregulatory guidance. Except as was noted in the proposed rule, our intent was to codify the current policy, and we solicited specific comment as to whether we overlooked any feature of the current policy that should be codified and if there were other exceptional circumstances we did not identify for which we should consider establishing a special election period.

We also proposed to revise § 423.40(c) to clarify that for SEPs that are described in § 423.38(c), elections are effective as of the first day of the first calendar month following the month in which the election is made, unless otherwise noted. In addition, we noted that, consistent with longstanding subregulatory guidance, the organization is not required to contact an applicant to confirm SEP eligibility if the enrollment request includes the applicant's attestation of SEP eligibility.

The proposed Part D SEPs are summarized below. (Readers should refer to the proposed rule for more detail on these SEPs.

SEP for Employer/Union Group Health Plan (EGHP) elections. At new § 423.38(c)(11), we proposed to codify that individuals making enrollment requests into or out of employer sponsored Part D plans (PDPs), for individuals to disenroll from a PDP to take employer sponsored coverage of any kind, and for individuals disenrolling from employer sponsored coverage (including COBRA coverage) would be eligible for a SEP to elect a PDP.

SEP for Individuals Who Disenroll in Connection with a CMS Sanction. At new § 423.38(c)(12), we proposed to codify the SEP for individuals enrolled in a PDP offered by a Part D plan sponsor that is sanctioned by CMS.

SEP for Individuals Enrolled in Cost Plans that are Non-renewing their Contracts. At new § 423.38(c)(13), we proposed to codify the SEP for individuals enrolled in cost plans that are non-renewing their contracts for the area in which the enrollee lives.

SEP for Individuals in the Program of All-inclusive Care for the Elderly (PACE). At new § 423.38(c)(14), we proposed to codify the SEP allowing individuals to disenroll from a PDP at any time in order to enroll in PACE.

SEP for Institutionalized Individuals. At new § 423.38(c)(15), we proposed to codify the SEP allowing individuals who move into, reside in, or move out of an institution, as defined at § 422.2, to enroll in or disenroll from a PDP.

SEP for Individuals Who Enroll in Part B during the Part B General Enrollment Period (GEP). At new § 423.38(c)(16), we proposed to codify the SEP for individuals who are not entitled to premium free Part A and who enroll in Part B during the GEP for Part B (January–March) for an effective date of July 1st to enroll in a PDP.

SEP for Individuals Who Belong to a Qualified SPAP or Who Lose SPAP Eligibility. At new § 423.38(c)(17), we proposed to codify a SEP for individuals who belong to a qualified SPAP to make one election to enroll in a Part D plan each calendar year.

SEP for Disenrollment from Part D to Enroll in or Maintain Other Creditable Coverage. At new § 423.38(c)(18), we proposed to codify the SEP that provides an opportunity for individuals to disenroll from a Part D plan in order to enroll in or maintain other creditable drug coverage (such as TriCare or VA coverage) as defined in § 423.56(b).

SEP for Individuals Disenrolling from a Cost Plan who also had the Cost Plan Optional Supplemental Part D Benefit. At new § 423.38(c)(19), we proposed to codify that individuals who disenroll from a cost plan and the cost plan's optional supplemental Part D benefit would have a SEP to enroll in a PDP.

SEP to Enroll in a PDP with a Star Rating of 5 Stars. At new § 423.38(c)(20), we proposed to codify the SEP allowing an eligible individual to enroll in a PDP with a Star Rating of 5 stars during the plan contract year in which that plan has the 5-star overall rating.

SEP for Non-U.S. Citizens who become Lawfully Present. At § 423.38(c)(21), we proposed to codify the SEP for non-U.S. citizens who become lawfully present in the United States.

SEP for Providing Individuals who Requested Materials in Accessible Formats Equal Time to Make Enrollment

Decisions. At § 423.38(c)(22), we proposed to codify the SEP in situations where the Part D plan sponsor or CMS was unable to provide required notices or information in an accessible format, as requested by an individual, within the same timeframe that it was able to provide the same information to individuals who did not request an accessible format.

SEP for Individuals Affected by a FEMA-Declared Weather Related Emergency or Major Disaster. At § 423.38(c)(23), we proposed to codify the SEP for individuals affected by a weather-related emergency or major disaster who were unable to make an election during another valid election period.

SEP for Individuals Enrolled in a Plan Placed in Receivership. We proposed to establish a new SEP, at new § 423.38(c)(31), for individuals enrolled in a Part D plan offered by a plan sponsor that is experiencing financial difficulties to such an extent that a state or territorial regulatory authority has placed the sponsor in receivership.

SEP for Individuals Enrolled in a Plan that has been Identified by CMS as a Consistent Poor Performer. We proposed to establish a new SEP, at new § 423.38(c)(32), for individuals who are enrolled in plans identified with the low performing icon (LPI) in accordance with § 423.186(h)(1)(ii).

SEP for Other Exceptional Circumstances. We proposed to retain the authority currently at § 423.38(c)(8)(ii) to create SEPs for individuals who meet other exceptional conditions established by CMS and move it to new § 423.38(c)(34).

Also based on the Secretary's authority to create SEPs for individuals who meet exceptional conditions, we proposed to codify the following SEPs currently outlined in manual instructions that coordinate with Part C election periods:

SEP for Individuals Who Terminated a Medigap Policy When They Enrolled For the First Time in an MA Plan, and Who Are Still in a Trial Period. We proposed to codify at new § 423.38(c)(24) a coordinating Part D SEP for individuals who disenrolled from their MA plan during their trial period (and have guaranteed issue rights).

SEP for an Individual using the MA Open Enrollment Period for Institutionalized Individuals (OEPI) to Disenroll from a MA–PD plan. At new § 423.38(c)(25), we proposed to codify that an individual disenrolling from an MA–PD plan has a SEP to request enrollment in a PDP.

Medicare Advantage Open Enrollment Period (MA OEP). At new § 423.38(c)(26), we proposed to codify that MA enrollees using the MA OEP would have a SEP to add or change Part D coverage.

SEP to request enrollment into a PDP after loss of special needs status or to disenroll from a PDP in order to enroll in an MA SNP. At new § 423.38(c)(27), we proposed to codify the SEP to request enrollment in a PDP for those who are no longer eligible for a SNP because they no longer meet the plan's special needs criteria.

SEP for Enrollment into a Chronic Care SNP and for Individuals Found Ineligible for a Chronic Care SNP. At proposed § 423.38(c)(28), we proposed to codify the SEP for both Part C and Part D for those individuals with severe or disabling chronic conditions to enroll in a Chronic Care SNP (C–SNP) designed to serve individuals with those conditions.

SEP for Individuals Using the 5-Star SEP to Enroll in a 5-Star Plan without Part D Coverage. At new § 423.38(c)(29), we proposed to codify that individuals who use the 5-star SEP we proposed to be codified at § 422.62(b)(15) to enroll in a 5-star MA plan that does not include Part D benefits or a 5-star cost plan would have a SEP to enroll in a PDP or in the cost plan's optional supplemental Part D benefit.

SEP to enroll in a PDP for MA enrollees using the ''SEP for Significant Change in Provider Network'' to disenroll from an MA Plan. We proposed to codify at new § 423.38(c)(30) that MA enrollees using the ''SEP for Significant Change in Provider Network'' to disenroll from an MA plan (proposed at § 422.62(b)(23)) would be able to request enrollment in a PDP.

The revisions we proposed would codify existing subregulatory guidance for SEPs that Part D sponsors have previously implemented and are currently following, except for the *SEP for Individuals Enrolled in a Plan Placed in Receivership* and the *SEP for Individuals Enrolled in a Plan that has been Identified by CMS as a Consistent Poor Performer.* We also proposed a few minor editorial changes in § 423.38(c), such as changing ''3'' to ''three.''

While most of the comments received on our SEP proposals related to SEPs that are applicable to both MA and Part D and, thus, were addressed above, we did receive one Part D-specific SEP comment.

Comment: While commenting on the proposed SEPs, a few commenters requested that we revisit the changes to the dual SEP finalized in April 2018 (83 FR 16514), when this SEP was changed from a monthly SEP to one that allows an individual to enroll in, or disenroll from, an MA plan once per calendar quarter during the first nine months of the year. A commenter stated that an ongoing SEP for dual eligible individuals to enroll in either a FIDE SNP or a HIDE SNP would provide greater choice and access to integrated care options. Other commenters believed these beneficiaries needed the flexibility to change their healthcare coverage at any time during the year and viewed the previous ongoing dual SEP as an important beneficiary protection.

Response: As we noted in the April 2018 final rule, we understood that many commenters preferred an ongoing dual SEP, but we believed that adopting limitations was an appropriate step toward encouraging care coordination, achieving positive health outcomes, and discouraging extraneous beneficiary movement during the plan year. We were—and continue to be—mindful of the unique health care challenges that dual and other LIS-eligible beneficiaries may face. Under the revised rules, dual and other LIS-eligible beneficiaries continue to have additional flexibilities not afforded to other Part D-eligible beneficiaries and are able to make elections during the year. Given that our overall goals of improving administration of benefits and coordination of care have not changed, and we believe that continuity of enrollment helps us achieve these goals, we will not be revising the dual SEP at this time.

After considering the public comments, we are finalizing all SEPs as proposed, with the exception of the following:

- The SEP for Individuals Affected by a FEMA-Declared Weather-Related Emergency or Major Disaster at § 423.38(c)(23) will be renamed the SEP for Government Entity-Declared Disaster or Other Emergency. This paragraph is being revised to change the scope of the SEP so that it applies to FEMA-declared emergencies/disasters, as well as disaster or other emergency declarations issued by a federal, state or local government entity. We are also specifying in this paragraph that the SEP will—
  - Start as of the date the declaration is made, the incident start date or, if different, the start date identified in the declaration, whichever is earlier; and
  - End 2 full calendar months following the end date identified in the declaration or, if different, the date the end of the incident is announced, whichever is later. This 2 month period

is consistent with other longstanding SEPs.

- As discussed in the MA SEP section, at § 423.38(c)(33) we are codifying the SEP for Individuals Involuntarily Disenrolled from an MA–PD plan due to loss of Part B. This SEP is currently in subregulatory guidance, but was inadvertently omitted from the proposed rule.
- We are designating the SEP for Other Exceptional Circumstances from proposed § 423.38(c)(33) to § 423.38(c)(34).

In addition, we are adopting without modification the minor editorial changes in § 423.38(c) and the changes proposed at § 423.40 regarding effective dates of the SEPs.

VI. Technical Changes

A. Advance Notice and Announcement of Part D Risk Adjustment Factors (§ 423.329)

The Part D statute, and the regulations implementing the statute, specify that we must publish the Part D risk adjustment factors at the time of publication of the Part C risk adjustment factors (section 1860D–15(c)(1)(D) of the Act and § 423.329(b)(4)). We proposed to amend § 423.329(b)(4) to stipulate our intention to publish Part D risk adjustment factors using the process through which we would adopt, and announce the capitation rates and risk adjustment methodology for the MA program (section 1853(b)(1)(B) of the Act and § 422.312(a)(1)(ii)).

The existing regulation codifying section 1860D–15(c)(1)(D) of the Act mirrors the statutory language of publishing Part D risk adjustment at the time of Part C risk adjustment factor publication but does not specify the means by which CMS will do so. In the vein of the MMA, which added a new ''Part D'' to the Medicare statute (sections 1860D–1 through 42 of the Act), and directed that important aspects of the Part D program be similar to, and coordinated with law for, the MA program, CMS interpreted section 1860D–15(c)(1)(D) of the Act to mean that Part D risk adjustment factors should be published as part of the Advance Notice and Rate Announcement process used for Part C (section 1853(b)(1)(B) of the Act and § 422.312(a)(1)(ii)). This amendment revises the regulation text to clarify our interpretation of the statute under which we will continue to publish Part D risk adjustment factors through the Advance Notice and Rate Announcement process. This final rule codifies the current interpretation of the statutory requirement and will not change how we propose and finalize the Part D risk adjustment model.

We did not receive comments on this proposal and therefore are finalizing this provision without modification.

B. Advance Notice and Announcement of Part C Annual Capitation Rate, Benchmarks, and Methodology Changes (§ 422.312)

In the February 18, 2020 proposed rule, we proposed a technical change to align the timeframes identified in § 422.312(b)(1) and (2) with the current statutory text (section 1853(b) of the Act). Section 1853(b) of the Act specifies the process through which we propose, adopt, and announce changes in risk adjustment methodology and capitation rates for the MA program. When first written, section 1853(b)(2) of the Act called for a 45-day advance notice period for the annual capitation rate and factors (for example, risk) used to adjust those rates and did not explicitly address a minimum comment period. However, the Securing Fairness in Regulatory Timing Act of 2015 (Pub. L. 114–106) (SFRTA) amended section 1853(b) of the Act to require a 60-day advance notice period and a 30-day comment period.

The regulation implementing the advance notice and comment period, as written, mirrors the statute's original timeframe for issuance of the advance notice and requires only a 15-day comment period. While CMS adjusted operational practices to comply with current statutory requirements, we did not update the CFR provision. In this final rule, we update the advance notice of changes in methodology requirements at § 422.312(b)(1) and (2) by revising paragraph (b)(1) to refer to 60 days and paragraph (b)(2) to refer to 30 days, as stated in statute.

Comment: A commenter supported the proposal to revise the timeframes to follow the current statute to provide a 60-day advance notice period and a 30-day comment period. The commenter believes the 60-day timeframe allows more time for analysis and comment on methodology changes, including risk adjustment in MA.

Response: We thank the commenter for their support. We are finalizing this provision as proposed without modification.

VII. Collection of Information Requirements

Under the Paperwork Reduction Act of 1995 (PRA) (44 U.S.C. 3501 *et seq.*), we are required to provide 60-day notice in the **Federal Register** and solicit public comment before a ''collection of information,'' as defined under 5 CFR 1320.3(c) of the PRA's implementing regulations, is submitted to the Office of Management and Budget (OMB) for review and approval. To fairly evaluate whether an information collection requirement 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.

In our February 18, 2020, proposed rule (85 FR 9002), we solicited public comment on our proposed information collection requirements, burden estimates, and assumptions. We did not receive any such public comments as it pertains to the proposed information collection requirements, burden estimates, and assumptions that are being finalized in this rule.

However, five changes were made to this section based on our further consideration of these issues:

- We have added section VII.B.1. of this final rule specifically addressing information collection requirements regarding SSBCI.
- Section VII.A. of this final rule reflects wage updates for 2019 as well as the differences between the 2019 and 2018 rates. The changes in Table 2 were then used to update the estimates for each of the provisions.
- As discussed more fully in section VII.B.3. of this final rule regarding the impact of the ESRD provision, CMS expects a shortened enrollment form to be available starting in 2021. This enrollment form is expected to reduce the time burden for completing an enrollment form from 30 minutes to 20 minutes. This reduction affects the impacts of several provisions in this section.
- As discussed in the next few paragraphs, and as further detailed in the provisions whose impact is estimated in this section, the implementation of certain provisions finalized in this rule will be delayed compared to the proposal. This has resulted in recalculations that are specific to several provisions and discussed as appropriate in the respective sections.
- The implementation date for the contract limitation on existing D–SNP look-alikes finalized in § 422.514(d) has been delayed one year, as discussed in

section II.B of this final rule. As a result, we assume that the burden related to this provision will take place over the two years prior to the implementation rather than one year, as we assumed in the proposed rule. The details are provided later in this section.

- This final rule does not finalize all provisions in the proposed rule. Given the need to focus our attention on more immediate regulatory actions, this final rule implements a subset of the provisions that were proposed in the February 2020 proposed rule. In this regard, we are limiting this rule to this set of provisions. The remaining proposals will be addressed in a separate final rule that we expect to publish later in 2020. Thus, the collection of information requirements are expected to be addressed as follows:
- Rule Number 1: PRA-related Requirements/Burden Finalized in this Rule
  - ++ Special Supplemental Benefits for the Chronically Ill (SSBCI) (§ 422.102)
  - ++ Contracting Standards for Dual Eligible Special Needs Plan (D–SNP) Look-Alikes (§ 422.514)
  - ++ Medicare Advantage (MA) Plan Options for End-Stage Renal Disease (ESRD) Beneficiaries (§§ 422.50, 422.52, and 422.110)
  - ++ Medical Loss Ratio (MLR) (§ 422.2440)
  - ++ Special Election Periods (SEPs) for Exceptional Conditions (§§ 422.62 and 423.38)
- Rule Number 2: PRA-related Requirements to be Addressed Later in 2020
  - ++ Improvements to Care Management Requirements for Special Needs Plans (SNPs) (§ 422.101)
  - ++ Mandatory Drug Management Programs (DMPs) (§ 423.153)
  - ++ Beneficiaries with History of Opioid-Related Overdose Included in Drug Management Programs (DMPs) (§ 423.100)
  - ++ Eligibility for Medication Therapy Management Programs (MTMPs) (§ 423.153) and Information on the Safe Disposal of Prescription Drugs
  - ++ Beneficiaries' Education on Opioid Risks and Alternative Treatments (§ 423.128)
  - ++ Suspension of Pharmacy Payments Pending Investigations of Credible Allegations of Fraud and Program Integrity Transparency Measures (§§ 405.370, 422.500, 422.503, 423.4, 423.504, and 455.2)
  - ++ Beneficiary Real Time Benefit Tool (RTBT) (§ 423.128)
  - ++ Establishing Pharmacy Performance Measure Reporting Requirements (§ 423.514)
  - ++ Service Delivery Request Processes under PACE (§§ 460.104 and 460.121)
  - ++ Appeals Requirements under PACE (§§ 460.122 and 460.124)
  - ++ Documenting and Tracking the Provision of Services under PACE (§ 460.98)
  - ++ Documentation in Medical Records under PACE (§ 460.210)
  - ++ PACE Participant Rights: Contact Information and Access Requirements (§ 460.112)
  - ++ Stipulated Decisions in Part C (§ 422.562)

A. Wage Data

To derive average costs, we are using data from the U.S. Bureau of Labor Statistics' (BLS's) May 2019 National Occupational Employment and Wage Estimates for all salary estimates (*http://www.bls.gov/oes/current/oes_nat.htm*). In this regard, Table 1 presents the mean hourly wage, the cost of fringe benefits and overhead (calculated at 100 percent of salary), and the adjusted hourly wage.

TABLE 1—NATIONAL OCCUPATIONAL EMPLOYMENT AND WAGE ESTIMATES

Occupation title	Occupation code	Mean hourly wage ($/hr)	Fringe benefits and overhead ($/hr)	Adjusted hourly wage ($/hr)
Actuaries	15–2011	58.16	58.16	116.32
All Occupations [used for impact on enrollees filling out forms].	00–0000	25.72	n/a	n/a
Business Operations Specialist, all others	13–1198	38.57	38.57	77.14
Compliance Officer	13–1041	35.03	35.03	70.06
Computer Programmers	15–1251	44.53	44.53	89.06
General Operations Manager	11–1021	59.15	59.15	118.30
Health Technician, All Other	29–9098	28.17	28.17	56.34
Office Support and Administrative Support	43–9199	18.41	18.41	36.82
Physician	29–1216	96.85	96.85	193.70

As indicated, we are adjusting our employee hourly wage estimates by a factor of 100 percent. This is necessarily a rough adjustment, both because fringe benefits and overhead costs vary significantly from employer to employer and because methods of estimating these costs vary widely from study to study. We believe that doubling the hourly wage to estimate total cost is a reasonably accurate estimation method.

Wages for Individuals: For beneficiaries, we believe that the burden will be addressed under All Occupations (at $25.72/hr) since the group of individual respondents varies widely from working and nonworking individuals and by respondent age, location, years of employment, and educational attainment, etc. Unlike our private sector wage adjustment, we are not adjusting this figure for fringe benefits and overhead since the individuals' activities will occur outside the scope of their employment.

Revised Wage and Cost Estimates: While our proposed rule's costs were based on BLS's May 2018 wages, this final rule uses BLS's May 2019 wages which are the most current as of the publication date of this rule. Changes to the adjusted wages represent shifts in average wages of occupations between 2018 and 2019 and are presented in Table 2. This table only contains wage estimates for occupations used in both the proposed rule and this final rule. However, provisions which were not estimated in the proposed rule but were estimated in the final rule require consideration of additional occupational titles beyond those in this table.

TABLE 2—COMPARISON OF PROPOSED AND FINALIZED ADJUSTED HOURLY WAGES

Occupation title	Occupation code	CMS–4190–P: May 2018 ($/hr)	CMS–4190–F: May 2019 ($/hr)	Difference ($/hr)
Actuaries	15–2011	111.78	116.32	+4.54
All Occupations *	00–0000	24.98	25.72	+0.74
Business Operations Specialist, all others	13–1198	74.00	77.14	+3.14
Compliance Officer	13–1041	69.72	70.06	+0.34
Computer Programmers	15–1251	86.14	89.06	+2.92
General Operations Manager	11–1021	119.12	118.30	−0.82
Health Technician, All Other	29–9098	50.90	56.34	+5.44
Office Support and Administrative Support	43–9199	36.04	36.82	+0.78
Physician	29–1216	202.86	193.70	−9.16

* Represents the mean hourly rate for individuals which, as explained above, is not adjusted for fringe benefits and overhead.

B. Information Collection Requirements (ICRs)

The following ICRs are listed in the order of appearance within the preamble (see sections II through VI) of this final rule.

1. ICRs Regarding Special Supplemental Benefits for the Chronically Ill (SSBCI) (§ 422.102)

As explained in section II.A. of this final rule, CMS is finalizing provisions for furnishing SSBCI. In section II.A. of this final rule, CMS adopts a regulation to implement section 1852(a)(3)(D) of the Act, which authorizes MA plans to furnish special supplemental benefits exclusively to chronically ill enrollees, as defined in the statute. SSBCI are currently allowed in 2020.

In this final rule, we are finalizing four SSBCI provisions with paperwork burden. We are finalizing the proposed requirements at § 422.102(f)(3) requiring MA plans offering SSBCI to: (i) Develop written policies for determining enrollee eligibility and document the determination that an enrollee is a chronically ill enrollee based on the definition in statute and regulation; (ii) make information and documentation related to determining enrollee eligibility available to CMS upon request; (iii) have written policies based on objective criteria for determining a chronically ill enrollee's eligibility to receive a particular SSBCI and document these criteria; and (iv) document each determination that an enrollee is eligible to receive an SSBCI and make this information available to CMS upon request. We address the collection of information in a reorganized fashion to address the functions that are required by the regulation as a whole rather than by how the regulation is structured and codified. We address these required MA organization functions and activities as follows:

In this final rule, we are finalizing four SSBCI provisions with paperwork burden. We are finalizing the proposed requirements at § 422.102(f)(3)(i) through (iv) requiring MA plans offering SSBCI to:

(1) Have written policies for determining enrollee eligibility to be considered chronically ill and must have written policies based on objective criteria for determining a chronically ill enrollee's eligibility to receive a particular SSBCI;

(2) document in writing the criteria for determining enrollee eligibility for being considered chronically ill and must also document in writing the enrollee's eligibility to receive a particular SSBCI;

(3) Make information and documentation related to determining enrollee eligibility available upon request;

(4) document each determination that an enrollee is eligible to receive an SSBCI, and make information concerning enrollee eligibility criteria available to CMS.

In this section, we estimate the paperwork burden of each of these four functions required by the final regulation. The following changes will be submitted to OMB for approval under control number 0938–0763 (CMS–R–262).

a. Per § 422.102(f)(3)(i), plans must have written policies for determining enrollee eligibility to be considered chronically ill and, per paragraph (f)(3)(iii), must have written policies based on objective criteria for determining a chronically ill enrollee's eligibility to receive a particular SSBCI.

Since the authority to offer and cover SSCBI is already being implemented, we assume most MA organizations already have developed the required policies since it would be difficult to score the cost in their bids without having such policies. We similarly assume that most plans have internal written memos documenting these criteria and that they have updated their systems to record enrollee eligibility for SSBCI (since without such documentation they would have no way of knowing when to reimburse providers for furnishing SSBCI to enrollees).

Therefore, this provision codifies existing practice.

However, even though we expect that the policies have already been developed, we have inadvertently neglected to account for the requirement and burden in any of our collection of information requests. We are correcting this oversight via this proposed and final rulemaking activity.

We estimate that it will take a team of one compliance officer (at $70.06/hr), one physician (at $193.70/hr), and one general operations manager (at $118.30/hr) a total of 5 hours to develop the necessary policies. The team's hourly cost is $382.06/hr ($70.06/hr + $193.70/hr + $118.30/hr). In aggregate, the annual burden for 234 parent organizations is 1,170 hours (234 plans * 5 hrs) at a cost of $447,010 (1,170 hr * $382.06/hr) or $1,910 ($447,010/234) per organization.

This is an annual requirement/burden since plan packages renew each year and the SSBCI criteria must therefore be reevaluated, including confirmation of existing criteria, each year.

b. Per § 422.102(f)(3)(i), plans must also document in writing those criteria for determining enrollee eligibility for being considered chronically ill and, per § 422.102(f)(3)(iii), must also document in writing the enrollee's eligibility to receive a particular SSBCI.

We estimate it will take 2 hours at $56.34/hr for a health technician to document in writing the objective criteria for determining an enrollee's eligibility to be considered chronically ill and to be eligible to receive a particular SSBCI. In aggregate, we estimate an annual burden of 468 hours (234 plans * 2 hr/plan) at a cost of $26,367 (468 hrs * $56.34/hr) or $113 per plan.

This is an annual requirement/burden since documentation must be performed each contract year.

c. Per § 422.102(f)(3)(iv), plans must also document each determination that an enrollee is eligible to receive an SSBCI and make this information available to CMS upon request. To date, MA organizations have only been able to include non-primarily health related SSBCI in the plan offerings since January 1, 2020, during one contract year (that is, 2020). While early indications show that utilization for these benefits have been low, we expect the use of these benefits to grow over time as MA organizations become more familiar with them and have time to include them in future plan offerings. Thus, our data is not indicative of future usage.

To offer SSBCI, a plan must determine, as defined in legislation, that an enrollee is chronically ill and that the items or services furnished under the SSBCI have a reasonable expectation of improving or maintaining the health or overall function of the chronically ill enrollee. This determination would require a review of the enrollee's health records (for example, diagnosis codes, frequency of hospitalizations, and doctor's notes) as well as a determination and review by plan medical staff that the SSBCI has a reasonable expectation of improving or maintaining the health or overall function of the chronically ill enrollee.

Thus the process may be partially automated with the remainder of the process requiring medical review. We accordingly must account for three contributions to total impact:

(1) Initial creation of software, annualized over 3 years: Initially, software will be created to collect basic data elements (claims, diagnoses, hospitalizations, drug utilization) for physician review. We expect a team of three professionals: A compliance officer would identify categories of eligible SSBCI, the physician would identify needed data elements for review, and the computer programmer would automate this part of the process. We expect a burden of 2,808 hours (234 parent organizations times 12 hours (8 hours for a programmer plus 2 hours for a compliance officer plus 2 hours for a physician)) at an annualized cost of $96,717 ((⅓) times 2808 hours times a team wage of $103.33/hr ([8 hours times $89.06 (computer programmer) + (2 hours times 70.06 (compliance officer) + (2 hours times $193.70 (physician))]/12).

(2) Annual physician review of cases: We expect ongoing plan physician review in all years (including the first) to ascertain if the SSBCI is expected to have the desired impact on enrollees. We assume 3 hours of review per month per parent organization, resulting in 36 hours per parent organization per year. In aggregate, we expect a burden of 8,424 hours (234 parent organization times 36 hours per parent organization) at an annual burden of $1,631,729 (8,424 hours times $193.70/hr, physician wage).

(3) Annual update of software: It would clearly be overly burdensome to review each SSBCI case. Thus as cases are reviewed, we expect the continual review of new cases to generate additional criteria that can be automated. We assume half the time for updates as for the initial first-year creation. We assume a burden of 1,170 hours (234 parent organizations times 5 hours (1 hour for a compliance officer plus 4 hours for a computer programmer) at a cost of $99,754 (1170 hours times a team wage of $85.26/hr ([4 hours times $89.06 (computer programmer) plus 1 hour times $70.06 (compliance officer)]/5). Table 3 summarizes all burdens connected with SSBCI.

(4) Make information concerning enrollee eligibility criteria available to CMS.

We are not requiring MA plans to report or submit this information on a regular or consistent basis to CMS. We do not intend to closely monitor or regularly request this documentation and reiterate that MA plans will have discretion in designing which items and services to offer as SSBCI and for which chronically ill enrollees to cover them, so long as the statutory and regulatory standards are met. CMS intends to use this authority to collect information as necessary for program oversight, such as if there are specific, consistent, and/or severe complaints that an MA plan is violating the rules set forth in § 422.102(f). Based on our experience with serious plan complaints, we anticipate requesting no more than 5 plans per year to complete this task. Consequently, since this provision is expected to affect less than 10 entities per year, it is exempt from paperwork burden (5 CFR 1320.3(c)(4)). Table 3 summarizes the various burdens associated with SSBCI.

TABLE 3—SUMMARY OF BURDEN FOR SSBCI AT § 422.102

Provision	Regulatory citation	OMB Control No.	Subject	Number of respondents	Total number of responses	Time per response (hr)	Total time (hr)	Labor cost ($/hr)	Annual cost ($)
SSBCI	422.102(f)(3)(i)		SSBCI: Criteria (Initial Software).	234	1	12	2808	103.33	96,717
SSBCI	422.102(f)(3)(i)		SSBCI: Criteria (Physician review).	234	1	36	8424	193.7	1,631,729
SSBCI	422.102(f)(3)(i)		SSBCI: Criteria (Software updates).	234	1	5	1170	85.26	99,754
SSBCI	422.102(f)(3)(ii)		Written criteria	234	1	2	468	56.34	26,367
SSBCI	422.102(f)(3)(iii)		Enrollee eligibility	234	1	9	2106	86.95	179,465
Total				234		Varies	14,976		2,034,032

2. ICRs Regarding Contracting Standards for Dual Eligible Special Needs Plan (D–SNP) Look-Alikes (§ 422.514)

The following changes will be submitted to OMB for approval under control numbers 0938–0753 (CMS–R–267) and 0938–NEW (CMS–10718). The requirements under CMS–R–267 are associated with burden on MA plans identified as D–SNP look-alikes under § 422.514(d) and (e) (see section VII.B.1.a. of this final rule). The requirements under CMS–10718 are associated with burden on the enrollees in these MA plans (see section VII.B.1.b. of this final rule).

We did not receive any comments on our proposed collection of information requirements and burden estimates; however, we are updating our proposed burden estimates to reflect the change in this final rule delaying the prohibition on the renewal of existing D–SNP look-alikes by one year. As indicated above in section VII.A. of this final rule, we have also revised our proposed cost figures based on more recent BLS wage estimates.

As described in section II.B. of this final rule, we are establishing new contract requirements that we believe are necessary to fully implement federal D–SNP requirements, especially those related to Medicare-Medicaid integration codified at §§ 422.2, 422.107, and 422.629 through 422.634 pursuant to the BBA of 2018. We are finalizing a prohibition on CMS entering into a new contract for plan year 2022 and future years for any non-SNP MA plan that projects in its bid submitted under § 422.254 that 80 percent or more of the plan's total enrollment are enrollees entitled to medical assistance under a state plan under Title XIX of the Act. Additionally, we are finalizing a prohibition for plan year 2023 and future years on CMS renewing an existing contract for any non-SNP MA plan that an MA organization offers that has actual enrollment, as determined by CMS in January of the current year, consisting of 80 percent or more of enrollees who are entitled to medical assistance under a state plan under title XIX of the Act, unless the MA plan has been active for less than 1 year and has enrollment of 200 or fewer individuals at the time of such determination.

Our dually eligible enrollment threshold at § 422.514(d) will apply to any plan that is not a SNP as defined in § 422.2. We are applying this requirement only to non-SNP plans to allow for the disproportionate dually eligible enrollment that characterizes D–SNPs, institutional SNPs, and some chronic or disabling condition SNPs by virtue of the populations that the statute expressly permits each type of SNP to exclusively enroll. The requirement is also limited to states where there is a D–SNP or any other plan authorized by CMS to exclusively enroll dually eligible individuals, such as a Medicare-Medicaid Plan (MMP). We are establishing this limitation because it is only in such states that the implementation of D–SNP requirements necessitates our new contracting requirements. That is, in a state with no D–SNP or comparable managed care plan, the D–SNP requirements have not had any relevance historically, and therefore the operation of a D–SNP look-alike does not have any material impact on the full implementation of federal D–SNP requirements.

The contract requirement based on the projected enrollment in the plan bid at § 422.514(d)(1) will prevent MA organizations from designing new D–SNP look-alikes. Under at § 422.514(d)(2), we will make the determination whether an MA organization has an existing non-SNP MA plan with actual enrollment exceeding the established threshold using the enrollment in January of the current year. Using data from the most recently available contract year, the 2020 bid submission process, we estimate that there are 67 MA plans that have enrollment of dually eligible individuals that is 80 percent or more of total enrollment. Of these 67 MA plans, 62 plans are in 19 states [53] where there are D–SNPs or comparable managed care plans and will be subject to § 422.514(d). These 62 plans projected a total enrollment of 180,758 for contract year 2020.

MA organizations will likely non-renew for plan year 2022 or 2023 those plans that exceed our criteria in § 422.514(d)(1) and (2). The MA organization has the opportunity to make an informed business decision to transition enrollees into another MA–PD plan (offered by it or by its parent organization) by: (1) Identifying, or applying and contracting for, a qualified MA–PD plan, including a D–SNP, in the same service area; or (2) creating a new D–SNP through the annual bid submission process. We expect the vast majority of D–SNP look-alike enrollees to be transitioned into a plan offered by the same parent organization as the D–SNP look-alike, and we expect in rare instances that the non-renewing plan may choose to not transition enrollees.

The changes required of MA organizations based on this final rule impact D–SNP look-alikes (see section VII.B.1.a. of this final rule) and their enrollees (see section VII.B.1.b. of this final rule). While we cannot predict the actions of each affected MA organization with 100 percent certainty, we base our burden estimates on the current landscape of D–SNP look-alikes, the availability of D–SNPs or MA–PD plans under the same parent organization in the same service area, and the size and resources of the MA organization.

a. MA Plan Requirements and Burden

As indicated, the following changes will be submitted to OMB for approval under control number 0938–0753 (CMS–R–267). Subject to renewal, the control number is currently set to expire on December 31, 2021.

At § 422.514(e), we are finalizing a process for an MA organization with a D–SNP look-alike to transition individuals who are enrolled in its D–SNP look-alike to another MA–PD plan offered by the MA organization, or by another MA organization with the same parent organization as the MA organization, to minimize disruption as a result of the prohibition on contract renewal for existing D–SNP look-alikes. Under this final rule, an MA organization with a non-SNP MA plan determined to meet the enrollment threshold in § 422.514(d)(2) could transition enrollees into another MA–PD plan offered by the same MA organization (or by another MA organization with the same parent organization as the MA organization), as long as that receiving MA–PD plan meets certain criteria specified in § 422.514(e)(1)(i)–(iv). The process finalized at § 422.514(e) allows, but does not require, the MA organization to transition dually eligible enrollees from D–SNP look-alikes into D–SNPs and other qualifying MA–PD plans for which the enrollees are eligible without the transitioned enrollees having to complete an election form. This transition process is conceptually similar with the proposed ''crosswalk exception'' procedures at § 422.530(a) and (b) as described in the proposed rule; however, this final rule allows the transition process to apply across contracts or legal entities and from non-SNP to SNPs provided that the receiving plan is otherwise be of the same plan type (for example, HMO or PPO) as the D–SNP look-alike.

While the contract limitation for existing D–SNP look-alikes begins in the 2023 plan year, we intend for the transition process to take effect in time for D–SNP look-alikes operating in 2020 and 2021 to utilize the transition process for enrollments effective January 1, 2021 or January 1, 2022, respectively. Based on the current landscape for D–SNP look-alikes, we believe the vast majority of D–SNP look-alikes are able to move current enrollees into another MA–PD plan using the transition process we are finalizing in this rule. We expect many of these plans will choose to transition membership for the 2022 and 2023 plan years. Therefore, we are assuming the burden of the 62 plans transitioning enrollees will happen for half the plans in 2021 (for a 2022 effective date) and half the plans in 2022 (for a 2023 effective date).

We estimate each plan will take a one-time amount of 2 hours at $77.14/hr for a business operations specialist to submit all enrollment changes to CMS necessary to complete the transition process. D–SNP look-alikes that transition enrollees into another non-SNP plan will take less time than D–SNP look-alikes that transition eligible beneficiaries into a D–SNP because they will not need to verify enrollees'

[53] These 62 plans are located in Arizona, Arkansas, California, Hawaii, Idaho, Illinois, Indiana, Louisiana, Michigan, Mississippi, New Jersey, New Mexico, North Carolina, Ohio, Oregon, South Carolina, Tennessee, Utah, and Washington.

Medicaid eligibility. The 2-hour time estimate accounts for any additional work to confirm an enrollee's Medicaid eligibility for D–SNP look-alikes transitioning eligible enrollees to a D–SNP. The burden for MA organizations to transition enrollees to other MA–PD plans during the 2021 and 2022 plan years is 124 hours (62 D–SNP look-alikes * 2 hr/plan) at a cost of $9,565 (124 hr * $77.14/hr). We averaged this burden for the 62 plans over the 2021 and 2022 plan years, resulting in an annual burden of 62 hours (124 hr/2 yr) at a cost of $4,783 ($9,565/2 yr).

The vast majority of MA organizations with existing D–SNP look-alikes also have an MA–PD plan with a premium of $0 or a D–SNP in the same service area as the D–SNP look-alike. Consequently, we do not believe many MA organizations will choose to create a new D–SNP as a result of this final rule. The prevalence of existing MA–PD plans and D–SNPs also makes it unlikely that an MA organization will need to expand a service area for an existing MA–PD plan or D–SNP. Therefore, we do not expect this provision to have further impact beyond the currently burden approved under control number 0938–0935 (CMS–10237) for creating a new MA–PD plan or D–SNP and expanding a service area.

As finalized in § 422.514(e)(2)(ii), the MA organization will be required to describe changes to MA–PD plan benefits and provide information about the MA–PD plan into which the individual is enrolled in the Annual Notice of Change (ANOC) that the MA organization must send, consistent with § 422.111(a), (d), and (e). Consistent with § 422.111(d)(2), enrollees will receive this ANOC describing the change in plan enrollment and any differences in plan enrollment at least 15 days prior to the first day of the annual election period (AEP). As each MA plan must send out the ANOC to all enrollees annually, we do not estimate that MA organizations will incur additional burden for transitioned enrollees. The current burden for the ANOC is approved under control number 0938–1051 (CMS–10260).

Additionally, we do not expect any plans will be required to send affected enrollees a written notice consistent with the non-renewal notice requirements at § 422.506(a)(2) and described at § 422.514(e)(4), as we anticipate all MA organizations with D–SNP look-alikes will be able to transition their enrollees into another MA–PD plan (or plans). However, we are finalizing the requirement to ensure protection of enrollees if the situation does occur.

In subsequent years (2023 and beyond), we estimate that at most five plans per year will be identified as D–SNP look-alikes under § 422.514(d) due to meeting the enrollment threshold for dually eligible individuals or operating in a state that will begin contracting with D–SNPs or other integrated plans. We believe that these plans would non-renew and transition their membership into another MA–PD plan or a D–SNP. Therefore, the annual burden for the 2023 plan year and subsequent years is estimated at 10 hours (5 plans * 2 hr/plan) at a cost of $771 (10 hr * $77.14/hr) for a business operations specialist to transition enrollees into a new MA–PD plan.

The average annual burden for MA plans over three years is 45 hours ([62 hr + 62 hr + 10 hr]/3 yr) at a cost of $3,446 ([$4,783 + $4,783 +$771]/3 yr). The impact is summarized in Table 4.

b. MA Plan Enrollee Requirements and Burden

The following changes will be submitted to OMB for approval under control number 0938–NEW (CMS–10718). The control number for CMS–10718 has yet to be issued. The status of OMB's review/approval can be monitored at *https://www.reginfo.gov/public/do/PRAViewICR?ref_nbr=202003-0938-002.*

Section 422.514(e)(2) allows any individual transitioned from a D–SNP look-alike to another MA–PD plan to stay in the MA–PD plan receiving the enrollment or make a different election. The enrollees may choose new forms of coverage for the following plan year, including a new MA–PD plan or receiving services through the original Medicare fee-for-service program option and enrollment in a stand-alone Prescription Drug Plan (PDP). Because the enrollment transition process will be effective on January 1 and notices would be provided during the AEP, affected individuals have opportunities to make different plan selections through the AEP (prior to January 1) or the Medicare Advantage Open Enrollment Period (after January 1). Affected individuals may also qualify for a Special Election Period (SEP), such as the SEP for plan non-renewals at § 422.62(b)(1) or the SEP for dually eligible/LIS beneficiaries at § 423.38(c)(4).

Based on our experience with passive enrollment of dually eligible beneficiaries into a new plan under the same parent organization for MMPs in the Financial Alignment Initiative, we estimate that one percent of the 180,758 transitioning D–SNP look-alike enrollees will select a new plan or the original Medicare fee-for-service program and PDP option rather than accepting the transition into a different MA–PD plan or D–SNP under the same MA organization as the D–SNP look-alike in which they are currently enrolled. We estimate that 1,808 enrollees (180,758 transitioning D–SNP look-alike enrollees * 0.01), will opt out of the new plan into which the D–SNP look-alike transitioned them. Consistent with the burden estimates under the aforementioned control number, the enrollment process requires 20 minutes (0.3333 hours) and remains unchanged. For this final rule, the total added burden for enrollees will be 603 hours (1,808 enrollees * 0.3333 hr/response) at a cost of $15,509 (603 hr * $25.72/hr). We are averaging this burden over the 2021 and 2022 plan years, resulting in an annual burden of 302 hours (603 hr/2 yr) at a cost of $7,755 ($15,509/2 yr).

As stated previously, we believe that in subsequent years (2023 and beyond), at most five plans will be identified as D–SNP look-alikes and therefore this final regulation would have a much smaller impact on MA enrollees after the initial period of implementation. Since the current 62 D–SNP look-alike plans have 180,758 enrollees in 62 plans, we estimate 14,577 enrollees (180,758 enrollees * 5/62 plans) in 5 plans. Therefore, the maximum number of enrollees affected per year is estimated to be 146 enrollees (14,577 total enrollees estimated in five plans * 0.01 who would select another plan). This would amount to a maximum annual burden of 49 hours (146 enrollees * 0.3333 hr) at a cost of $1,260 (49 hr * $25.72/hr).

The average annual enrollee burden over three years is therefore 218 hours ([302 hr + 302 hr + 49 hr]/3 yr) at a cost of $5,590 ([$7,755 + $7,755 + $1,260]/3yr). The estimates are summarized in Table 4.

c. Burden Summary

The burden for the provisions are summarized in Table 4.

TABLE 4—SUMMARY OF BURDEN ESTIMATES FOR CONTRACT REQUIREMENTS AT § 422.514

Respondents	Subject	OMB Control No. (CMS ID No.)	2021	2022	2023	3-year average
MA organization	Transition enrollees (§ 422.514(e)).	0938–0753 (CMS–R–267).	$4,783 (62 hr).	$4,783 (62 hr).	$771 (10 hr)	$3,446 (45 hr)
Beneficiaries	Enrollment request (§ 422.514(e)).	0938–NEW (CMS–10718)	$7,755 (302 hr).	$7,755 (302 hr).	$1,260 (49 hr).	$5,590 (218 hr)
Total			$12,538 (364 hr).	$12,538 (364 hr.	$2,031 (59 hr).	$9,036 (263 hr)

3. ICRs Regarding Medicare Advantage (MA) Plan Options for End-Stage Renal Disease (ESRD) Beneficiaries (§§ 422.50, 422.52, and 422.110)

As discussed in section III.A. of this final rule, we are revising §§ 422.50(a)(2), 422.52(c), and 422.110(b) to allow ESRD beneficiaries, without any limitation not otherwise applicable for enrollment in the MA program to enroll in an MA plan. In estimating the impact of this provision, we are required to separately estimate impact on beneficiaries and plans. Enrollment processing and notification requirements codified at § 422.60, are not being revised as part of this rulemaking, and no new or additional information collection requirements are being imposed.

Additionally, as explained in section VIII.D.1 of this final rule, OACT has already incorporated an increase in ESRD enrollment in the Medicare Trust Fund baseline due to the legislation. Therefore, there is no need to estimate plan burden. However, the burden to enrollees for completing enrollment forms has not been incorporated into the OACT baseline and therefore is estimated later in this section.

We did not receive any public comments on our proposed requirements. In the proposed rule, beneficiary burden was estimated using the ''long'' enrollment form that is currently approved by OMB under control number 0938–0753 (CMS–R–267). Based on internal review, in this final rule, the beneficiaries will instead, be completing a new, ''shortened'' form (OMB control number 0938–NEW (CMS–10718)) for enrollment into MA plans beginning with the 2020 AEP, for a January 1, 2021 effective date. The new ''shortened'' enrollment form, which is three pages in length, (compared to the current model form which is seven pages), limits the data collection to the minimum that is lawfully required to process the enrollment and other limited information that the sponsor is required to, or chooses to, provide to the beneficiary.

As indicated in the beginning of this section, the shortened form has been subject to the standard non-rule PRA process (see 84 FR 63655 (November 18, 2019), 84 FR 64319 (November 21, 2019), and 85 FR 13163 (March 6, 2020)) and is currently under OMB review.

In this final rule, we are correcting our proposed beneficiary burden estimates by considering the completion of the shortened enrollment form (CMS–10718) in lieu of (CMS–R–267). As indicated in section VII.A. of this final rule, we have also revised our proposed cost figures based on more recent BLS wage estimates.

To elect a MA plan, an individual must complete and sign an election form, complete another CMS-approved election method offered by the MA plan, or call 1–800–MEDICARE, and provide information required for enrollment. Regardless of the enrollment mechanism, similar identifying information is collected by the MA plan to process the enrollment.

Although not effective until January 1, 2021, section 17006 of the Cures Act amends the Act by allowing ESRD beneficiaries, without any limitation not otherwise applicable for enrollment in the MA program, to enroll in an MA plan. The burden is associated with the effort for an ESRD beneficiary seeking to enroll in a MA plan to complete an enrollment request. Because there will be an increase in the number of beneficiaries eligible to elect an MA plan starting in plan year 2021, the number of beneficiaries who are expected to initiate an enrollment action will increase. However, the erroneous per response time estimate of 30 minutes (0.5 hr) (CMS–R–267) that was set out in our proposed rule will decrease to 20 minutes (0.3333 hr) per response based on beneficiary completion of the new, shortened enrollment form (CMS–10718)).

As detailed in section VIII.D.1. of this final rule, OACT estimates an average increase of 59,000 ESRD beneficiaries to enroll in MA plans per year in 2021 through 2023. Therefore, we expect an average annual burden of 19,665 hours (59,000 new ESRD enrollees * 0.3333 hr) at a cost of $505,784 (19,665 hr * $25.72/hr).

4. ICRs Regarding Medical Loss Ratio (MLR) (§ 422.2440)

MSA Enrollment

The anticipated changes affecting MSA enrollment will be submitted to OMB for approval under control number 0938–0753 (CMS–R–267). Subject to renewal, the control number is currently set to expire on December 31, 2021. We did not receive any comments pertaining to our proposed requirements or burden estimates. However, based on internal review, we have updated our proposed time to complete the enrollment form and adjusted (increased) our enrollment figures to better reflect implementation in 2022–2024. As indicated above in section VII.A. of this final rule, we have also revised our proposed cost figures based on more recent BLS wage estimates.

As discussed in section IV.D.4. of this rule, we are finalizing our proposal to amend § 422.2440 to provide for the application of a deductible factor to the MLR calculation for MA MSA contracts that receive a credibility adjustment. The deductible factor would serve as a multiplier on the credibility factor. The application of the deductible factor would increase the MLRs of MSA contracts that receive this adjustment.

We believe that the change to the MLR calculation for MSAs could potentially cause the number of enrollees in MSA plans to increase relative to enrollment projections under the current regulations because we expect more MA organizations to offer MA MSA plans based on this change in the MLR calculation. Consistent with the proposed rule, for this impact estimate, we assume the following:

- Enrollment in MSAs will double over the first 3 years that the change is in effect. We believe 3 years is a reasonable time frame for the enrollment changes resulting from this policy to be phased in. We project that enrollment will double in order to avoid potentially understating the cost for the

proposal. Our estimate is based on the largest potential change in enrollment that we could reasonably anticipate. We acknowledge that the change could have no impact on enrollment.

- Relative to projections in the baseline, MSA enrollment will be 33.33 percent higher in contract year 2022 (increasing from 7,812 to 10,416), 66.67 percent higher in 2023 (increasing from 8,179 to 13,632), and 100 percent higher in contract year 2024 (increasing from 8,531 to 17,062) to contract year 2030 (increasing from 10,354 to 20,708).
- Half of the new enrollees in MA MSA plans would otherwise have been enrolled in other types of MA plans, and half would otherwise have been enrolled in FFS Medicare. We did not have a basis for assuming whether migration to MSAs would predominantly be from FFS Medicare or from non-MSA MA plans.

The process for enrolling in an MA plan is the same regardless of whether that plan is an MSA or a non-MSA. Therefore, we assume that the burden to enroll in an MSA plan and a non-MSA plan is the same. Therefore, the increased burden related to changes in MSA enrollment is attributable only to the portion of potential new MSA enrollees who would be expected to enroll in (or remain in) FFS Medicare if the proposal were not finalized. The cost burden of the provision is summarized in Table 5.

a. Beneficiary Requirements and Burden

For beneficiaries, the burden associated with the expected increase in MSA enrollment as a consequence of the addition of a deductible factor to the MSA MLR calculation is related to the effort it takes for a beneficiary to complete an enrollment request. It takes 0.5 hours at $25.72/hr for a beneficiary to complete an enrollment form. We assume no burden increase for the estimated 50 percent of additional MSA enrollees who would otherwise be enrolled in a non-MSA MA plan. For 2022, the burden for all beneficiaries is estimated at 434 hours (2,604/2 beneficiaries * 0.3333 hr) at a cost of $11,162 (651 hr * $25.72/hr). For 2023, the burden for all beneficiaries is estimated at 909 hours (5,453/2 beneficiaries * 0.3333 hr) at a cost of $23,379 (1,302 hr * $25.72/hr). For 2024, the burden for all beneficiaries is estimated at 1,422 hours (8,531/2 beneficiaries * 0.3333 hr) at a cost of $ $36,574 (1,422 hr * $25.72/hr).

The average burden per year is 922 hours ([434 + 909 + 1422]/3) at a cost of $23,705 ([11,162 + 23,379 + 36,574]/3).

b. MA Organization Estimate

There are currently four MA organizations offering MSA plans in 2020. We project that this number will double in 2022 as a result of the change. We therefore estimate that the change would result in approximately 2,604 total additional enrollments in MSAs in 2022, or 326 additional enrollments per organization (2,604 individuals/8 organizations); in 2023, 5,453 total additional enrollments in MSAs, or 682 additional enrollments per organization (5,453 individuals/8 organizations); and in 2024, and 8,531 total additional enrollments, or 1,066 additional enrollments per organization (8,531 individuals/8 organizations).

An MA organization must give a beneficiary prompt written notice of acceptance or denial of the enrollment request in a format specified by CMS that meets the requirements set forth in this section. The burden associated with each organization providing the beneficiary prompt written notice, performed by an automated system, is estimated at 1 minute per application processed. We estimate that it will take 1 minute at $77.14/hr for a business operations specialist to electronically generate and submit a notice to convey the enrollment or disenrollment decision for each beneficiary. As noted previously, we anticipate that half of the new enrollees in MSAs will already be enrolled in other MA plans, meaning the current burden estimate for their enrollment is already accounted for in the currently approved collection.

For 2022, the burden to complete the notices for the other half of new MSA enrollees (that is, the new enrollees who would otherwise enroll in FFS Medicare) is approximately 22 hours (2,604/2 notices * 1 min/60) at a cost of $1,697 (22 hr * $77.14/hr) or $1.30 per notice ($1,697/1,302 notices) or $212 per organization ($1,697/8 MA organizations). For 2023, the burden to complete the notices for the half of new MSA enrollees who would otherwise enroll in FFS Medicare is approximately 45 hours (5,453/2 notices * 1 min/60) at a cost of $3,471 (45 hr * $77.14/hr) or $1.28 per notice ($3,471/2,727 notices) or $434 per organization ($3,471/8 MA organizations). For 2024, the burden is approximately 71 hours (8,531/2 notices * 1 min/60) at a cost of $5,477 (71 hr * $77.14/hr) or $1. 1.34 per notice ($5,470/4,090 notices) or $685 per organization ($5,246/8 MA organizations).

The average burden per year is 46 hours ([22 hr + 45 hr + 71 hr]/3) at an average cost of $3,548 ([$1,697 + $3,471 + $5,477]/3).

The burden associated with electronic submission of enrollment information to CMS is estimated at 1 minute at $77.14/hr for a business operations specialist to submit the enrollment information to CMS during the open enrollment period. For 2022, the burden to complete the notices for the other half of new MSA enrollees (that is, the new enrollees who would otherwise enroll in FFS Medicare) is approximately 22 hours (2,604/2 notices * 1 min/60) at a cost of $1,697 (22 hr * $77.14/hr) or $1.30 per notice ($1,697/1,302 notices) or $212 per organization ($1,697/8 MA organizations). For 2023, the burden to complete the notices for the half of new MSA enrollees who would otherwise enroll in FFS Medicare is approximately 45 hours (5,453/2 notices * 1 min/60) at a cost of $3,471 (45 hr * $77.14/hr) or $1.28 per notice ($3,471/2,727 notices) or $434 per organization ($3,471/8 MA organizations). For 2024, the burden is approximately 71 hours (8,531/2 notices * 1 min/60) at a cost of $5,477 (71 hr * $77.14/hr) or $1.33 per notice ($5,477/4,090 notices) or $685 per organization ($5,477/8 MA organizations).

The average burden per year is 46 hours ([22 hr + 45 hr + 71 hr]/3) at an average cost of $3,548 ([$1,697 + $3,471 + $5,477]/3).

Additionally, MA organizations will have to retain a copy of the notice in the beneficiary's records. The burden associated with this task is estimated at 5 minutes at $36.82/hr for an office and administrative support worker to perform record retention for the additional MA MSA enrollees.

In aggregate, we estimate an annual burden for 2022 of 109 hours (2,604/2 beneficiaries * 5 min/60) at a cost of approximately $4,013 (109 hr * $36.82/hr) or $502 per organization ($4,013/8 MA organizations). For 2023, we estimate an aggregated annual burden of 227 hours (5,453/2 beneficiaries * 5 min/60) at a cost of approximately $8,358 (227 hr * $36.82/hr) or $1,634 per organization ($7,821/8 MA organizations). For 2024, we estimate an aggregated annual burden of 355 hours (8,531/2 beneficiaries * 5 min/60) at a cost of approximately $13,071 (355 hr * $36.82/hr) or $1,634 per organization ($13,071/8 MA organizations).

The average burden per year is 230 hours ([109 hr + 227 hr + 355 hr]/3) at an average cost of $8,481 ([$4,013 + $8,358 + $13,071]/3).

MLR Calculation

The changes affecting the MLR calculation will be submitted to OMB for approval under control number 0938–1232 (CMS–10476). Subject to

renewal, the control number is currently set to expire on December 31, 2021.

We did not receive any public comments on our proposed requirements or burden estimates. We are finalizing the requirements as proposed. We are also finalizing the burden estimates, with the following revisions: (1) We updated our cost figures using more recent BLS wage estimates; (2) we reduced the hour burden for an enrollee to fill out an enrollment form; and (3) we adjusted the 3-year phase-in period for the anticipated enrollment changes from 2021 to 2023 in the proposed rule to 2022 to 2024 in this final rule.

MA organizations will need to spend additional time calculating the MLRs for MSA contracts in order to apply the deductible factor. We estimate that for each of the 8 MA organizations that we anticipate will offer MSA contracts in 2022 and in each year through 2030, it will take an actuary approximately 5 minutes (0.0833 hr) at $116.32/hr to calculate the deductible factor for the contract. In aggregate, we estimate an annual burden of 0.6664 hours (0.0833 hr * 8 MA organizations) at a cost of $78 (0.6664 hr × $116.32/hr) or $10 per organization ($78/8 organizations).

For 2022, we estimate a total burden for all MA organizations resulting from this provision to be 154 hours (22 hr + 22 hr + 109 hr + 0.6664 hr) at a cost of $7,485 ($1,697 + $1,697 + $4,013 + $78). Per organization, we estimate an annual burden of 19.3 hours (154 hr/8 MA organizations) at a cost of $935.63 ($7,485/8 organizations).

For 2022, we estimate a total burden for all MA organizations resulting from this provision to be 154 hours (22 hr + 22 hr + 109 hr + 0.6664 hr) at a cost of $7,485 ($1,697 + $1,697 + $4,013 + $78). Per organization, we estimate an annual burden of 19.3 hours (154 hr/8 MA organizations) at a cost of $935.63 ($7,485/8 organizations).

For 2023, we estimate a total burden for all MA organizations resulting from this provision to be 318 hours (45 hr + 45 hr + 227 hr + 0.6664 hr) at a cost of $15,378 ($3,471 + $3,471 + $8,358 + $78). Per organization, we estimate an annual burden of approximately 40 hours (318 hr/8 MA organizations) at a cost of $1,922.50 ($15,378/8 organizations).

For 2024, we estimate a total burden for all MA organizations resulting from this provision to be 498 hours (71 hr + 71 hr + 355 hr + 0.6664 hr) at a cost of $24,103 ($5,477 + $5,477 + $13,071 + $78). Per organization, we estimate an annual burden of approximately 62 hours (498 hr/8 MA organizations) at a cost of $3,013 ($24,103/8 organizations).

The burden for beneficiaries is a single burden for each year and has been estimated above.

d. Summary

The figures in Table 5 associated with beneficiaries' enrollment requests, MA organizations providing beneficiaries with notice of acceptance or denial of the enrollment request, MA organizations' submission of enrollment information to CMS, and MA organizations' retention of a copy of the notice in beneficiaries' records will be submitted to OMB for approval under control number 0938–0753 (CMS–R–267). The figures associated with the calculation of the deductible factor for MA MSA contracts will be submitted to OMB for approval under control number 0938–1232 (CMS–10476).

TABLE 5—IMPACT OF MSA/MLR BY SUBJECT

Respondents	Subject	OMB Control No. (CMS ID No.)	2022	2023	2024	Average
Beneficiaries	Enrollment request (§ 422.2440)	0938–0753 (CMS–R–267)	$11,162 (434 hr)	$23,379 (909 hr)	$36,574 (1,422 hr)	$23,705 (922 hr)
MA organizations	Notice to beneficiaries (§ 422.2440)	0938–0753 (CMS–R–267)	$1,697 (22 hr)	$3,471 (45 hr)	$5,477 (71 hr)	$3,548 (46 hr)
MA organizations	Submission to CMS (§ 422.2440)	0938–0753 (CMS–R–267)	$1,697 (22 hr)	$3,471 (45 hr)	$5,477 (71 hours)	$3,548 (46 hrs)
MA organizations	Record retention (§ 422.2440)	0938–0753 (CMS–R–267)	$4,013 (109 hr)	$8,358 (227 hr)	$13,071 (355 hr)	$8,481 (230 hr)
MA organizations	Calculation of deductible factor. (§ 422.2440)	0938–1232 (CMS–10476)	$78 (0.6664 hr)	$78 (0.6664 hr)	$78 (0.6664 hr)	$78 (0.6664 hr)
Total			$7,485 (154 hr)	$15,378 (318 hr)	$24,103 (498 hr)	$15,655 (322 hr)

5. ICRs Regarding Special Election Periods (SEPs) for Exceptional Conditions (§§ 422.62 and 423.38)

The following changes will be submitted to OMB for approval under control number 0938–0753 (CMS–R–267) for Part C and 0938–0964 (CMS–10141) for Part D.

As discussed in section V.B. of this final rule, we are finalizing all SEPs as proposed, with the exception of the SEP for Government Entity—Declared Disaster or Other Emergency at §§ 422.68(b)(18) and 423.38(c)(23), which we are finalizing, with modification. We are also codifying the SEP for Individuals Involuntarily Disenrolled from an MA–PD plan due to loss of Part B, which was inadvertently omitted from the proposed rule.

We did not receive any comments on our proposed requirements and are finalizing them without change. As indicated in section VII.A. of this final rule, we have revised our proposed cost figures based on more recent BLS wage estimates. We are not making any changes to our proposed time estimates.

We are codifying certain Part C (at § 422.62(b)(4) through (25)) and Part D (at § 423.38(c)(11) through (32)) SEPs for exceptional circumstances currently set out in sub-regulatory guidance that MA organizations and Part D plan sponsors have implemented and are currently following. We are also establishing two new additional SEPs for exceptional circumstances: The SEP for Individuals Enrolled in a Plan Placed in Receivership and the SEP for Individuals Enrolled in a Plan that has been identified by CMS as a Consistent Poor Performer.

We do not believe the changes will adversely impact individuals requesting enrollment in Medicare health or drug plans, the plans themselves, or their current enrollees. Similarly, we do not believe the changes would have any impact on the Medicare Trust Fund.

MA organizations and Part D plan sponsors are currently assessing applicants' eligibility for election

periods as part of existing enrollment processes; therefore, no additional burden is anticipated from this change. However, because the burden for determining an applicant's eligibility for an election period has not previously been submitted to OMB, due to inadvertent oversight, we are seeking their approval under the aforementioned OMB control numbers.

The following changes will be submitted to OMB for approval under control number 0938–0753 (CMS–R–267). We estimate it would take 5 minutes (0.0833 hr) at $77.14/hr for a business operations specialist to determine an applicant's eligibility for an election period.

The burden for all MA organizations is estimated at 142,497 hours (1,710,650 beneficiary SEP elections * 0.0833 hr) at a cost of $10,992,219 (142,497 hr * $77.14/hr) or $60,731 per parent organization ($10,992,219/181 MA parent organizations).

The following changes will be submitted to OMB for approval under control number 0938–0964 (CMS–10141). The burden for all Part D parent organizations is estimated at 155,564 hours (1,867,519 beneficiary SEP elections * 0.0833 hr) at a cost of $12,000,207 (155,564 hr * $77.14/hr) or $226,419 per Part D parent organization ($12,000,207/53 Part D parent organizations).

As discussed in section V.B. of this final rule, we are finalizing all SEPs as proposed, with the exception of the SEP for Government Entity—Declared Disaster or Other Emergency at §§ 422.68(b)(18) and 423.38(c)(23). We are also codifying the SEP for Individuals Involuntarily Disenrolled from an MA–PD plan due to loss of Part B, which was inadvertently omitted from the proposed rule.

C. Summary of Information Collection Requirements and Associated Burden Estimate

TABLE 6—ANNUAL INFORMATION COLLECTION REQUIREMENTS

Provision	Regulatory citation	OMB Control No.	Respondent type	Response summary	Total number of respondents	Total number of responses	Time per response (hr)	Total annual time (hr)	Labor cost ($/hr)	Total annual cost ($)
D–SNP Look-Alikes.	§ 422.514(e)	0938–NEW.	Enrollees	D–SNP Look-Alikes: Enrollment.	1,954	1,954	0.3333	218	25.72	5,590
ESRD	§§ 422.50 and 422.52.	0938–NEW.	Enrollees	ESRD: Enrollment.	59,000	59,000	0.3333	19,665	25.72	505,784
MSA MLR	§§ 422.2420, 422.2440, and 422.2430.	0938–0753.	Enrollees	MSA MLR: Filling out enrollment forms.	16,588	16,588	0.3333	922	25.72	23,705
	Subtotal Enrollees.	Varies ..	Enrollees	Varies	77,542	77,542	Varies	20,805	Varies	535,079
SSCBI	422.102(f)(3)(i)	0938–0763.	MA Plans	SSBCI: Criteria (initial software update).	234	1	12	2,808	103.33	96,717
SSCBI	422.102(f)(3)(i)	0938–0763.	MA Plans	SSBCI: Criteria (Annual physician review).	234	1	36	8,424	193.7	1,631,729
SSCBI	422.102(f)(3)(i)	0938–0763.	MA Plans	SSBCI: Criteria (Software updates).	234	1	5	1,170	85.26	99,754
SSCBI	422.102(f)(3)(ii)	0938–0763.	MA Plans	SSBCI: Documentation.	234	1	2	468	56.34	26,367
SSCBI	422.102(f)(3)(iii)	0938–0763.	MA Plans	SSBCI: Enrollee records.	234	1	9	702	86.95	61,039
D–SNP Look-Alikes.	§ 422.514 (e) ...	0938–0753.	MA Plans	D–SNP Look-Alikes: Transition.	67	67	2	45	77.14	3,446
MSA MLR	§§ 422.2420, 422.2440, and 422.2430.	0938–0753.	MA Plans	MSA MLR: Notify enrollees.	8	8	0.0167	46	77.14	3,548
MSA MLR	§§ 422.2420, 422.2440, and 422.2430.	0938–0753.	MA Plans	MSA MLR: Submit to CMS.	8	8	0.0167	46	77.14	3,548
MSA MLR	§§ 422.2420, 422.2440, and 422.2430.	0938–0753.	MA Plans	MSA MLR: Archive.	8	8	0.0833	230	36.82	8,481
MSA MLR	§§ 422.2420, 422.2440, and 422.2430.	0938–1252.	MA Plans	MSA MLR: Calculation of the deductible factor.	8	8	0.0833	0.6664	116.32	78
Part C Election Period.	§ 422.62	0938–0753.	MA Plans	Part C Election Period: Determine eligibility.	181	1,710,650	0.0833	142,497	77.14	10,992,219

TABLE 6—ANNUAL INFORMATION COLLECTION REQUIREMENTS—Continued

Provision	Regulatory citation	OMB Control No.	Respondent type	Response summary	Total number of respondents	Total number of responses	Time per response (hr)	Total annual time (hr)	Labor cost ($/hr)	Total annual cost ($)
Part D Election Period.	§ 422.38	0938–0964.	Part D Plans.	Part D Election Period: Determine eligibility.	53	1,867,519	0.0833	155,564	77.14	12,000,207
	Subtotal MA Plans.	Varies ..	MA Plans	Varies	309	Varies	Varies	312,001	Varies	24,927,133
	Grand Total All	Varies ..	Varies	Varies	77,851	.....	.....	332,806	.....	25,462,212

VIII. Regulatory Impact Analysis

A. Statement of Need

This final rule implements a subset of the proposals from the proposed rule. We took a measured approach to review each provision proposed and focused finalizing in this first final rule those most helpful for bidding, those that address the COVID–19 pandemic and public health emergency, as well as those topics on which issuing a final rule now would advance the MA program.

Summaries of the public comments that are within the scope of the provisions' proposed regulatory impact analyses implemented in this final rule are included in this section with our responses under the appropriate headings. The provisions in this final rule implement specific provisions of the BBA of 2018 and the 21st Century Cures Act. The statutory need for these policies is clear. However, this rule also contains discretionary policies, hence we provide economic justification in the following paragraphs.

We estimate that the proposed Star Ratings provisions would result in an overall net savings for the Medicare Trust Fund. There are two changes that may impact a contract's Star Rating: (1) We proposed to increase measure weights for patient experience/complaints and access measures from two to four to further emphasize the patient voice, and (2) we proposed the use of Tukey outlier deletion, which is a standard statistical methodology for removing outliers, to increase the stability and predictability of the non-CAHPS measure cut points. The increased weight reflects CMS's commitment to put patients first and to empower patients to work with their doctors to make health care decisions that are best for them. Since more outliers tend to be at the low end of the distribution (worse performers), directly removing outliers causes some shifting downward in overall Star Ratings. The increased measure weights for patient experience/complaints and access revision is assumed to be a cost to the Medicare Trust Fund given the ratings for these measures tend to be higher relative to other measures, and the Tukey outlier deletion is assumed to be a saver to the Medicare Trust Fund after the first year since directly removing outliers results in a shift downward in ratings. The aggregate savings to the Medicare Trust Fund over 2024–2030 is $4.1 billion.

B. Overall Impact

We examined the impact of this final rule as required by Executive Order 12866 on Regulatory Planning and Review (September 30, 1993), Executive Order 13563 on Improving Regulation and Regulatory Review (January 18, 2011), the Regulatory Flexibility Act (RFA) (September 19, 1980, Pub. L. 96–354), Executive Order 13272 on Proper Consideration of Small Entities in Agency Rulemaking (August 13, 2002), section 1102(b) of the Act, section 202 of the Unfunded Mandates Reform Act of 1995 (UMRA) (March 22, 1995; Pub. L. 104–4), Executive Order 13132 on Federalism (August 4, 1999), the Congressional Review Act (5 U.S.C. 804(2)), and Executive Order 13771 on Reducing Regulation and Controlling Regulatory Costs (January 30, 2017). This rule, under Executive Order 12866, is economically significant with over $100 million in costs, benefits, or transfers annually. Pursuant to the Congressional Review Act (5 U.S.C. 801 *et seq.*), the Office of Information and Regulatory Affairs designated this rule as a major rule as defined by 5 U.S.C. 804(2).

A regulatory impact analysis must be made for major rules with economically significant effects ($100 million or more in any one year). We estimate that this final rule is economically significant as measured by the $100 million threshold and hence, it is 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 this rulemaking.

Section 202 of 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 2020, that threshold is approximately $156 million. This final rule is not anticipated to have an unfunded effect on state, local, or tribal governments, in the aggregate, or on the private sector of $154 million or more.

Executive Order 13132 establishes certain requirements that an agency must meet when it promulgates a final rule that imposes substantial direct requirement costs on state and local governments, preempts state law, or otherwise has federalism implications. Since this final rule does not impose any substantial costs on state or local governments, preempt state law or have federalism implications, the requirements of Executive Order 13132 are not applicable.

If regulations impose administrative costs on reviewers, such as the time needed to read and interpret this final rule, then we should estimate the cost associated with regulatory review. There are currently 795 contracts (which includes MA, MA–PD, and PDP contracts), 55 state Medicaid agencies, and 300 Medicaid MCOs. We also expect a variety of other organizations to review (for example, consumer advocacy groups, major Pharmacy Benefit Managers). We expect that each organization will designate one person to review the rule. A reasonable maximal number is 2,000 total reviewers. We note that other assumptions are possible.

Using the BLS wage information for medical and health service managers (code 11–9111), we estimate that the cost of reviewing this final rule is $110.74 per hour, including fringe benefits and overhead costs (*http://www.bls.gov/oes/current/oes_nat.htm*). Assuming an average reading speed, we estimate that it will take approximately 100 hours for each person to review this final rule. For each entity that reviews the rule, the estimated cost is therefore $11,074 (100 hours * $110.74). Therefore, we estimate that the

maximum total cost of reviewing this final rule is $22 million ($11,074 * 2,000 reviewers). We expect that many reviewers will not review the entire rule but just the sections that are relevant to them. If each person on average reviews 10 percent of the rule, then the cost would be $2.2 million.

Note that this analysis assumed one reader per contract. Some alternatives include assuming one reader per parent organization. Using parent organizations instead of contracts will reduce the number of reviewers. However, we believe it is likely that review will be performed by contract. The argument for this is that a parent organization might have local reviewers assessing potential region-specific effects from this final rule.

In accordance with the provisions of Executive Order 12866, this rule was reviewed by OMB.

C. Impact on Small Businesses—Regulatory Flexibility Analysis (RFA)

The RFA, as amended, requires agencies to analyze options for regulatory relief of small businesses if a rule has a significant economic impact on a substantial number of small entities. For purposes of the RFA, small entities include small businesses, nonprofit organizations, and small governmental jurisdictions.

This final rule has several provisions. Although some provisions are technical or codify existing guidance, and therefore are not expected to have economic impact beyond current operating expenses, there are other provisions with paperwork or other costs. These provisions are analyzed in both this section and in section VII of this final rule. A compact summary of burdens by year and provision are summarized in Tables 6 and 16 of this final rule.

This rule has several affected stakeholders. They include (1) insurance companies, including the five types of Medicare health plans, MA organizations, PDPs, cost plans, Medical Savings Account plans (MSA), PACE organizations, and demonstration projects, (2) providers, including institutional providers, outpatient providers, clinical laboratories, and pharmacies, and (3) enrollees.

Some descriptive data on these stakeholders are as follows:

- Pharmacies and Drug Stores, NAICS 446110, have a $30 million threshold for ''small size'' with 88 percent of pharmacies, those with less than 20 employees, considered small.
- Direct Health and Medical Insurance Carriers, NAICS 524114, have a $41.5 million threshold for ''small size,'' with 75 percent of insurers having under 500 employees meeting the definition of small business.
- Ambulatory Health Care Services, NAICS 621, including about 2 dozen sub-specialties, including Physician Offices, Dentists, Optometrists, Dialysis Centers, Medical Laboratories, Diagnostic Imaging Centers, have a threshold ranging from $8 to $35 million (Dialysis Centers, NAICD 621492, have a $41.5 million threshold). Almost all firms are big, and this also applies to sub-specialties. For example, for Physician Offices, NAICS 621111, receipts for offices with under 9 employees exceed $34 million.
- Hospitals, NAICS 622, including General Medical and Surgical Hospitals, Psychiatric and Substance Abuse Hospitals, and Specialty Hospitals have a $41.5 million threshold for small size, with half of the hospitals (those with between 20–500 employees) considered small.
- Skilled Nursing Facilities (SNFs), NAICS 623110, have a $30 million threshold for small size, with half of the SNFs (those with under 100 employees) considered small.

We are certifying that this final rule does not have a significant economic impact on a substantial number of small entities. To defend our position, we first describe at a high level the cash flows related to the Medicare program. We then provide more specific details.

The high-level underlying idea in creating the MA, Medicare Cost-plan, and MA–PD Medicare health insurance programs, is to allow private insurers to coordinate care, resulting in efficiencies of cost. The high-level underlying idea in creating the non-government-managed Prescription Drug program (PDPs and drug portion of MA–PDs) is to allow beneficiaries to obtain prescription drugs in a competitive market to reduce costs. For MA, MA–PD and Cost plans, enrollees obtain the same Original Medicare Part A and Part B services they would otherwise obtain in the original Medicare program, albeit at reduced cost (however, for the small percentage of plans bidding above the benchmark, enrollees pay more, but this percentage of plans is not ''significant'' as defined by the RFA and as justified below).

The savings achieved by the MA and the MA–PD plans, the amount of reduced cost, can then be used by the private insurers in a variety of ways, including providing benefits supplemental to original Medicare. Some examples of these supplemental benefits include vision, dental, and hearing. The cost for furnishing these supplemental benefits comes from a combination of the Trust Fund and enrollee premiums.

Part D plans submit bids and are paid by the Medicare Trust Fund for their projected costs in the form of direct premium subsidy and reinsurance. For any enrolled low-income beneficiaries, they receive low-income premium subsidy and low-income cost-sharing subsidy in addition. The national average monthly bid amount, or NAMBA, determines the base premium. A plan's premium is the sum of the base premium and the difference between its bid amount and the NAMBA.

Thus the cost of providing services by these insurers is met by a variety of government funding and in some cases by enrollee premiums.

In order to achieve these goals, the government pays the MA health plans a portion of the funds that would have been paid had plan enrollees remained in original Medicare. These funds are then used to provide additional benefits on behalf of the health plans' enrollees. Thus, by the initial design of the Medicare health plan programs, the various insurance programs were not expected to suffer burden or losses since, in this very unique insurance relationship, the private companies are being supported by the government who, in turn, is saving money because health plans, by virtue of coordinating care, are furnishing the same services, albeit at reduced cost. This lack of expected burden applies to both large and small health plans.

The unique MA regulations, such as those in this final rule, are defined so that small entities are not expected to incur additional burden since the cost of complying with any final rule is passed on to the government.

We next examine in detail each of the stakeholders and explain how they can bear cost. (1) For Pharmacies and Drug Stores, NAICS 446110; (2) for Ambulatory Health Care Services, NAICS 621, including about two dozen sub-specialties, including Physician Offices, Dentists, Optometrists, Dialysis Centers, Medical Laboratories, Diagnostic Imaging Centers, and Dialysis Centers, NAICD 621492; (3) for Hospitals, NAICS 622, including General Medical and Surgical Hospitals, Psychiatric and Substance Abuse Hospitals, and Specialty Hospitals; and (4) for SNFs, NAICS 623110: Each of these are providers (inpatient, outpatient, or pharmacy) that furnish plan-covered services to plan enrollees. Whether these providers are contracted or, in the case of PPOs, PFFS, and MSA, non-contracted with the MA plan, their aggregate payment for services is the sum of the enrollee cost sharing and

plan payments. For non-contracted providers, § 422.214 requires that a non-contracted provider accept payment that is least what they would have been paid had the services been furnished in a fee-for-service setting. For contracted providers, § 422.520 requires that the payment is governed by a contract which the provider and plan mutually agree to. Consequently, for these providers, there is no additional cost burden above the already existing burden in original Medicare.

For Direct Health and Medical Insurance Carriers, NAICS 524114, plans estimate their costs for the coming year and submit bids and proposed plan benefit packages. Upon approval, the plan commits to providing the proposed benefits, and CMS commits to paying the plan either (1) the full amount of the bid, if the bid is below the benchmark, which is a ceiling on bid payments annually calculated from original Medicare data; or (2) the benchmark, if the bid amount is greater than the benchmark.

Theoretically, there is additional burden if plans bid above the benchmark. However, consistent with the RFA, the number of these plans is not substantial. Historically, only two percent of plans bid above the benchmark, and they contain roughly one percent of all plan enrollees. Since the CMS criteria for a substantial number of small entities is 3 to 5 percent, the number of plans bidding above the benchmark is not substantial.

The preceding analysis shows that meeting the direct cost of this final rule does not have a significant economic impact on a substantial number of small entities, as required by the RFA.

There are certain indirect consequences of these provisions which also create impact. We have already explained that 98 percent of the plans bid below the benchmark. Thus, their estimated costs for the coming year are fully paid by the government. However, the government additionally pays the plan a ''beneficiary rebate'' amount that is an amount equal to a percentage (between 50 and 70 percent depending on a plan's quality rating) multiplied by the amount by which the benchmark exceeds the bid. The rebate is used to provide additional benefits to enrollees in the form of reduced cost sharing, lower Part B or Part D premiums, or supplemental benefits. (Supplemental benefits may also partially be paid by enrollee premiums if the plan choses to use premiums.) It would follow that if the provisions of this final rule cause the bid to increase and if the benchmark remains unchanged or increases by less than the bid does, the result would be a reduced rebate and possibly fewer supplemental benefits for the health plans' enrollees.

However, supplemental benefits are only one approach to using the rebate. The experience of OACT at CMS is that from year to year plans prefer to reduce their administrative costs, including profit margins, rather than substantially change their benefit package. This is true due to marketing forces; a plan lowering supplemental benefits even one year may lose its enrollees to competing plans that offer these supplemental benefits. Thus, it is advantageous to the plan to temporarily reduce administrative costs, including margins, rather than reduce benefits.

We note that we do not have definitive data on this. That is, we can at most note the way administrative costs and supplemental benefits vary from year to year. The thought processes behind the plan are not reported. More specifically, when supplemental benefits are reduced, we have no way of knowing the cause for this reduction, whether it be new provisions, market forces, or other causes.[54]

Based on the above, we certify that this final rule does not have a significant economic impact on a substantial number of small entities.

Finally, we note that this rule has an impact on enrollees. While enrollees as a group do not constitute a ''small business'' as defined by the RFA, and hence the impact of this final rule on enrollees is not discussed in this section, throughout this final rule we have carefully noted the impact on enrollees. One major impact on enrollees as presented in section VII of this final rule is the estimated half hour burden at a cost of $13 per enrollee for filling out enrollment forms. While the aggregate amount for all enrollees is several million, the per enrollee burden is not significant.

D. Anticipated Effects

Some provisions of this final rule have negligible impact either because they are technical provisions or are provisions that codify existing guidance. Other provisions have an impact although it cannot be quantified or whose estimated impact is zero. Throughout the preamble, we have noted when provisions have no impact. Additionally, this Regulatory Impact Analysis discusses several provisions with either zero impact or impact that cannot be quantified. The remaining provisions are estimated in section VII of this final rule and in this Regulatory Impact Analysis. Where appropriate, when a group of provisions have both paperwork and non-paperwork impact, this Regulatory Impact Analysis cross-references impacts from section VII of this final rule in order to arrive at total impact. Additionally, this Regulatory Impact Analysis provides pre-statutory impact of several provisions whose additional current impact is zero because their impact has already been experienced as a direct result of the statute. For further discussion of what is estimated in this Regulatory Impact Analysis, see Table 16 and the discussion afterwards.

1. Medicare Advantage (MA) Plan Options for End-Stage Renal Disease (ESRD) Beneficiaries (§§ 422.50, 422.52, and 422.110)

We are codifying requirements under section 17006 of the Cures Act that, effective for the plan year beginning January 1, 2021, would remove the prohibition on beneficiaries with ESRD enrolling in an MA plan. Since we are codifying existing statute, there is no impact to program expenditures. In order to estimate the impact of requirements under section 17006 of the Cures Act, a pre-statute baseline was used to estimate the impacts.

There are two primary assumptions that contribute to the regulatory impact analysis for this provision: (1) The increased number of beneficiaries with ESRD who choose to enroll in an MA health plan; and (2) the cost differential between MA and FFS for those enrollees with ESRD.

We are expecting that there will be an influx of beneficiaries switching from FFS to MA beginning on January 1, 2021 due to the provision. In 2019, there were 532,000 enrollees in ESRD status with Medicare Part A benefits as shown in the Medicare Enrollment Projections tables of the 2020 Rate Announcement. Of these, 401,000 enrollees were in the FFS program, which results in 131,000 in Private Health Plans. This equates to a private health penetration rate of about 25 percent. Absent the ESRD enrollment provision of the Cures Act, we project that ESRD enrollment in Private Health plans will grow to 144,000 in 2021, representing about 26 percent of the projected 2021 total ESRD population of 559,000. Based on an analysis by OACT, ESRD enrollment in MA plans is expected to increase by 83,000 due to the Cures Act provision. This increase is assumed to be phased in over 6 years, with half of the beneficiaries (41,500) enrolling during 2021.

Next, we determine the cost differential of the projected ESRD

[54] *https://www.ncbi.nlm.nih.gov/pmc/articles/PMC3893317/.*

enrollees that are new to MA in 2021 due to the Cures Act. The cost differential between MA and FFS ESRD enrollees is attributed to the adjustment to MA risk scores for differences in diagnosis coding between MA and FFS beneficiaries. The Coding Intensity (Annual) was derived by examining historical risk score data and computing the differences between MA and FFS risk scores. Demographic differences (age, gender factors) for enrollees have been separated and removed from risk score comparisons so that the final differences are considered health status differences.

Table 7 shows the cost for codifying section 17006 of the Cures Act, removing the prohibition for ESRD beneficiaries to enroll in MA plans. The United States Per Capita Cost (USPCC) amounts for Part A and Part B can be found in the 2020 Rate Announcement. The Gross Costs (before backing out the Part B premium portion) is calculated by multiplying the Additional MA ESRD Enrollment by the ESRD–USPCC rates, which are on a per member per month basis, multiplied by 12 (the number of months in a year) multiplied by the Composite Coding Intensity. The Net Cost is calculated by multiplying the Gross Costs by the Net of Part B Premium amount which averages between 85.6% and 84.9% from 2021–2030. The Net Costs range from $23 million in contract year 2021 to $440 million in contract year 2030.

TABLE 7—ESTIMATED COST PER YEAR (MILLIONS) TO THE MEDICARE TRUST FUND FOR REMOVING THE PROHIBITION FOR ESRD BENEFICIARIES TO ENROLL IN MA PLANS

Contract year	2021	2022	2023	2024	2025	2026	2027	2028	2029	2030
Additional MA ESRD Enrollment:	41,500	62,250	73,317	78,850	81,617	83,000	83,000	83,000	83,000	83,000
USPCC Pt A FFS ($):	3,206	3,328	3,447	3,562	3,681	3,801	3,924	4,052	4,184	4,320
USPCC Pt B FFS ($):	4,900	5,109	5,329	5,573	6,383	6,662	6,953	7,257	7,574	7,905
USPCC FFS ($):	8,106	8,437	8,776	9,136	10,063	10,462	10,877	11,309	11,758	12,225
Coding Intensity (Annual) (%):	0.65	0.80	0.79	0.63	0.46	0.30	0.14	0.14	0.13	0.13
Coding Intensity (Composite) (%):	0.65	1.46	2.26	2.90	3.38	3.69	3.84	3.98	4.12	4.25
Gross Cost ($ millions):	26	92	174	251	333	384	416	448	482	518
Net of Part B Premium (%):	85.60	85.60	85.50	85.40	85.30	85.20	85.00	84.90	84.90	84.90
Net Cost ($ millions):	23	79	149	214	284	327	353	381	410	440

Because these increases are already included in the baseline, they are not included in Table 15, nor do they contribute to the monetized table calculations (Table 15). However, notes to Table 15 and observations in the conclusion do mention this impact.

Comment: A commenter thanked CMS for sharing its projection of the magnitude of ESRD migration from Original Medicare to Medicare Advantage in 2021 and in future years; however, the commenter expressed several concerns with the methods and assumptions used. For example, the commenter requested CMS (i) produce a range of impacts, (ii) produce an alternative methodology based on adjustment to MOOP limits, and (iii–iv) reconsider certain assumptions about MLR and migration patterns. The commenter also asked if CMS, in considering migration patterns, took note that many ESRD retirees are already in EGWPs or that migration to MA plans will likely be higher in the under-65 ESRD population due to the lack of alternatives.

Response: A range of impacts for the estimated costs to the Medicare Trust Funds for removing the prohibition for ESRD beneficiaries to enroll in MA plans is described in section VIII.E.1. of this final rule.

CMS does not have the information readily available to produce an alternative adjustment to MOOPs; the proposal related to the MOOP limits for MA plans will be addressed in a future final rule. The cost to the plan sponsor of having a MOOP is captured as a supplemental benefit in the bid pricing. The plan sponsor bid pricing models and methodologies are proprietary health plan information and are not readily available to CMS. Furthermore, the MOOP for 2021 applies to all MA enrollees (ESRD and non-ESRD) and we do not believe it is reasonable to project alternative ESRD enrollment projections based on a MOOP that applies to all MA enrollees.

We did consider the migration patterns for EGWP ESRD beneficiaries versus Individual ESRD beneficiaries. We surmised that the costs differences between EGWP and Individual ESRD coverages are not significant enough to display the migration patterns separately. Displaying projections at that coverage level would not provide further understanding of the financial projections since the cost differences are not too different.

We did consider the migration patterns for younger versus older ESRD beneficiaries. In response to the commenter on page G24, we noted that the higher average age of the MA ESRD enrollee versus the lower average age of the FFS ESRD enrollee is a main reason that there are fewer kidney transplants in the MA population. Our expectation is that younger ESRD beneficiaries will begin to enroll in MA starting in 2021 and that the kidney transplant incidence rate for the two programs will begin to merge.

After review and consideration of the comments, we are finalizing this provision without modification.

2. Medicare Fee-for-Service (FFS) Coverage of Costs for Kidney Acquisitions for Medicare Advantage (MA) Beneficiaries (§ 422.322) and Exclusion of Kidney Acquisition Costs From Medicare Advantage (MA) Benchmarks (§§ 422.258 and 422.306)

Section 17006(b) of the Cures Act amended section 1853(k) and (n) of the Act to exclude standardized costs for kidney acquisitions from MA benchmarks starting in 2021. As such, we will codify these requirements so that, effective for the contract year beginning January 1, 2021, MA

organizations will no longer be responsible for costs for organ acquisitions for kidney transplants for their beneficiaries. Removing these costs from the MA benchmarks will decrease the amounts paid to the plans from the Medicare trust funds. Instead, as required by statute, Medicare FFS will cover the kidney acquisition costs for MA beneficiaries, effective 2021.

Since the budget baseline has reflected this change from the Cures Act, there is no additional impact of the proposed codification of this change to the computation of rates. To estimate the impact of the statute when published we used a pre-statute baseline. This impact of the statute will therefore not be included in Table 15 or Table 14, which deal with impacts of current provision.

Our analysis in the next section shows that: (1) FFS coverage of kidney acquisition costs for MA beneficiaries results in net costs to the Medicare Trust Funds ranging from $212 million in 2021 to $981 million in 2030; (2) Excluding kidney acquisition costs from MA benchmarks results in net savings estimated to range from $594 million in 2021 to $1,346 million in 2030. In addition, we anticipate no change in plan, provider, or beneficiary burden for these provisions. Plan burden would not be impacted by the change in their payment rate. Provider burden will not be impacted because they continue to bill for kidney acquisition regardless of whether they receive payment from FFS Medicare or MA organizations. Finally, beneficiaries would not be impacted by the change in the source of payment for the acquisition of the organ.

Next, we describe the steps used to calculate the savings associated with excluding kidney acquisition costs from MA benchmarks as well as the costs associated with requiring FFS coverage of kidney acquisition costs for MA beneficiaries.

First, we examined the FFS cost of kidney acquisition coverage. We calculate the expected costs to the FFS program for covering kidney acquisitions from the MA population starting in 2021. The costs for these services are expected to be lower than the amount that is expected to be excluded from the MA benchmarks for two reasons.

- The MA penetration rate for ESRD enrollees is lower than for the non-ESRD enrollees. This means that a higher percentage of beneficiaries with ESRD are in FFS than in MA, so there will likely be fewer kidney transplants in MA versus FFS. However, this enrollment difference will likely lessen as ESRD enrollees are permitted to enroll in MA plans beginning in 2021.
- The kidney transplant incidence rate for MA ESRD enrollees has historically been much lower than the kidney transplant incidence rate for FFS ESRD enrollees. We suspect that this is due to MA ESRD enrollees being in dialysis status for a shorter duration than FFS enrollees. Again, we believe that this difference (between MA and FFS) in the kidney transplant incidence rate will decrease over time as more ESRD beneficiaries enroll in MA plans.

The kidney transplant incidence rate is computed by dividing the number of kidney transplants by the ESRD enrollment separately for the MA and FFS programs. As shown in Table 8, the FFS kidney transplant incidence rate has historically often been more than three times the MA rate.

TABLE 8—MEDICARE FFS AND MA KIDNEY TRANSPLANTS (2013–2017)

	2013	2014	2015	2016	2017
Number of Kidney Transplants FFS:	13,964	13,866	14,400	15,191	15,346
ESRD Enrollment FFS (000's):	385	390	394	401	402
Transplant Incidence FFS (%):	3.6	3.6	3.7	3.8	3.8
Number of Kidney Transplants MA:	929	1,015	957	1,137	1,382
ESRD Enrollment MA (000's):	69	78	89	96	108
Transplant Incidence MA (%):	1.3	1.3	1.1	1.2	1.3

As mentioned, we expect that as a greater portion of enrollees with ESRD will join MA plans, starting in 2021, the difference in the kidney transplant incidence rate between MA and FFS will begin to lessen, as shown in Table 9. The total number of MA and FFS kidney transplants are expected to grow by 3 percent per year which is based on the 2013–2017 historical growth rate. That rate is higher than the average increase in MA and FFS ESRD enrollment of 2 percent for 2013–2017. Since the kidney transplant growth is projected to be higher than the ESRD enrollment growth, we expect the kidney transplant incidence rate to increase over time.

TABLE 9—MEDICARE FFS AND MA KIDNEY TRANSPLANTS (2018–2030)

	2018	2019	2020	2021	2022	2023	2024
Number of Kidney Transplants MA & FFS:	17,230	17,747	18,279	18,828	19,392	19,974	20,573
Kidney Transplant Incidence FFS (%):	3.9	4.0	4.0	4.2	4.3	4.4	4.3
Kidney Transplant Incidence MA (%):	1.4	1.4	1.4	1.6	1.8	2.0	2.2
ESRD Enrollment FFS (000's):	401	401	408	373	358	353	352
ESRD Enrollment MA (000's):	120	131	137	186	213	231	242
	2025	2026	2027	2028	2029	2030	
Number of Kidney Transplants MA & FFS:	21,191	21,826	22,481	23,155	23,850	24,566	
Kidney Transplant Incidence FFS (%):	4.3	4.2	4.2	4.1	4.1	4.0	
Kidney Transplant Incidence MA (%):	2.4	2.6	2.8	3.0	3.2	3.4	
ESRD Enrollment FFS (000's):	354	358	364	369	374	379	
ESRD Enrollment MA (000's):	250	256	261	266	270	274	

Then we calculate the average kidney acquisition costs using FFS claims data from CMS data systems. The average kidney acquisition costs ranged from $69,000 in 2013 to $83,000 in 2017, which equates to an annual growth rate of 4.7 percent. This percentage was used to estimate average kidney acquisition costs during the projection period of 2018 to 2030.

The gross costs to the FFS program for covering MA kidney acquisition costs are computed by multiplying the MA transplant incidence rate by the number of MA ESRD enrollees multiplied by the average kidney acquisition cost. This computation was completed for the years 2021–2030. The gross costs, as found in the Table 10, range from $298 million in 2021 to $1,384 million in 2030. Again, we apply the government share of the gross savings factors as well as the Part B premium factors to compute the net costs to the Medicare Trust Funds. These factors are the same as those used to calculate the savings for excluding kidney acquisition costs from the MA benchmarks. The net costs to the Medicare Trust Funds after applying these factors are expected range from $212 million in 2021 to $981 million in 2030.

TABLE 10—COSTS TO THE FFS PROGRAM FOR COVERING MA KIDNEY ACQUISITION COSTS

	2021	2022	2023	2024	2025	2026	2027	2028	2029	2030	2021–2030
Kidney Transplant Incidence MA (%):	1.6	1.8	2.0	2.2	2.4	2.6	2.8	3.0	3.2	3.4	
ESRD Enrollment MA (000's):	186	213	231	242	250	256	261	266	270	274	
Avg Kidney Acq Costs ($'s):	99,146	103,804	108,680	113,786	119,131	124,728	130,587	136,722	143,145	149,870	
Gross Costs ($Millions):	297.9	401.3	503.0	605.7	713.5	828.7	950.2	1,082.5	1,226.1	1,383.7	7,992.6
Avg Gov't Share of Gross Savings (%):	83.0	83.0	83.0	83.1	83.2	83.2	83.2	83.4	83.4	83.4	
Net of Part B Premium (%):	85.6	85.6	85.5	85.4	85.3	85.2	85.0	84.9	84.9	84.9	
Net Costs ($Millions):	211.7	284.9	357.0	429.5	506.0	587.1	672.3	766.5	869.1	980.8	5,664.9

Next, we examined the MA cost of kidney acquisition coverage. We used data based on the kidney acquisition costs for the FFS beneficiaries to compute the portion of the MA benchmark that has been attributed to kidney acquisition costs. In order to compute the amount that the MA health plans have been reimbursed for these costs in the past, we tabulated Medicare's share of kidney acquisition costs and the number of Medicare discharges from the Medicare Cost Reports (Form CMS–2552–10) for certified kidney transplant centers. The kidney acquisition costs were computed for the years 2013–2017 (the latest data that was available at the time of this study) using information from the Medicare Cost Reports for FFS beneficiaries at the county-level. The county level per member per month (PMPM) costs are derived by summing the kidney acquisition costs for each county and dividing these amounts by the county specific Medicare FFS enrollment. These annual costs per member are then divided by 12 in order to compute the PMPM's.

Next, we examine the historical kidney acquisition cost PMPM trend for the years 2013–2017 to project these costs for the years 2018–2030. In aggregate, the kidney acquisition PMPM costs grew at an average rate of 6.4 percent during 2013–2017. This trend is used to estimate these costs for the 2018–2030 period.

To calculate the gross savings to the Medicare Trust Funds, we multiply the projected MA enrollment by the annual per member kidney acquisition costs. We then apply two additional factors to the gross savings in order to compute the net savings to the Medicare Trust Funds:

- Average government share of gross savings. Government expenditures are the sum of bids and rebates. Rebates are the portion of the difference between the MA benchmarks and MA bids that the health plans use to pay for additional supplemental benefits or reductions in enrollee cost sharing. The government retains the remaining difference between MA benchmarks and MA bids. We estimate that bids will be reduced by 50 percent of the total reduction in benchmarks.
- Net of Part B premium. Medicare enrollees, not the Trust Funds, are responsible for approximately 25 percent of their Part B costs.

The government share of gross savings factors are expected to be between 83.0 percent and 83.4 percent during the period 2021–2030. The net of Part B premium factors are expected to be 85.6 percent and 84.9 percent during that same period. The results can be found in Table 11. The net savings due to excluding kidney acquisition costs from MA benchmarks is estimated to range from $594 million in 2021 to $1,346 million in 2030.

TABLE 11—PER-YEAR CALCULATIONS, REPRESENTING THE PRE-STATUTE BASELINE BASED ON MEDICARE FFS COVERAGE OF KIDNEY ACQUISITION COST

	2013	2014	2015	2016	2017	2018	2019	2020			
Kidney Acq Costs (PMPM):	1.72	1.82	1.95	2.08	2.20	2.34	2.49	2.65			
	2021	2022	2023	2024	2025	2026	2027	2028	2029	2030	2021–2030
Kidney Acq Costs (PMPM):	2.82	3.00	3.20	3.40	3.62	3.85	4.10	4.36	4.64	4.94	
Medicare Advantage Enrollment Projection (000's):	24,690	25,624	26,508	27,380	28,237	29,070	29,861	30,607	31,313	32,035	
Gross Savings ($Millions):	836.2	923.5	1,016.6	1,117.4	1,226.3	1,343.4	1,468.4	1,601.7	1,743.7	1,898.4	13,175.6

TABLE 11—PER-YEAR CALCULATIONS, REPRESENTING THE PRE-STATUTE BASELINE BASED ON MEDICARE FFS COVERAGE OF KIDNEY ACQUISITION COST—Continued

	2013	2014	2015	2016	2017	2018	2019	2020			
Average government share of Gross Savings (%):	83.0	83.0	83.0	83.1	83.2	83.2	83.2	83.4	83.4	83.4	.....
Net of Part B Premium (%): ..	85.6	85.6	85.5	85.4	85.3	85.2	85.0	84.9	84.9	84.9	.....
Net Savings ($Millions):	594.1	655.7	721.5	792.3	869.5	951.7	1,038.9	1,134.1	1,235.9	1,345.6	9,339.3

Comment: A commenter expressed concern about the estimates in the regulatory impact analysis that concluded the net savings attributable to the exclusion of kidney acquisition costs from MA benchmarks exceed the net costs attributable to FFS coverage of kidney acquisition costs. The commenter also pointed to the Congressional Budget Office's November 2016 cost estimate of the Cures Act, which reported no change in federal spending, to underscore the notion that the net savings estimated in the proposed rule were not intended by the change in law.

Response: We thank the commenter for this feedback. Total MA kidney acquisition costs have historically been lower than total FFS kidney acquisition costs for two main reasons: (1) MA transplant incidence has been lower than FFS transplant incidence; and (2) MA ESRD enrollment (as a percent of total MA enrollment) has been lower than FFS ESRD enrollment (as a percent of total FFS enrollment). These factors result in a lower number of MA kidney transplants per capita versus FFS kidney transplants per capita. We expect savings from the exclusion of kidney acquisition costs from the MA benchmarks since MA plans have historically been reimbursed for these costs based on the higher rate of transplantation in FFS. We believe our impact analysis sufficiently outlined why the shift in responsibility from MA to FFS is not budget neutral.

Comment: Some commenters requested that we explain why the estimates in the 2021 Advance Notice appear to diverge from the estimates included in the proposed rule. The commenters indicated that the FFS cost of kidney acquisition would be an estimated $2.82 PMPM while the Advance Notice indicated that the carve-out impact estimate would be $4 PMPM.

Response: The Medicare FFS cost of kidney acquisitions estimate provided in the proposed rule is a national estimate of the impact on the Medicare Trust Funds. In contrast, the preliminary estimate provided in the calendar year 2021 Advance Notice represents a county-level average impact of excluding kidney acquisition costs from FFS experience on the MA non-ESRD county rates. Additionally, the estimates provided in the proposed rule and the Advance Notice were calculated using different trending assumptions and underlying data. The updated estimate of the impact figure that was provided in the calendar year 2021 Advance Notice is $3.

Comment: A few commenters questioned the credibility of county level data in determining the kidney acquisition cost carve-out amounts and requested that CMS release the supporting data and analyses. A commenter specifically pointed to Tables 26 and 27 in the proposed rule, noting that there were approximately 75,000 kidney transplants paid by FFS during 2014–2018 (the data period used to compute the kidney acquisition carve-out amounts). The commenter expressed concern regarding the credibility of using 75,000 events to develop 3,225 county specific carve-out factors, and requested that the kidney acquisition cost factors be developed across broader geographic areas than counties in order to mitigate variability and potential credibility issues that may exist when forecasting county level carve-out amounts.

Response: CMS provided a step-by-step description of the methodology for calculating the kidney acquisition costs to be excluded from the MA benchmarks on pages 25 and 26 of the calendar year 2021 Advance Notice.[55] Consistent with the statutory requirement to exclude the cost of kidney acquisitions for organ transplants from the primary components of the MA capitation rates, CMS finalized the kidney acquisition carve-out methodology after considering all public comments received.

Organ acquisition costs for transplants are paid on a reasonable cost basis, separately from the MS–DRG (Medicare Severity Diagnosis Related Group) payment. Hospitals are paid the estimated amount for these costs through interim biweekly payments throughout the year, referred to as ''pass-through amounts'' (pass-through amounts include other costs as well). For MA rate calculations to date, these FFS pass-through amounts are estimated and specifically added to the inpatient claim records to account for the eventual payment in the FFS program on a reasonable cost basis. The kidney acquisition costs included in the pass-through amounts are added to all discharges from kidney transplant centers by the county of the beneficiary's residence. Since the number of these discharges greatly exceeds the number of transplants, there is sufficient data to calculate credible kidney carve out factors and there is no need to adjust for credibility. Kidney acquisition costs are not allocated by the number of transplants. Since the pass-through KAC amounts are calculated and included at the county level, the carve-out factors must be developed at the county level to be consistent.

Comment: A commenter expressed concern about potential barriers to access to transplantation in MA, citing language in the proposed rule that stated that the transplant incidence rate for ESRD beneficiaries has historically been higher in FFS than in MA.

Response: Our data indicated that MA ESRD enrollees have been in dialysis status for a shorter duration and are typically older than FFS ESRD enrollees. We have observed that in the Medicare program, the incidence of kidney transplants is typically inversely correlated with age; the younger the ESRD enrollee, the more likely that a kidney transplant will occur. Historically, MA enrollees are less likely than FFS enrollees to receive a kidney transplant since the average age of MA ESRD enrollees is higher than the average age of FFS ESRD enrollees. It is our interpretation of this data that on average, older ESRD enrollees are not as likely to be eligible for a kidney transplant due to other underlying health conditions that typically occur as these enrollees age. The 2020 Kidney Disease: Improving Global Outcomes (KDIGO) Clinical Practice Guideline on the Evaluation and Management of Candidates for Kidney Transplantation

[55] The Advance Notice and Rate Announcement for each year are available online at: *https://www.cms.gov/Medicare/Health-Plans/MedicareAdvtgSpecRateStats/Announcements-and-Documents.*

outlines a comprehensive, evidence-based set of guidelines and recommendations designed to assist health care professionals assess suitability for candidacy for kidney transplantation. While clinicians are advised against excluding patients because of age alone, the guidelines recommend that they consider age in the context of other comorbidities, including frailty, which may affect outcomes. As MA enrollees have typically become eligible for Medicare due to age and disability and are, on average, older than FFS enrollees, MA ESRD enrollees may, on average, be more likely to have comorbidities that make them less suitable for kidney transplantation. As more ESRD beneficiaries enroll in MA plans, we anticipate that the profile of these beneficiaries will change and the difference in the transplant incidence rate for ESRD beneficiaries enrolled in MA and those in FFS will decrease.

After careful consideration of all comments received, we are finalizing the exclusion of kidney acquisition costs from MA benchmarks and coverage under FFS Medicare as proposed.

3. Reinsurance Exceptions (§ 422.3)

It is difficult to determine whether there would be a cost or savings impact to this proposal. The use of reinsurance or other arrangements permitted by the proposal is a choice for MA organizations, which they can exercise if they believe it is in their business interests to purchase. While purchasing reinsurance coverage has a cost associated with it, the use of reinsurance provides financial protection that may generate offsetting savings to the MA organization, or reduce their risk. Therefore, we are unable to quantitatively estimate the impacts of this provision.

We solicited stakeholder comment on (i) how this provision may be used, (ii) likely costs and savings, and (iii) other related impacts. We received no comments on this regulatory impact analysis for this proposal and therefore are finalizing this provision without modification.

4. Medicare Advantage (MA) and Part D Prescription Drug Program Quality Rating System (§§ 422.162, 422.166, 423.182, and 423.186)

We proposed measure updates as well as the methodology changes (concerning outliers and the weight of patient experience/complaints and access measures). These measure updates are routine and do not have an impact on the highest ratings of contracts (that is, overall rating for MA–PDs, Part C summary rating for MA-only contracts, and Part D summary rating for PDPs). These type of routine changes have historically had very little or no impact on the highest ratings. Hence, there will be no, or negligible, impact on the Medicare Trust Fund from the routine changes.

The cost impacts due to the Star Ratings updates are calculated by quantifying the difference in the MA organization's final Star Rating with the final rule and without the final rule. There are two ways that our final rule could cause a contract's Star Rating to change: (1) To increase measure weights for patient experience/complaints and access measures from two to four; and (2) the use of Tukey outlier deletion, which is a standard statistical methodology for removing outliers. There are assumed to be Medicare Trust Fund impacts due to the Star Ratings changes associated with these two revisions to the methodology. The increased measure weights for patient experience/complaints and access revision is assumed to be a cost to the Medicare Trust Fund, as there are more contracts that would see their Star Ratings increase than decrease. The Tukey outlier deletion is assumed to be a saver to the Medicare Trust Fund after the first year, as more contracts would see their Star Ratings decrease rather than increase.

All impacts are considered transfers since no goods or services are increased or decreased.

The impact analysis for the Star Ratings updates takes into consideration the final quality ratings for those contracts that would have Star Ratings changes under this final rule. There are two ways that Star Ratings changes will impact the Medicare Trust Fund:

- A Star Rating of 4.0 or higher will result in a QBP for the MA organization, which, in turn, leads to a higher benchmark. MA organizations that achieve an overall Star Rating of at least 4.0 qualify for a QBP that is capped at 5 percent (or 10 percent for certain counties).
- The rebate share of the savings will be higher for those MA organizations that achieve a higher Star Rating. The rebate share of savings amounts to 50 percent for plans with a rating of 3.0 or fewer stars, 65 percent for plans with a rating of 3.5 or 4.0 stars, and 70 percent for plans with a rating of 4.5 or 5.0 stars.

In order to estimate the impact of the Star Ratings updates, the MA baseline assumptions are updated with the assumed Star Ratings changes described in this final rule. The MA baseline is completed using a complicated, internal CMS model. The main inputs into the MA baseline model include enrollment and expenditure projections. Enrollment projections are based on three cohorts of beneficiaries: (i) Dual-eligible beneficiaries; (ii) beneficiaries with employer-sponsored coverage; and (iii) all others, including individual-market enrollees. MA enrollment for all markets is projected by trending the growth in the penetration rates for the 2011 through 2018 base data. The key inputs for the expenditure projections include the following:

- United States Per Capita Cost (USPCC) growth rates.
- Adjustment to MA risk scores for differences in diagnosis coding between MA and fee-for-service beneficiaries.
- Quality bonus (county-specific).
- Phase-out of Indirect Medical Education (county-specific).

Projections are performed separately for payments from the Part A and Part B trust funds. Aggregate projected payments are calculated as the projected per capita cost times the projected enrollment. The Medicare Trust Fund impacts are calculated by taking the difference of the MA baseline with the Star Ratings changes and the original MA baseline.

The results are presented in Table 12. The last column of Table 12 presents net savings to the Medicare Trust Fund once both provisions are in place; in 2024 the costs are $345.1 million; the net savings will grow over time reaching $999.4 million by 2030. The first year only includes the implementation of the weight change, while future years include both the weight change and Tukey outlier deletion resulting in a change from the first year as a cost to the Medicare Trust Fund to a net savings in future years. The aggregate savings over 2024 to 2030 are $4.1 billion. Ordinary inflation is carved out of these estimates. The source for ordinary inflation is Table II.D.1. of the 2019 Medicare Trustees report. It should be noted that there are inflationary factors that are used in the projected Star Ratings and are used in these estimates. The Star Ratings are assumed to inflate at a higher rate for the lower rated contracts than for the higher rated contracts. MA organizations with low Star Ratings have a better chance of improving their quality ratings than MA organizations that have already achieved a high Star Rating. For instance, a contract with a Star Rating of 4.5 has less room to increase its Star Rating than a contract with a Star Rating of 3.0.

There is a large projected reduction in the costs associated with the increase in the weight of measures classified as

patient experience/complaints and access measures in 2029. This is due to several contracts that are projected to achieve a 4.0 Star Rating in 2029 and are eligible for the QBP at that time, even after this final rule is applied. This narrows the difference in costs between the final rule and the original baseline.

The impact on costs is not seen until 2024 for the increase in weights and 2025 for the Tukey outlier deletion since these policies are being implemented for the 2021 and 2022 measurement years (meaning performance periods), respectively. A change for the 2021 measurement year impacts the 2023 Star Ratings which determines the MA QBPs for the 2024 contract year. Similarly, a change for the 2022 measurement year impacts the 2024 Star Ratings which determines the MA QBPs for the 2025 contract year.

TABLE 12—CALCULATIONS OF NET SAVINGS PER YEAR TO THE MEDICARE TRUST FUND FOR STAR RATINGS UPDATES

Calendar year	Ordinary inflation (%)	Increased cost (weight) in patient access and experience/complaints ($ millions)	Increased cost (weight) in patient access and experience/complaints ($ millions) with ordinary inflation carved out	Savings from Tukey outlier deletion ($ millions)	Savings from Tukey outlier deletion ($ millions) with ordinary inflation carved out	Net savings with ordinary inflation carved out ($ millions)
2024	3.20	391.4	345.1	0	0.0	–345.1
2025	3.20	305.4	260.9	935	798.8	537.9
2026	3.20	296.1	245.1	1,029.00	851.8	606.7
2027	3.20	343.4	275.4	1,110.50	890.8	615.3
2028	3.20	301.1	234.0	1,296.50	1007.7	773.7
2029	2.60	93.9	71.1	1,356.90	1027.9	956.8
2030	2.60	95.7	70.7	1,449.20	1070.0	999.4
Totals with inflation carved out			1502.3		5647.0	4144.6

Note: In all but the last column both costs and savings are expressed as positive numbers. Positive numbers in the last column indicate savings while negative numbers indicate net cost.

We received the following comments on our estimates of cost impacts, and our responses follow.

Comment: A couple of commenters wanted more information on the modeling related to the financial impacts.

Response: The modeling is based on taking the difference of the MA baseline with the Star Ratings changes (Tukey outlier deletion and the weight increase for patient experience/complaints and access measures) and the original MA baseline which is described in the Medicare Trustees Report available at *https://www.cms.gov/Research-Statistics-Data-and-Systems/Statistics-Trends-and-Reports/ReportsTrustFunds/Downloads/TR2019.pdf.* CMS assumptions related to enrollment and revenue growth are available in the Medicare Trustees Report. Some commenters referenced analyses that Wakely [56] conducted that suggested a higher impact for deletion of outliers. As we are implementing these changes on top of guardrails, which will already limit significant movements of cut points from year-to-year, we do not believe that the estimates should be higher than what was included in the notice of proposed rulemaking.

As many commenters noted, the COVID–19 public health emergency does create more uncertainly in terms of how performance and quality metrics will change following the pandemic. At this time there is too much uncertainty to revise these estimates to reflect the impact of the pandemic on quality measure scores. CMS will continue to monitor the impact for additional changes.

Comment: A few commenters mentioned the analysis by Wakely referenced in the prior comment which suggests that CMS may have overestimated the weight impact on Star Ratings for plans. The report also found there is significant year-over-year volatility in average Star Ratings for patient experience/complaints and access measures, despite consistent trends in plan performance over time and that increasing the weight of these measures could impact the stability of the Star Ratings program.

Response: The Wakely report claims that the volatility in cut points over time is primarily driven by the clustering methodology. CMS disagrees with this conclusion. The majority of measures included in the patient experience/complaints and access categories do not use the clustering methodology. CAHPS measure Star Ratings are calculated using relative distribution and significance testing, per §§ 422.166(a)(3) and 423.186(a)(3). CMS has seen over time that changes in measure cut points are primarily driven by differences in the distribution of scores over time and changes in industry performance. It is also not clear whether Wakely took into consideration other changes to the Star Ratings methodology over time, including the retirement of the Part D appeals and BMI measures.

In the proposed rule, CMS proposed outlier deletion using the Tukey outer fence outlier removal. The main objective of removing outliers is to stabilize cut points and prevent large year-to-year fluctuations in cut points. Even for skewed distributions, Tukey outlier removal works to stabilize cut points to avoid substantial year-to-year fluctuations in cut points that can be caused by extreme outliers.

Comment: A couple of commenters questioned the budget estimates for the new policies. They mentioned the Wakely report noting that the report estimated that increasing the weights of patient experience/complaints and access measures in the 2023 Star Ratings would only increase MA plan payments by $83 million—nearly 5 times less than what CMS estimated. A commenter stated that when combined with the proposal to exclude outliers, more MA enrollees would be in plans negatively impacted than those who would see positive results. The commenter requested CMS to first provide more details on its methodology to allow plans to run similar simulations to better understand the impact of the

[56] Wakely Consulting Group. Star Rating Variability of Patient Experience and Access Measures: Analyzing the Impact of Variable Star Rating Cut Points and Measure Level Results. March 2020.

proposed change to the weighting for these measures and plan ratings

Response: It is unclear to CMS how Wakely did their simulations. For example, it appears that Wakely did not understand that the CAHPS measures are not calculated using the clustering methodology, and consequently, Tukey outlier deletion would not be applied to that group of measures. CMS simulations were conducted assuming the implementation of guardrails which limits the fluctuation in cut points and assuming the retirement of the Part D appeals and BMI measures. Wakely stated they applied mean resampling and guardrails to the Star Rating cut points prior to applying Tukey outlier deletion; therefore, the estimated impact of Tukey outlier deletion does not include the impact of mean resampling and guardrails. We specifically proposed that prior to applying mean resampling with hierarchal clustering, Tukey outer fence outliers are removed and this is how CMS conducted the simulations. This may be causing some of the discrepancies. As described above, CMS estimated the change in the ratings of MA contracts and then modeled the cost impact using that information and enrollment and expenditure projections. Enrollment projections are based on three cohorts of beneficiaries: (i) Dual-eligible beneficiaries; (ii) beneficiaries with employer-sponsored coverage; and (iii) all others, including individual-market enrollees. MA enrollment for all markets is projected by trending the growth in the penetration rates for the 2011 through 2018 base data. The key inputs for the expenditure projections include the USPCC growth rates, adjustment to MA risk scores, quality bonuses (county-specific), and phase-out of indirect medical education (county-specific).

After careful consideration of all comments received, and for the reasons set forth in our responses to the related comments summarized earlier, we are finalizing our impact analysis for the Star Ratings updates to include delayed implementation of Tukey outlier deletion by one year.

5. Medical Loss Ratio (MLR) (§§ 422.2420, 422.2440, and 423.2440)

Regulatory Changes to Incurred Claims (§ 422.2420)

As discussed in section IV.D.2 of this final rule, we are finalizing our proposal to amend the regulation at § 422.2420(b)(2)(i) so that the incurred claims portion of the MLR numerator for an MA contract would include all amounts that an MA organization pays (including under capitation contracts) for covered services for all enrollees under the contract. Prior to this regulatory change, § 422.2420(b)(2)(i) specified that incurred claims include direct claims that an MA organization pays to providers as defined in § 422.2 (including under capitation contracts with physicians) for covered services provided to all enrollees under the contract.

We proposed this amendment so that incurred claims in the MLR numerator will include expenditures for certain supplemental benefits that MA organizations are newly authorized to offer to MA enrollees as a result of recent policy and legislative changes. As explained in greater detail in section II.A. of this final rule and sections II.A. and VI.F. of the proposed rule, recent subregulatory guidance and statutory changes have expanded the types of supplemental benefits that MA organizations may offer to enrollees. Beginning in 2020, pursuant to section 1852(a)(3)(D) of the Act, as amended by the BBA of 2018, MA organizations may provide SSBCI. SSBCI can include benefits that are not primarily health related, as long as the item or service has the reasonable expectation to improve or maintain the chronically ill enrollee's health or overall function. In addition, effective January 1, 2019, CMS' interpretation of ''primarily health related benefits,'' which is used as a criterion for supplemental benefits, has been changed to include services or items used to diagnose, compensate for physical impairments, ameliorate the functional/psychological impact of injuries or health conditions, or reduce avoidable emergency and healthcare utilization. To be considered ''primarily health related,'' a supplemental benefit must focus directly on an enrollee's health care needs and should be recommended by a licensed medical professional as part of a health care plan, but it need not be directly provided by one.

This impact analysis assumes that the amendments to § 422.2420(b)(2)(i) would not impact MA enrollee benefits. In other words, the analysis assumes the amendments would change the types of expenditures that could be included in the MLR numerator as incurred claims, but there would be no impact on the level or number of permissible enrollee benefits that MA plans elect to offer.

The requirements pertaining to the calculation and reporting of MA contracts' MLRs are presented in 42 CFR part 422, subpart X. MA organizations that do not meet the 85 percent minimum MLR requirement for a contract year are required to remit funds to us (§ 422.2410(b)). We collect remittances by deducting the amounts owed from MA organizations' monthly payments (§ 422.2470(c)). In the absence of statutory language directing us to return remitted funds to the Medicare Trust Fund, we transfer remittances to the Treasury. For purposes of this impact analysis, we assume contracts that have an MLR of less than 85 percent for one contract year do not continue to fail to meet the MLR requirement for an additional two consecutive contract years, which would result in imposition of enrollment sanctions, or for an additional four consecutive contract years, which would result in contract termination. This is consistent with our experience; although the MLR requirement has only been in effect for five contract years, to date, very few contracts have been subject to MLR-related enrollment sanctions, and only one contract has failed to meet the MLR requirement for more than three consecutive contract years. No contract has been terminated for failure to meet the MLR requirement for five consecutive contract years.

Total remittances for individual contract years can be substantial. Based on internal CMS data, the simple average of total remittances across all contracts for contract years 2014—2017 is $131 million. If we adjusted these payments to a 2017 level by trending for enrollment and per capita growth but carving out ordinary inflation, the average would be $139 million.

We anticipate that the amendments to § 422.2420(b)(2)(i), which we are finalizing in this final rule, would increase the numerator of the MLR because the incurred claims category would include certain expenditures that would not qualify for inclusion in the numerator under the current regulations. Specifically, under the amendments to § 422.2420(b)(2)(i) that we are finalizing, incurred claims would include amounts that an MA organization pays (including under capitation contracts) for covered services, regardless of whether payment is made to an individual or entity that is a provider as defined at § 422.2. We expect that this will cause some MA contracts which formerly would not have satisfied the 85 percent minimum MLR requirement to now meet or exceed it. For contracts that still fail to meet the 85 percent threshold, we anticipate that the amount of remittances would decrease. In other words, we anticipate that the amendments to § 422.2420(b)(2)(i) that we are finalizing will effectively result in a transfer of funds from the Treasury

to the MA organizations through the Medicare Trust Fund. Amounts that MA organizations would remit and which the Treasury would receive under the regulations prior to their amendment by this final rule will instead remain with the MA organizations, implying that MA organizations will enjoy cost savings while the Treasury has a cost impact. The net impact on the Medicare Trust Fund is expected to be zero, since there will be no additional transfers from or to the Medicare Trust Fund; the only issue will be whether the MA organizations retain additional funds or the Treasury receives fewer funds.

To estimate the amount of payments made for services that would be included in incurred claims under the amendments to § 422.2420(b)(2)(i) that we are finalizing, we used data in the 2019 submitted bids to estimate the increase in the supplemental benefits category for the primarily health related benefits that MA organizations could include in their PBPs starting in 2019. This estimate is complicated by the fact that, in the absence of the amendments to § 422.2420(b)(2)(i), some types of supplemental benefits that MA organizations could offer starting in 2019 could potentially meet the requirements at § 422.2430 to be quality improvement activities (QIAs) for MLR purposes, meaning expenditures for those benefits could be included in the MLR numerator. Based on the 2019 submitted bid information, a consideration of the types of benefits that MA organizations could offer under our reinterpretation of the ''primarily health related'' definition, and the likelihood that some of these benefits would meet the requirements at § 422.2430(a) to be QIAs, we estimated a 52 percent increase in projected expenditures for the categories of ''primarily health related'' supplemental benefits that would not qualify for inclusion in the MLR numerator as ''incurred claims'' under § 422.2420(b)(2)(i), as defined prior to the amendment that we are finalizing in this final rule, or as QIA under § 422.2430(a). The first year that the expanded interpretation of ''primarily health related benefits'' was implemented was 2019, and so the increase seen in these categories for 2019 is attributed to this reinterpretation. To date, MA organizations have only been able to include non-primarily health related SSBCI in their plan offerings for one year (that is, 2020). While early indications show that utilization for these benefits have been low, we expect the use of these benefits to grow over time as MA organizations become more familiar with them and have time to include them in future plan offerings. Due to the absence of credible data for SSBCI, the impact on future MLR remittances is currently unquantifiable. We will continue to track SSBCI information and adjust the forecasts as more information becomes available.

We then reevaluated the MLRs for those contracts that failed to meet the 85 percent MLR requirement for contract years 2014—2017 by revising the numerator calculation to incorporate the 52 percent increase in the previously listed benefits. The change in the numerator calculation resulted in several of the contracts passing the MLR requirement instead of failing. For contracts that would not have met the MLR requirement even with the revised numerator calculation, the amount of remittances decreased. The average decrease in remittance payments over the four-year period (that is, 2014—2017) is estimated to be $25.8 million (in 2017 dollars).

In order to project the decrease in remittances for the years 2021—2030, the $25.8 million was increased using estimated enrollment and per capita increases based on Tables IV.C1 and IV.C3 of the 2019 Medicare Trustees Report, with ordinary inflation (Table II.D1 of the 2019 Medicare Trustees Report) carved out of the estimates.

The results are presented in Table 13, which shows that for the first year of the finalized provision, 2021, there will effectively be a transfer from the Treasury through the Medicare Trust Fund of $35.3 million to MA organizations. (For computational transparency, the table also shows the amounts that would have been transferred to MA organizations for 2017—2020 if the change we are finalizing in this final rule had been in place in those years.) This transfer is in the form of a reduction in the remittance amounts withheld from MA capitated payments. This amount (that is, the amount of remittances *not* withheld from MA capitated payments under the finalized provision) is projected to grow over 10 years, resulting in a $56.4 million transfer from the Treasury through the Medicare Trust Fund to MA organizations in 2030. The total transfer from the Treasury to MA organizations over 10 years is $455 million. There is $0 impact on the Medicare Trust Fund.

TABLE 13—TRANSFER OF REMITTANCES FROM THE TREASURY TO MA ORGANIZATIONS

Year	Medicare Advantage enrollment increase	Average annual per capita increase %	Ordinary inflation	Net costs ($ millions)
2017				25.8
2018	7.7	5.5	3.2	28.4
2019	6.7	5.5	3.2	31.0
2020	5.0	5.5	3.2	33.3
2021	3.6	5.5	3.2	35.3
2022	3.8	5.5	3.2	37.5
2023	3.5	5.5	3.2	39.7
2024	3.3	5.5	3.2	41.9
2025	3.1	5.5	3.2	44.2
2026	3.0	5.5	3.2	46.5
2027	2.7	5.5	3.2	48.8
2028	2.5	5.5	3.2	51.1
2029	2.3	5.5	2.6	53.8
2030	2.0	5.5	2.6	56.4
Total 2021–2030				455.2

We received no comments on our impact analysis and are finalizing the proposal without modification.

Deductible Factor for MA Medical Savings Account (MSA) Contracts (§ 422.2440)

As discussed in section IV.D.4. of this final rule, we are finalizing our proposal to amend § 422.2440 to provide for the application of a deductible factor to the MLR calculation for MA MSA contracts that receive a credibility adjustment. The deductible factor will serve as a multiplier on the credibility factor. We are also finalizing our proposal to adopt and codify in new paragraph (g) of § 422.2440 the same deductible factors that appear in the commercial MLR regulations at 45 CFR 158.232(c)(2). For partially credible MA MSA contracts, the deductible factor will range from 1.0 for MA MSA contracts that have a weighted average deductible of less than $2,500 to 1.736 for MA MSA contracts have a weighted average deductible of $10,000 or more.

In section IV.D.4. of this final rule, we explain that we proposed to add a deductible factor to the MLR calculation for MSAs so that organizations currently offering MSA plans, or those that are considering entering the market, are not deterred from offering MSAs due to concern that they will be unable to meet the MLR requirement as a result of random variations in claims experience. Although we believe that the deductible factors would adequately address any such concerns by making it less likely that an MSA contract will fail to meet the MLR requirement due to random variations in claims experience, we are uncertain whether or how the proposed change to the MLR calculation for MA MSA contracts will impact the availability of MA MSAs or the number of beneficiaries enrolled in MA MSAs. Due to this uncertainty, we estimate that the cost impact of the change to the MLR calculation for MA MSAs will be as low as $0 or as high as $40 million over 10 years (2021–2030).

We do not anticipate that applying a deductible factor to the MLR calculation for MA MSA contracts will have an impact on remittances to the federal government. For contract years 2014–2018 (the most recent contract year for which MA MSAs have submitted MLR data), no MA MSA contract has failed to meet the 85 percent minimum MLR requirement. If the deductible factor had applied to the MLR calculation for MA MSAs for contract years 2014–2018, although the MLRs for partially credible MA MSAs would have been higher, total remittances by MA MSAs would have remained at $0. We do not anticipate that MSA contracts that currently meet the MLR requirement will have more difficulty doing so after the deductible factor is applied to the MLR calculation, starting in contract year 2021. We anticipate that new MA MSA contracts that MA organizations may choose to offer as a result of this regulatory change will also succeed in meeting the MLR requirement, in light of the experience of current MSAs and in consideration of the more generous credibility adjustment that potential new MSAs would be expected to receive as a result of the application of the deductible factor.

We believe that the cost impact of this regulatory change, if any, will be attributable to an increase in MA MSA enrollment as these plans become more widely available as a result of MA organizations choosing to offer MA MSAs in response to the change to the MLR calculation. To develop the upper limit of the cost estimate for this impact analysis ($40 million over 10 years), we assumed that the change to the MLR calculation for MSAs would cause MA MSA enrollment to double over the first 3 years that the change is in effect. We estimated that, relative to previous enrollment projections that did not account for the amendments that we are finalizing in this final rule, this regulatory change MSA enrollment will be 33.33 percent higher in 2022, 66.67 percent higher in 2023, and 100 percent higher in 2024 to 2030. We assumed that half of the new enrollees in MA MSA plans would otherwise have been enrolled in other types of MA plans, and half would otherwise have been enrolled in FFS Medicare.

We did consider the migration patterns for EGWP ESRD beneficiaries versus Individual ESRD beneficiaries. We surmised that the costs differences between EGWP and Individual ESRD coverages are not significant enough to display the migration patterns separately. Displaying projections at that coverage level would not provide further understanding of the financial projections since the cost differences are not too different. Furthermore, EGWP plans have not submitted bids since 2017 and their payments are based on aggregated Individual bids so the cost differences would not be expected to be too different.

We then determined the difference between the amount we pay for each MA MSA plan enrollee and the amount we pay for each enrollee in a non-MSA MA plan or FFS Medicare. We generally incur greater costs for MA MSA enrollees relative to enrollees in other MA plans because 100 percent of the difference between the MA MSA's projection of the cost of A/B services (referred to as the MSA premium) and the benchmark is deposited in the enrollee's account. By contrast, for non-MSA MA plans that bid under the benchmark, we retain between 30 percent and 50 percent of the amount by which the benchmark exceeds the bid. FFS spending per enrollee is approximately 100 percent of the amount we pay to MA plans for each enrollee. Therefore, the cost to the Medicare program for each additional MA MSA enrollee is approximately the same regardless of whether the enrollee would otherwise have been enrolled in a non-MSA MA plan or in FFS Medicare.

The estimated annual cost to the Medicare Trust fund by contract year is presented in Table 14. This estimate takes into account the projected growth in MSA enrollment in the part C baseline projection supporting the Mid-Session Review of the FY 2020 President's Budget. The estimated annual cost reflects the additional cost to the Medicare program for each beneficiary who enrolls in an MA MSA plan in lieu of a non-MSA MA plan or FFS Medicare, multiplied by the projected increase in the number of enrollees in MA MSA plans.

TABLE 14—ESTIMATED COST PER YEAR TO THE MEDICARE TRUST FUND FOR CHANGES TO MLR CALCULATION FOR MA MSA CONTRACTS

Contract year	2021	2022	2023	2024	2025	2026	2027	2028	2029	2030	2021–2030
Annual cost (millions)	$0.0	$1.2	$2.4	$4.0	$4.4	$4.8	$5.2	$5.6	$6.0	$6.4	$40.0
Proposed Annual Increase in MA MSA Enrollment	0	2,604	5,453	8,531	8,876	9,213	9,531	9,833	10,118	10,354	

We received no comments on our impact analysis and are finalizing the proposal without modification.

6. Medicare Advantage (MA) and Cost Plan Network Adequacy (§§ 417.416 and 422.116)

Our final rule codifies the standards and methodology used currently, with some modifications, to evaluate network adequacy for MA plans and section 1876 cost plans; the final rule includes the list of provider and facility specialty types subject to network adequacy reviews, county type designations and ratios, maximum time and distance standards and minimum number requirements. The final rule also formalizes the CMS exceptions process and requires the annual publishing of the Health Services Delivery (HSD) reference file, which will provide updated numbers and maximums for these standards in subsequent years, and the Provider Supply File, which lists available providers and facilities, including their corresponding office locations and specialty types. CMS will continue to use the current PRA-approved collection of information in conjunction with the HPMS Network Management Module as a means for MA organizations to submit network information when required. As this has been the process for conducting network adequacy reviews since 2016, we do not expect any additional burden on MA plans as it relates to the network adequacy review process.

Our final rule is solely related to the sufficiency of contracted networks that MA organizations must maintain and has no impact on the provision of Medicare benefits that must be provided in either in-network and out-of-network settings. As a result, we do not expect any impact on the Medicare Trust Fund.

However, we are finalizing three modifications to current network adequacy policy that may have qualitative impacts on MA organizations. In Micro, Rural, and CEAC county designation types, we are reducing the percentage of beneficiaries residing within maximum time and distance standards from 90 percent to 85 percent. We will allow for a 10-percentage point credit towards the percentage of beneficiaries residing within maximum time and distance when MA organizations contract with one or more telehealth providers in the specialties of Dermatology, Psychiatry, Neurology, Otolaryngology, Cardiology, Ophthalmology, Allergy and Immunology, Nephrology, Primary Care, Gynecology/OB/GYN, Endocrinology, and Infectious Diseases. Similarly, MA organizations may receive a 10-percentage point credit towards the percentage of beneficiaries residing within published time and distance standards for affected provider and facility types in states that have CON laws, or other state imposed anti-competitive restrictions, if the laws limit the number of providers or facilities in a county or state.

With respect to the reduction in percentage of beneficiaries residing within maximum time and distance standards in rural counties, we expect that MA organizations will have a greater likelihood of complying with our reduced percentage in the initial network submission and will not need to request an exception for CMS's consideration. It is not possible to fully quantify the level of effort or hours required for an MA organization to submit an exception request, as they are submitted for multiple reasons. However, generally, we expect that this change will decrease the administrative burden on MA organizations when going through the network review process. Conceivably, the administrative costs included in an MA organization's bid could decrease. However, the decrease in administrative burden could be offset by the increase in administrative burden of contracting with telehealth providers. Additionally, more MA organizations may consider providing contracted services in areas that have traditionally been difficult to establish a sufficient network. The ability to meet compliance standards in new markets is a reasonable factor that may drive MA organization behavior, but we cannot quantify the likelihood of this, as many other factors are considered when entering new markets. In theory, the reduction in the rural percentage could conceivably increase MA enrollment, however our enrollment projections currently do not consider health plans' network adequacy information, and any changes to enrollment projections would be very minor.

By crediting MA organizations 10-percentage points towards the percentage of beneficiaries residing within time and distance standards for contracting with telehealth providers for certain specialties, we anticipate that this will be one of many factors that will help encourage MA organizations to contract with providers that offer telehealth services. However, we do not expect this policy change to significantly alter MA organization contracting patterns related to telehealth providers.

For the 10-percentage point credit for affected providers and facilities in states with CON laws, we expect that MA organizations will have a greater likelihood of complying with network adequacy standards in the initial network submission and will not need to request an exception for CMS's consideration. As we discussed earlier, it is not possible to fully quantify the level of effort or hours required for an MA organization to submit an exception request, but it is possible the administrative costs included in an MA organization's bid could decrease. However, we believe time associated with completing exception requests is nominal will not have a significant impact on the overall administrative costs submitted in a plan's bid.

In summary, we believe this proposal will have a non-quantifiable, negligible economic impact. We received no comments on the regulatory impact of this proposal, and therefore, we are finalizing this provision without modification.

E. Alternatives Considered

We intend to address the proposals that had Alternatives Considered sections from the February 2020 proposed rule in subsequent rulemaking. CMS did not develop Alternatives Considered sections for most of the provisions in this final rule as they generally are direct implementations of federal laws or codifications of existing policy for the Part C and D programs. In this section, CMS includes discussions of Alternatives Considered for the provisions to which they are applicable.

1. Medicare Advantage (MA) Plan Options for End-Stage Renal Disease (ESRD) Beneficiaries (§§ 422.50, 422.52, and 422.110)

We have considered alternatives to estimated costs to the Medicare Trust Funds for removing the prohibition for ESRD beneficiaries to enroll in MA plans. Table 7 above displays the baseline scenario that ESRD enrollment in MA plans is expected to increase by 83,000 due to the Cures Act provision. This increase is assumed to be phased in over 6 years, with half of the beneficiaries (41,500) enrolling during 2021. Table 7 shows the net cost to range from $23 million in CY 2021 to $440 million in CY 2030 which sums to $2.66 billion cost for those 10 years.

The upper scenario uses the assumption that the entire ESRD enrollment increase in MA plans of 83,000 will occur in 2021. All other assumptions are expected to remain the same as those in the baseline. Under this upper scenario, net costs are expected to range from $45 million in CY 2021 to $440 million in CY2030

which sums to $2.73 billion cost for the 10 year projection period.

The lower scenario uses a slower ESRD enrollment increase assumption. Under this scenario, the ESRD enrollment will linearly increase from 8,300 in 2021 to 83,000 in 2030. All other assumptions are expected to remain the same as those in the baseline. Under this lower scenario, net costs are expected to range from $5 million in CY 2021 to $440 million in CY2030 which sums to $1.87 billion cost for the 10 year projection period.

2. Medicare Advantage (MA) and Part D Prescription Drug Program Quality Rating System (§§ 422.162, 422.164, 422.166, 422.252, 423.182, 423.184, and 423.186)

We have considered alternative methodologies for deleting outliers prior to clustering for determining cut points for non-CAHPS measures for the Star Ratings program.

For example, we have considered trimming, which removes scores below and above a certain percentile. As stated in the NPRM, this methodology would remove scores regardless of whether they are true outliers; thus, this methodology would not meet the policy goal of removing outliers as well as the approach we proposed and might not have a negligible impact on the cost estimates.

For the Tukey outlier deletion provision as described in section VIII.D.5. of this final rule, we considered which year it should begin. In the NPRM we proposed for it to begin for the 2021 measurement year, which impacts the 2023 Star Ratings and 2024 Quality Bonus Payment ratings. To provide more time for the healthcare delivery system to adapt to changes from the COVID–19 pandemic, we are finalizing a delay until the 2022 measurement year, which impacts the 2024 Star Ratings and the 2025 Quality Bonus Payment ratings. The cost impact of this change is $713 million (that is, this amount will not be saved from the Medicare Trust Fund in 2024).

We have also considered alternatives to the doubling of the weight from 2 to 4 for patient experience/complaints measures and access measures for the Star Ratings program as described in section VIII.D.5. of this final rule. For example, we considered a weight increase to 3 or 5 for these measures. With a weight increase to 3, there are very small changes in the number of contracts that would increase their highest Star Rating, resulting in negligible impacts on Quality Bonus Payments and costs to the Medicare Trust Fund relative to a weight of 4. Similarly, if we were to increase the weight even further to 5, we anticipate even greater impacts on the Quality Bonus Payments and, consequently, costs to the Medicare Trust Fund.

Finally, we considered delaying any weight increase given the uncertainty about how COVID–19 will impact the healthcare system; however, we decided to proceed to further emphasize the importance of patient experience/complaints measures and access measures.

3. Medical Loss Ratio (MLR) (§§ 422.2420, 422.2440, and 423.2440)

We considered finalizing the proposal to add a deductible factor to the MLR calculation for MA MSA contracts (section VIII.D.6. of this final rule) with an applicability date of January 1, 2022, rather than January 1, 2021, since this rule is not being finalized until after the deadline for MA organizations to apply to offer MSA plans in 2021. However, as discussed in greater detail in section IV.D.4. of this final rule, we believe that the credibility factors used to adjust the MLRs of low enrollment contracts do not adequately account for the impact of claims variability on the MLRs of high deductible MSA contracts. We therefore believe it is appropriate that we finalize the provision to add a deductible factor to the MLR calculation for MA MSA contracts with an applicability date of January 1, 2021, as this will allow the deductible factor to be applied when calculating the contract year 2021 MLRs for current MA MSA contracts. However, as no current MA MSA contract has failed to meet the minimum MLR requirement for a previous contract year, we do not anticipate that applying a deductible factor to those contracts' contract year 2021 MLRs will have an impact on remittances.

F. Accounting Statement and Table

The following table summarizes savings, costs, and transfers by provision. As required by OMB Circular A–4 (available at *https://obamawhitehouse.archives.gov/omb/circulars_a004_a-4/*), in Table 15, we have prepared an accounting statement showing the savings, costs, and transfers associated with the provisions of this final rule for calendar years 2021 through 2030. Table 15 is based on Tables 16A, 16B, and 16C which lists savings, costs, and transfers by provision. Table 15 is expressed in millions of dollars with both costs and savings listed as positive numbers; aggregate impact is expressed as a negative number (cost versus savings). The sign of the transfers follow the convention of Table 16 with positive numbers reflecting costs (as transfers) to government entities (the Medicare Trust Fund and the Treasury) and negative numbers reflecting savings to government entities. As can be seen, the net annualized impact of this rule is a cost of about $1.9 million per year. The raw aggregate cost over 10 years is $18.5 million. Due to transfers, there is net annualized reduced spending by government agencies (the Medicare Trust Fund and Treasury) of $290–$335 million. A breakdown of these savings from various perspectives may be found in Table 16.

TABLE 15—ACCOUNTING TABLE

(millions $) *

Item	Annualized at 7%	Annualized at 3%	Period	Who is impacted
Net Annualized Monetized Savings.	(1.9)	(1.9)	Contract Years 2021–2030	Federal government, MA organizations and Part D Sponsors.
Annualized Monetized Savings.			Contract Years 2021–2030	
Annualized Monetized Cost	1.9	1.9	Contract Years 2021–2030	Federal government, MA organizations and Part D Sponsors.

TABLE 15—ACCOUNTING TABLE—Continued

(millions $) *

Item	Annualized at 7%	Annualized at 3%	Period	Who is impacted
Transfers	(293.7)	(334.5)	Contract Years 2021–2030	Transfers between the Dept of Treasury and CMS (Medicare Trust Fund, Plans, and Sponsors).

* The ESRD enrollment and Kidney acquisition cost provisions which affected the pre-statutory baseline but did not further impact the codifications of this rule would have added $128.3 and $113.1 million respectively in annualized transfer savings, resulting in total annualized transfer savings of $421.99 and $447.65 savings at 7 percent and 3 percent respectively. *Note:* Negative numbers indicate a net reduction in dollar spending by the government.

The following Table 16 summarizes savings, costs, and transfers by provision and forms a basis for the accounting table. For reasons of space, Table 16 is broken into Table 16A (2021 through 2024), Table 16B (2025 through 2028), and Table 16C (2029–2030), as well as raw totals. In these tables, all numbers are positive; positive numbers in the savings columns indicate actual dollars saved while positive numbers in the costs columns indicate actual dollars spent; the aggregate row indicates savings less costs and does not include transfers. All numbers are in millions. Tables 16A, B, and C form the basis for Table 15.

TABLE 16A: AGGREGATE SAVINGS, COST, AND TRANSFERS IN MILLIONS BY PROVISION AND YEAR FROM 2021 THROUGH 2024

	2021 Savings	2021 Cost	2021 Transfers	2022 Savings	2022 Cost	2022 Transfers	2023 Savings	2023 Cost	2023 Transfers	2024 Savings	2024 Cost	2024 Transfers
Total Savings	-			-			-			-		
Total Costs		2.1			1.8			1.8			1.8	
Aggregate Total	(2.1)			(1.8)			(1.8)			(1.8)		
Total Transfers			35.3			38.1			40.9			389.0
Health Plan Quality Rating system												345.1
Medical Loss Ratio Regulation			35.30			37.50			39.70			41.9
MSA MLR						0.6			1.2			2.0
SSBCI		2.1			1.8			1.8			1.8	

TABLE 16B: AGGREGATE SAVINGS, COST, AND TRANSFERS IN MILLIONS BY PROVISION AND YEAR FROM 2025 THROUGH 2028

	2025 Savings	2025 Cost	2025 Transfers	2026 Savings	2026 Cost	2026 Transfers	2027 Savings	2027 Cost	2027 Transfers	2028 Savings	2028 Cost	2028 Transfers
Total Savings	-			-			-			-		
Total Costs		1.8			1.8			1.8			1.8	
Aggregate Total	(1.8)			(1.8)			(1.8)			(1.8)		
Total Transfers			(491.5)			(557.8)			(563.9)			(719.8)
Health Plan Quality Rating system			(537.9)			(606.7)			(615.3)	-		(773.7)
Medical Loss Ratio Regulation			44.2			46.5			48.8			51.1
MSA MLR			2.2			2.4			2.6			2.8
SSBCI		1.8			1.8			1.8			1.8	

TABLE 16C—AGGREGATE SAVINGS, COST, AND TRANSFERS IN MILLIONS BY PROVISION AND YEAR FROM 2029 THROUGH 2030 AND RAW TOTALS

	2029 Savings	2029 Cost	2029 Transfers	2030 Savings	2030 Costs	2030 Transfers	Raw 10 year totals (savings)	Raw 10 year totals (costs)	Raw 10 year totals (transfers)
Total Savings									
Total Costs		1.8			1.8			18.5	
Aggregate Total	(1.8)			(1.8)			(18.5)		
Total Transfers			(900.0)			(939.8)			(3,669.4)
Health Plan Quality Rating system			(956.8)			(999.4)			(4,144.6)
Medical Loss Ratio Regulation			53.8			56.4			455.2
MSA MLR			3.0			3.2			20.0
SSBCI		1.8			1.8			18.5	

The following information supplements Table 16 and also identifies how impacts calculated in section VII of this final rule affect the calculations of this section and the tables.

- Table 16 includes a row for the paperwork burden of the SSBCI provision, whose impact is about $1 million a year.
- For the transfer rows, positive numbers indicate transfers that result in increased dollar spending by the government, while negative numbers indicate transfers that result in reduced dollar spending by the government. Costs are expressed as positive numbers; however, net savings are expressed as negative numbers to reflect that the net impact is a cost, not a savings.
- For two provisions, Parts C and D SEPs, and ESRD enrollment, calculations of impact, either paperwork impact or Medicare Trust Fund impact, have been provided in the narrative along with tables providing 10-year summaries. However, since these impacts are already reflected in current spending, in other words, since the provisions do not change current spending, these impacts have not been included in Table 16. Similarly, as explained the section VII, since the SSBCI paperwork burden is already being spent (similar to SEP), the burden is not included in the summary table.
- Besides the enrollment burden for the SEP provision, there is an additional cost of $0.5 million arising from burden to beneficiaries for filling out enrollment forms in several provisions. These costs have been duly noted in section VII of this final rule but were not included in Table 16 since Table 16 deals mainly with impacts on the Medicare Trust Fund and industry.
- For two provisions, D–SNP look alike and MSA MLR, the impact calculated in section VII of this final rule is $0.0 million and hence these amounts are not included in Table 16. They are however included in Table 6 of section VII of this final rule.

We received comments on impacts in certain individual provisions. These comments as well as our responses have been addressed in the appropriate provision sections above. However, none of these comments led to changes in impacts. Additionally, we did not receive any comments on the summary or monetized table and are therefore finalizing these numbers as is with appropriate adjustments for provisions not included in this first final rule.

G. Conclusion

As indicated in Table 16, while the SSBCI provision has a paperwork burden of about $1 million per year, the other provisions of this final rule are all classified as transfers because consumption of goods or usage of services is neither increased nor decreased. However, we note that the provisions of this part 1 of this final rule will reduce dollar spending of the government by about $300 million a year. The primary driver of this is the Tukey outlier provision.

As indicated in Table 16, the government agencies have a net reduction in spending of $3.65 billion over 10 years. The driver of reduction is the use of the Tukey outlier deletion for Star Ratings after the first year of implementation. Other provisions also affect government spending: (1) The MLR provisions will reduce civil penalties to the Treasury by about 0.46 billion; (2) the MLA MSR provisions will cost the government an extra $40 million due to increased spending on benefits arising from expected increased MSA enrollment; (3) the increased weight in patient experience/complaints and access measures and Tukey outlier deletion in the health plan quality rating system (Star Ratings) will reduce Medicare Trust Fund spending by about $1.5 billion.

H. Reducing Regulation and Controlling Regulatory Costs

Executive Order 13771, titled Reducing Regulation and Controlling Regulatory Costs, was issued on January 30, 2017, and requires that the costs associated with significant new regulations ''shall, to the extent permitted by law, be offset by the elimination of existing costs associated with at least two prior regulations.'' This rule has an aggregate cost of $1 million a year arising from paperwork burden associated with the SSBCI provision, and consequently, this rule is classified as a regulatory action for the purposes of Executive Order 13771. At a 7 percent rate, this rule is estimated to cost $1.2 million a year in 2016 dollars over an infinite horizon.

List of Subjects

42 CFR Part 417

Administrative practice and procedure, Grant programs-health, Health care, Health insurance, Health maintenance organizations (HMO), Loan programs-health, Medicare, and Reporting and recordkeeping requirements.

42 CFR Part 422

Administrative practice and procedure, Health facilities, Health maintenance organizations (HMO), Medicare, Penalties, Privacy, Reporting and recordkeeping requirements.

42 CFR Part 423

Administrative practice and procedure, Emergency medical services, Health facilities, Health maintenance organizations (HMO), Medicare, Penalties, Privacy, Reporting and recordkeeping requirements.

For the reasons set forth in the preamble, the Centers for Medicare & Medicaid Services amends 42 CFR chapter IV as set forth below:

PART 417—HEALTH MAINTENANCE ORGANIZATIONS, COMPETITIVE MEDICAL PLANS, AND HEALTH CARE PREPAYMENT PLANS

■ 1. The authority citation for part 417 continues to read as follows:

Authority: 42 U.S.C. 1302 and 1395hh, 42 U.S.C. 300e, 300e–5, and 300e–9, and 31 U.S.C. 9701.

■ 2. Section 417.416 is amended by adding paragraph (e)(3) to read as follows:

§ 417.416 Qualifying condition: Furnishing of services.

* * * * *

(e) * * *

(3) The HMO or CMP must meet network adequacy standards specified in § 422.116 of this chapter.

PART 422—MEDICARE ADVANTAGE PROGRAM

■ 3. The authority citation for part 422 continues to read as follows:

Authority: 42 U.S.C. 1302 and 1395hh.

■ 4. Section 422.3 is added to read as follows:

§ 422.3 MA organizations' use of reinsurance.

(a) An MA organization may obtain insurance or make other arrangements for the cost of providing basic benefits to an individual enrollee in either of the following ways—

(1) The MA organization must retain risk for at least the first $10,000 in costs per individual enrollee for providing basic benefits during a contract year; or

(2) If the MA organization uses insurance or makes other arrangements for sharing such costs proportionately on a per member per year first dollar basis, the MA organization must retain risk based on the following:

(i) The actuarially equivalent value of the retained risk is greater than or equal to the value of risk retained in paragraph (a)(1) of this section.

(ii) The MA organization makes a determination of actuarial equivalence based on reasonable actuarial methods. For example, a reasonable method for determining actuarial equivalence would be to equate the percentage of net claim costs that the MA organization would retain under paragraphs (a)(1) and (a)(2)(i) of this section.

(b) In evaluating compliance with section 1855(b) of the Act and with paragraph (a) of this section, CMS will consider a parent organization and any of its subsidiaries to be part of the MA organization.

(c) The type of payment arrangement used between an MA organization and contracting physicians, other health professionals or institutions for the financial risk specified in section 1855(b)(4) of the Act (that is, the financial risk on a prospective basis for the provision of basic benefit by those physicians or other health professionals or through those institutions) is not limited by paragraph (a) of this section.

§ 422.50 [Amended]

■ 5. Section 422.50 is amended in paragraph (a)(2) introductory text by removing the phrase ''Has not been'' and adding in its place the phrase ''For coverage before January 1, 2021, has not been''.

§ 422.52 [Amended]

■ 6. Section 422.52 is amended in paragraph (c) by removing the phrase ''CMS may waive § 422.50(a)(2)'' and adding in its place the phrase ''For plan years beginning before January 1, 2021, CMS may waive § 422.50(a)(2)''.

■ 7. Section 422.62 is amended by—

■ a. Revising paragraphs (b) introductory text and (b)(3) introductory text;

■ b. Redesignating paragraph (b)(4) as paragraph (b)(26); and

■ c. Adding a new paragraph (b)(4) and paragraphs (b)(5) through (25).

The revisions and additions read as follows:

§ 422.62 Election of coverage under an MA plan.

* * * * *

(b) *Special election periods (SEPs).* An individual may at any time (that is, not limited to the annual coordinated election period) discontinue the election of an MA plan offered by an MA organization and change his or her election from an MA plan to original Medicare or to a different MA plan under any of the following circumstances:

* * * * *

(3) The individual demonstrates to CMS that—

* * * * *

(4) The individual is making an MA enrollment request into or out of an employer sponsored MA plan, is disenrolling from an MA plan to take employer sponsored coverage of any kind, or is disenrolling from employer sponsored coverage (including COBRA coverage) to elect an MA plan. This SEP is available to individuals who have (or are enrolling in) an employer or union sponsored MA plan and ends 2 months after the month the employer or union coverage of any type ends. The individual may choose an effective date that is not earlier than the first of the month following the month in which the election is made and no later than up to 3 months after the month in which the election is made.

(5) The individual is enrolled in an MA plan offered by an MA organization that has been sanctioned by CMS and elects to disenroll from that plan in connection with the matter(s) that gave rise to that sanction.

(i) Consistent with disclosure requirements at § 422.111(g), CMS may require the MA organization to notify current enrollees that if the enrollees believe they are affected by the matter(s) that gave rise to the sanction, the enrollees are eligible for a SEP to elect another MA plan or disenroll to original Medicare and enroll in a PDP.

(ii) The SEP starts with the imposition of the sanction and ends when the sanction ends or when the individual makes an election, whichever occurs first.

(6)(i) The individual is enrolled in a section 1876 cost contract that is not renewing its contract for the area in which the enrollee resides.

(ii) This SEP begins December 8 of the then-current contract year and ends on the last day of February of the following year.

(7) The individual is disenrolling from an MA plan to enroll in a Program of All-inclusive Care for the Elderly (PACE) organization or is enrolling in an MA plan after disenrolling from a PACE organization.

(i) An individual who disenrolls from PACE has a SEP for 2 months after the effective date of PACE disenrollment to elect an MA plan.

(ii) An individual who disenrolls from an MA plan has a SEP for 2 months after the effective date of MA disenrollment to elect a PACE plan.

(8) The individual terminated a Medigap policy upon enrolling for the first time in an MA plan and is still in a ''trial period'' and eligible for ''guaranteed issue'' of a Medigap policy, as outlined in section 1882(s)(3)(B)(v) of the Act.

(i) This SEP allows an eligible individual to make a one-time election to disenroll from his or her first MA plan to join original Medicare at any time of the year.

(ii) This SEP begins upon enrollment in the MA plan and ends after 12 months of enrollment or when the individual disenrolls from the MA plan, whichever is earlier.

(9) Until December 31, 2020, the individual became entitled to Medicare based on ESRD for a retroactive effective date (whether due to an administrative delay or otherwise) and was not provided the opportunity to elect an MA

plan during his or her Initial Coverage Election Period (ICEP).

(i) The individual may prospectively elect an MA plan offered by an MA organization, provided—

(A) The individual was enrolled in a health plan offered by the same MA organization the month before their entitlement to Parts A and B;

(B) The individual developed ESRD while a member of that health plan; and

(C) The individual is still enrolled in that health plan.

(ii) This SEP begins the month the individual receives the notice of the Medicare entitlement determination and continues for 2 additional calendar months after the month the notice is received.

(10) The individual became entitled to Medicare for a retroactive effective date (whether due to an administrative delay or otherwise) and was not provided the opportunity to elect an MA plan during their initial coverage election period (ICEP). This SEP begins the month the individual receives the notice of the retroactive Medicare entitlement determination and continues for 2 additional calendar months after the month the notice is received. The effective date would be the first of the month following the month in which the election is made but would not be earlier than the first day of the month in which the notice of the Medicare entitlement determination is received by the individual.

(11)(i) The individual enrolled in an MA special needs plan (SNP) and is no longer eligible for the SNP because he or she no longer meets the applicable special needs status.

(ii) This SEP begins the month the individual's special needs status changes and ends when the individual makes an enrollment request or 3 calendar months after the effective date of involuntary disenrollment from the SNP, whichever is earlier.

(12) The individual belongs to a qualified State Pharmaceutical Assistance Program (SPAP) and is requesting enrollment in an MA–PD plan.

(i) The individual may make one MA election per year.

(ii) This SEP is available while the individual is enrolled in the SPAP and, upon loss of eligibility for SPAP benefits, for an additional 2 calendar months after either the month of the loss of eligibility or notification of the loss, whichever is later.

(13)(i) The individual has severe or disabling chronic conditions and is eligible to enroll into a Chronic Care SNP designed to serve individuals with those conditions. The SEP is for an enrollment election that is consistent with the individual's eligibility for a Chronic Care SNP. Individuals enrolled in a Chronic Care SNP who have a severe or disabling chronic condition which is not a focus of their current SNP are eligible for this SEP to request enrollment in a Chronic Care SNP that focuses on this other condition. Individuals who are found after enrollment not to have the qualifying condition necessary to be eligible for the Chronic Care SNP are eligible for a SEP to enroll in a different MA plan.

(ii) This SEP is available while the individual has the qualifying condition and ends upon enrollment in the Chronic Care SNP. This SEP begins when the MA organization notifies the individual of the lack of eligibility and extends through the end of that month and the following 2 calendar months. The SEP ends when the individual makes an enrollment election or on the last day of the second of the 2 calendar months following notification of the lack of eligibility, whichever occurs first.

(14) The individual is enrolled in an MA–PD plan and requests to disenroll from that plan to enroll in or maintain other creditable prescription drug coverage.

(i) This SEP is available while the individual is enrolled in an MA–PD plan. The effective date of disenrollment from the MA plan is the first day of the month following the month a disenrollment request is received by the MA organization.

(ii) Permissible enrollment changes during this SEP are to disenroll from an MA–PD plan and elect original Medicare or to elect an MA-only plan, resulting in disenrollment from the MA–PD plan.

(15) The individual is requesting enrollment in an MA plan offered by an MA organization with a Star Rating of 5 Stars. An individual may use this SEP only once for the contract year in which the MA plan was assigned a 5-star overall performance rating, beginning the December 8th before that contract year through November 30th of that contract year.

(16) The individual is a non-U.S. citizen who becomes lawfully present in the United States.

(i) This SEP begins the month the individual attains lawful presence status and ends the earlier of when the individual makes an enrollment election or 2 calendar months after the month the individual attains lawful presence status.

(ii) [Reserved]

(17) The individual was adversely affected by having requested, but not received, required notices or information in an accessible format, as outlined in section 504 of the Rehabilitation Act of 1973 within the same timeframe that the MA organization or CMS provided the same information to individuals who did not request an accessible format.

(i) The SEP begins at the end of the election period during which the individual was seeking to make an enrollment election and the length is at least as long as the time it takes for the information to be provided to the individual in an accessible format.

(ii) MA organizations may determine eligibility for this SEP when the criterion is met, ensuring adequate documentation of the situation, including records indicating the date of the individual's request, the amount of time taken to provide accessible versions of the requested materials and the amount of time it takes for the same information to be provided to an individual who does not request an accessible format.

(18) Individuals affected by an emergency or major disaster declared by a Federal, state or local government entity are eligible for a SEP to make a MA enrollment or disenrollment election. The SEP starts as of the date the declaration is made, the incident start date or, if different, the start date identified in the declaration, whichever is earlier, and ends 2 full calendar months following the end date identified in the declaration or, if different, the date the end of the incident is announced, whichever is later. The individual is eligible for this SEP provided the individual—

(i)(A) Resides, or resided at the start of the SEP eligibility period described in this paragraph (b)(18), in an area for which a federal, state or local government entity has declared an emergency or major disaster; or

(B) Does not reside in an affected area but relies on help making healthcare decisions from one or more individuals who reside in an affected area; and

(ii) Was eligible for another election period at the time of the SEP eligibility period described in this paragraph (b)(18); and

(iii) Did not make an election during that other election period due to the emergency or major disaster.

(19) The individual experiences an involuntary loss of creditable prescription drug coverage, including a reduction in the level of coverage so that it is no longer creditable and excluding any loss or reduction of creditable coverage that is due to a failure to pay premiums.

(i) The individual is eligible to request enrollment in an MA–PD plan.

(ii) The SEP begins when the individual is notified of the loss of creditable coverage and ends 2 calendar months after the later of the loss (or reduction) or the individual's receipt of the notice.

(iii) The effective date of this SEP is the first of the month after the enrollment election is made or, at the individual's request, may be up to 3 months prospective.

(20) The individual was not adequately informed of a loss of creditable prescription drug coverage, or that they never had creditable coverage. CMS determines eligibility for this SEP on a case-by-case basis, based on its determination that an entity offering prescription drug coverage failed to provide accurate and timely disclosure of the loss of creditable prescription drug coverage or whether the prescription drug coverage offered is creditable.

(i) The individual is eligible for one enrollment in, or disenrollment from, an MA–PD plan.

(ii) This SEP begins the month of CMS' determination and continues for 2 additional calendar months following the determination.

(21) The individual's enrollment or non-enrollment in an MA–PD plan is erroneous due to an action, inaction, or error by a Federal employee.

(i) The individual is permitted enrollment in, or disenrollment from, the MA–PD plan, as determined by CMS.

(ii) This SEP begins the month of CMS approval of this SEP on the basis that the individual's enrollment was erroneous due to an action, inaction, or error by a Federal employee and continues for 2 additional calendar months following this approval.

(22) The individual is eligible for an additional Part D Initial Election Period, such as an individual currently entitled to Medicare due to a disability and who is attaining age 65.

(i) The individual is eligible to make an MA election to coordinate with the additional Part D Initial Election Period.

(ii) The SEP may be used to disenroll from an MA plan, with or without Part D benefits, to enroll in original Medicare, or to enroll in an MA plan that does not include Part D benefits, regardless of whether the individual uses the Part D Initial Election Period to enroll in a PDP.

(iii) The SEP begins and ends concurrently with the additional Part D Initial Election Period.

(23) Individuals affected by a significant change in plan provider network are eligible for a SEP that permits disenrollment from the MA plan that has changed its network to another MA plan or to original Medicare. This SEP can be used only once per significant change in the provider network.

(i) The SEP begins the month the individual is notified of eligibility for the SEP and extends an additional 2 calendar months thereafter.

(ii) An enrollee is affected by a significant network change when the enrollee is assigned to, currently receiving care from, or has received care within the past 3 months from a provider or facility being terminated from the provider network.

(iii) When instructed by CMS, the MA plan that has significantly changed its network must issue a notice, in the form and manner directed by CMS, that notifies enrollees who are eligible for this SEP of their eligibility for the SEP and how to use the SEP.

(24) The individual is enrolled in a plan offered by an MA organization that has been placed into receivership by a state or territorial regulatory authority. The SEP begins the month the receivership is effective and continues until it is no longer in effect or until the enrollee makes an election, whichever occurs first. When instructed by CMS, the MA plan that has been placed under receivership must notify its enrollees, in the form and manner directed by CMS, of the enrollees' eligibility for this SEP and how to use the SEP.

(25) The individual is enrolled in a plan that has been identified with the low performing icon in accordance with § 422.166(h)(1)(ii). This SEP exists while the individual is enrolled in the low performing MA plan.

* * * * *

■ 8. Section 422.68 is amended by revising paragraph (d) to read as follows:

§ 422.68 Effective dates of coverage and change of coverage.

* * * * *

(d) *Special election periods.* For an election or change of election made during a special election period as described in § 422.62(b), the coverage or change in coverage is effective the first day of the calendar month following the month in which the election is made, unless otherwise noted.

* * * * *

■ 10. Section 422.102 is amended by adding paragraph (f) to read as follows:

§ 422.102 Supplemental benefits.

* * * * *

(f) *Special supplemental benefits for the chronically ill (SSBCI)—*(1) *Requirements—*(i) *Chronically-ill enrollee.* (A) A chronically ill enrollee is an individual enrolled in the MA plan who has one or more comorbid and medically complex chronic conditions that meet all of the following:

(*1*) Is life threatening or significantly limits the overall health or function of the enrollee;

(*2*) Has a high risk of hospitalization of other adverse health outcomes; and

(*3*) Requires intensive care coordination.

(B) CMS may publish a non-exhaustive list of conditions that are medically complex chronic conditions that are life threatening or significantly limit the overall health or function of an individual.

(ii) *SSBCI definition.* A special supplemental benefit for the chronically ill (SSBCI) is a supplemental benefit that has, with respect to a chronically ill enrollee, a reasonable expectation of improving or maintaining the health or overall function of the enrollee; an SSBCI that meets the standard in this paragraph (f)(1)(ii) may also include a benefit that is not primarily health related.

(2) *Offering SSBCI.* (i) An MA plan may offer SSBCI to a chronically ill enrollee only as a mandatory supplemental benefit.

(ii) Upon approval by CMS, an MA plan may offer SSBCI that are not uniform for all chronically ill enrollees in the plan.

(iii) An MA plan may consider social determinants of health as a factor to help identify chronically ill enrollees whose health or overall function could be improved or maintained with SSBCI. An MA plan may not use social determinants of health as the sole basis for determining eligibility for SSBCI.

(3) *Plan responsibilities.* An MA plan offering SSBCI must do all of the following:

(i) Must have written policies for determining enrollee eligibility and must document its determination that an enrollee is a chronically ill enrollee based on the definition in paragraph (f)(1)(i) of this section.

(ii) Make information and documentation related to determining enrollee eligibility available to CMS upon request.

(iii) Must have written policies based on objective criteria for determining a chronically ill enrollee's eligibility to receive a particular SSBCI and must document these criteria.

(iv) Document each determination that an enrollee is eligible to receive an SSBCI and make this information available to CMS upon request.

§ 422.110 [Amended]

■ 11. Section 422.110 is amended in paragraph (b) by removing the phrase ''An MA organization'' and adding in its place the phrase ''For coverage before January 1, 2021, an MA organization''.

■ 12. Section 422.116 is added to read as follows:

§ 422.116 Network adequacy.

(a) *General rules*—(1) *Access.* (i) A network-based MA plan, as described in § 422.114(a)(3)(ii) but not including MSA plans, must demonstrate that it has an adequate contracted provider network that is sufficient to provide access to covered services in accordance with access standards described in section 1852(d)(1) of the Act and in §§ 422.112(a) and 422.114(a)(1) and by meeting the standard in paragraph (a)(2) of this section. When required by CMS, an MA organization must attest that it has an adequate network for access and availability of a specific provider or facility type that CMS does not independently evaluate in a given year.

(ii) CMS does not require information, other than an attestation, regarding compliance with § 422.116 as part of an application for a new or expanding service area and will not deny application on the basis of an evaluation of the applicant's network for the new or expanding service area.

(2) *Standards.* An MA plan must meet maximum time and distance standards and contract with a specified minimum number of each provider and facility-specialty type.

(i) Each contract provider type must be within maximum time and distance of at least one beneficiary (in the MA Medicare Sample Census) in order to count toward the minimum number.

(ii) The minimum number criteria and the time and distance criteria vary by the county type.

(3) *Applicability of MA network adequacy criteria.* (i) The following providers and facility types do not count toward meeting network adequacy criteria:

(A) Specialized, long-term care, and pediatric/children's hospitals.

(B) Providers that are only available in a residential facility.

(C) Providers and facilities contracted with the organization only for its commercial, Medicaid, or other products.

(ii) [Reserved]

(4) *Annual updates by CMS.* CMS annually updates and makes the following available:

(i) A Health Service Delivery (HSD) Reference file that identifies the following:

(A) All minimum provider and facility number requirements.

(B) All provider and facility time and distance standards.

(C) Ratios established in paragraph (e) of this section in advance of network reviews for the applicable year.

(ii) A Provider Supply file that lists available providers and facilities and their corresponding office locations and specialty types.

(A) The Provider Supply file is updated annually based on information in the Integrated Data Repository (IDR), which has comprehensive claims data, and information from public sources.

(B) CMS may also update the Provider Supply file based on findings from validation of provider information submitted on Exception Requests to reflect changes in the supply of health care providers and facilities.

(b) *Provider and facility-specialty types.* The provider and facility-specialty types to which the network adequacy evaluation under this section applies are specified in this paragraph (b).

(1) *Provider-specialty types.* The provider-specialty types are as follows:

(i) Primary Care.
(ii) Allergy and Immunology.
(iii) Cardiology.
(iv) Chiropractor.
(v) Dermatology.
(vi) Endocrinology.
(vii) ENT/Otolaryngology.
(viii) Gastroenterology.
(ix) General Surgery.
(x) Gynecology, OB/GYN.
(xi) Infectious Diseases.
(xii) Nephrology.
(xiii) Neurology.
(xiv) Neurosurgery.
(xv) Oncology—Medical, Surgical.
(xvi) Oncology—Radiation/Radiation Oncology.
(xvii) Ophthalmology.
(xviii) Orthopedic Surgery.
(xix) Physiatry, Rehabilitative Medicine.
(xx) Plastic Surgery.
(xxi) Podiatry.
(xxii) Psychiatry.
(xxiii) Pulmonology.
(xxiv) Rheumatology.
(xxv) Urology.
(xxvi) Vascular Surgery.
(xxvii) Cardiothoracic Surgery.

(2) *Facility-specialty types.* The facility specialty types are as follows:

(i) Acute Inpatient Hospitals.
(ii) Cardiac Surgery Program.
(iii) Cardiac Catheterization Services.
(iv) Critical Care Services—Intensive Care Units (ICU).
(v) Surgical Services (Outpatient or ASC).
(vi) Skilled Nursing Facilities.
(vii) Diagnostic Radiology.
(viii) Mammography.
(ix) Physical Therapy.
(x) Occupational Therapy.
(xi) Speech Therapy.
(xii) Inpatient Psychiatric Facility Services.
(xiii) Outpatient Infusion/Chemotherapy.

(3) *Removal of a provider or facility-specialty type.* CMS may remove a specialty or facility type from the network adequacy evaluation for a particular year by not including the type in the annual publication of the HSD reference file.

(c) *County type designations.* Counties are designated as a specific type using the following population size and density parameters:

(1) *Large metro.* A large metro designation is assigned to any of the following combinations of population sizes and density parameters:

(i) A population size greater than or equal to 1,000,000 persons with a population density greater than or equal to 1,000 persons per square mile.

(ii) A population size greater than or equal to 500,000 and less than or equal to 999,999 persons with a population density greater than or equal to 1,500 persons per square mile.

(iii) Any population size with a population density of greater than or equal to 5,000 persons per square mile.

(2) *Metro.* A metro designation is assigned to any of the following combinations of population sizes and density parameters:

(i) A population size greater than or equal to 1,000,000 persons with a population density greater than or equal to 10 persons per square mile and less than or equal to 999.9 persons per square mile.

(ii) A population size greater than or equal to 500,000 persons and less than or equal to 999,999 persons with a population density greater than or equal to 10 persons per square mile and less than or equal to 1,499.9 persons per square mile.

(iii) A population size greater than or equal to 200,000 persons and less than or equal to 499,999 persons with a population density greater than or equal to 10 persons per square mile and less than or equal to 4,999.9 persons per square mile.

(iv) A population size greater than or equal to 50,000 persons and less than or equal to 199,999 persons with a population density greater than or equal to 100 persons per square mile and less than or equal to 4999.9 persons per square mile.

(v) A population size greater than or equal to 10,000 persons and less than or

equal to 49,999 persons with a population density greater than or equal to 1,000 persons per square mile and less than or equal to 4999.9 persons per square mile.

(3) *Micro.* A micro designation is assigned to any of the following combinations of population sizes and density parameters:

(i) A population size greater than or equal to 50,000 persons and less than or equal to 199,999 persons with a population density greater than or equal to 10 persons per square mile and less than or equal to 99.9 persons per square mile.

(ii) A population size greater than or equal to 10,000 persons and less than or equal to 49,999 persons with a population density greater than or equal to 50 persons per square mile and less than 999.9 persons per square mile.

(4) *Rural.* A rural designation is assigned to any of the following combinations of population sizes and density parameters:

(i) A population size greater than or equal to 10,000 persons and less than or equal to 49,999 persons with a population density of greater than or equal to 10 persons per square mile and less than or equal to 49.9 persons per square mile.

(ii) A population size less than 10,000 persons with a population density greater than or equal 50 persons per square mile and less than or equal to 999.9 persons per square mile.

(5) *Counties with extreme access considerations (CEAC).* For any population size with a population density of less than 10 persons per square mile.

(d) *Maximum time and distance standards*—(1) *General rule.* CMS determines and annually publishes maximum time and distance standards for each combination of provider or facility specialty type and each county type in accordance with paragraphs (d)(2) and (3) of this section.

(i) Time and distance metrics measure the relationship between the approximate locations of beneficiaries and the locations of the network providers and facilities.

(ii) [Reserved]

(2) *By county designation.* The following base maximum time (in minutes) and distance (in miles) standards apply for each county type designation, unless modified through customization as described in paragraph (d)(3) of this section.

TABLE 1 TO PARAGRAPH (d)(2)

Provider/Facility type	Large metro		Metro		Micro		Rural		CEAC	
	Max time	Max distance	Max time	Max distance	Max time	Max distance	Max time	Max distance	Max time	Max distance
Primary Care	10	5	15	10	30	20	40	30	70	60
Allergy and Immunology	30	15	45	30	80	60	90	75	125	110
Cardiology	20	10	30	20	50	35	75	60	95	85
Chiropractor	30	15	45	30	80	60	90	75	125	110
Dermatology	20	10	45	30	60	45	75	60	110	100
Endocrinology	30	15	60	40	100	75	110	90	145	130
ENT/Otolaryngology	30	15	45	30	80	60	90	75	125	110
Gastroenterology	20	10	45	30	60	45	75	60	110	100
General Surgery	20	10	30	20	50	35	75	60	95	85
Gynecology, OB/GYN	30	15	45	30	80	60	90	75	125	110
Infectious Diseases	30	15	60	40	100	75	110	90	145	130
Nephrology	30	15	45	30	80	60	90	75	125	110
Neurology	20	10	45	30	60	45	75	60	110	100
Neurosurgery	30	15	60	40	100	75	110	90	145	130
Oncology—Medical, Surgical	20	10	45	30	60	45	75	60	110	100
Oncology—Radiation/Radiation Oncology	30	15	60	40	100	75	110	90	145	130
Ophthalmology	20	10	30	20	50	35	75	60	95	85
Orthopedic Surgery	20	10	30	20	50	35	75	60	95	85
Physiatry, Rehabilitative Medicine	30	15	45	30	80	60	90	75	125	110
Plastic Surgery	30	15	60	40	100	75	110	90	145	130
Podiatry	20	10	45	30	60	45	75	60	110	100
Psychiatry	20	10	45	30	60	45	75	60	110	100
Pulmonology	20	10	45	30	60	45	75	60	110	100
Rheumatology	30	15	60	40	100	75	110	90	145	130
Urology	20	10	45	30	60	45	75	60	110	100
Vascular Surgery	30	15	60	40	100	75	110	90	145	130
Cardiothoracic Surgery	30	15	60	40	100	75	110	90	145	130
Acute Inpatient Hospitals	20	10	45	30	80	60	75	60	110	100
Cardiac Surgery Program	30	15	60	40	160	120	145	120	155	140
Cardiac Catheterization Services	30	15	60	40	160	120	145	120	155	140
Critical Care Services—Intensive Care Units (ICU)	20	10	45	30	160	120	145	120	155	140
Surgical Services (Outpatient or ASC)	20	10	45	30	80	60	75	60	110	100
Skilled Nursing Facilities	20	10	45	30	80	60	75	60	95	85
Diagnostic Radiology	20	10	45	30	80	60	75	60	110	100
Mammography	20	10	45	30	80	60	75	60	110	100
Physical Therapy	20	10	45	30	80	60	75	60	110	100
Occupational Therapy	20	10	45	30	80	60	75	60	110	100
Speech Therapy	20	10	45	30	80	60	75	60	110	100
Inpatient Psychiatric Facility Services	30	15	70	45	100	75	90	75	155	140
Outpatient Infusion/Chemotherapy	20	10	45	30	80	60	75	60	110	100

(3) *By customization.* When necessary due to utilization or supply patterns, CMS may set maximum time and distance standards for provider or facility types for specific counties by customization in accordance with the following rules:

(i) CMS maps provider location data from the Provider Supply file against its MA Medicare Sample Census (which provides MA enrollee population distribution data) or uses claims data to identify the distances beneficiaries travel according to the usual patterns of care for the county.

(ii) CMS identifies the distance at which 90 percent of the population would have access to at least one provider or facility in the applicable specialty type.

(iii) The resulting distance is then rounded up to the next multiple of 5, and a multiplier specific to the county designation is applied to determine the analogous maximum time.

(iv) Customization may only be used to increase the base time and distance standards specified in paragraph (d)(2) of this section and may not be used to decrease the base time and distance standards.

(4) *Percentage of beneficiaries residing within maximum time and distance standards.* MA plans must ensure both of the following:

(i) At least 85 percent of the beneficiaries residing in micro, rural, or CEAC counties have access to at least one provider/facility of each specialty type within the published time and distance standards.

(ii) At least 90 percent of the beneficiaries residing in large metro and metro counties have access to at least one provider/facility of each specialty type within the published time and distance standards.

(5) *MA telehealth providers.* An MA plan receives a 10 percentage point credit towards the percentage of beneficiaries residing within published time and distance standards for the applicable provider specialty type and county when the plan includes one or more telehealth providers that provide additional telehealth benefits, as defined in § 422.135, in its contracted networks for the following provider specialty types:

(i) Dermatology.
(ii) Psychiatry.
(iii) Cardiology.
(iv) Neurology.
(v) Otolaryngology.
(vi) Ophthalmology.
(vii) Allergy and Immunology.
(viii) Nephrology.
(ix) Primary Care.
(x) Gynecology/OB/GYN.
(xi) Endocrinology.
(xii) Infectious Diseases.

(6) *State Certificate of Need (CON) laws.* In a State with CON laws, or other state imposed anti-competitive restrictions that limit the number of providers or facilities in the State or a county in the State, CMS will award the MA organization a 10-percentage point credit towards the percentage of beneficiaries residing within published time and distance standards for affected providers and facilities in paragraph (b) of this section or, when necessary due to utilization or supply patterns, customize the base time and distance standards.

(e) *Minimum number standard.* CMS annually determines the minimum number standard for each provider and facility-specialty type as follows:

(1) *General rule.* The provider or facility must—

(i) Be within the maximum time and distance of at least one beneficiary in order to count towards the minimum number standard (requirement); and

(ii) Not be a telehealth-only provider.

(2) *Minimum number requirement for provider and facility-specialty types.* The minimum number for provider and facility-specialty types are as follows:

(i) For provider-specialty types described in paragraph (b)(1) of this section, CMS calculates the minimum number as specified in paragraph (e)(3) of this section.

(ii) For facility-specialty types described in paragraph (b)(2)(i) of this section, CMS calculates the minimum number as specified in paragraph (e)(3) of this section.

(iii) For facility-specialty types described in paragraphs (b)(2)(ii) through (xiv) of this section, the minimum requirement number is 1.

(3) *Determination of the minimum number of for certain provider and facility-specialty types.* For specialty types in paragraphs (b)(1) and (b)(2)(i) of this section, CMS multiplies the minimum ratio by the number of beneficiaries required to cover, divides the resulting product by 1,000, and rounds it up to the next whole number.

(i)(A) The minimum ratio for provider specialty types represents the minimum number of providers per 1,000 beneficiaries.

(B) The minimum ratio for facility specialty type specified in paragraph (b)(2)(i) of this section (acute inpatient hospital) represents the minimum number of beds per 1,000 beneficiaries.

(C) The minimum ratios are as follows:

TABLE 2 TO PARAGRAPH (E)(3)(I)(C)

Minimum ratio	Large metro	Metro	Micro	Rural	CEAC
Primary Care	1.67	1.67	1.42	1.42	1.42
Allergy and Immunology	0.05	0.05	0.04	0.04	0.04
Cardiology	0.27	0.27	0.23	0.23	0.23
Chiropractor	0.10	0.10	0.09	0.09	0.09
Dermatology	0.16	0.16	0.14	0.14	0.14
Endocrinology	0.04	0.04	0.03	0.03	0.03
ENT/Otolaryngology	0.06	0.06	0.05	0.05	0.05
Gastroenterology	0.12	0.12	0.10	0.10	0.10
General Surgery	0.28	0.28	0.24	0.24	0.24
Gynecology, OB/GYN	0.04	0.04	0.03	0.03	0.03
Infectious Diseases	0.03	0.03	0.03	0.03	0.03
Nephrology	0.09	0.09	0.08	0.08	0.08
Neurology	0.12	0.12	0.10	0.10	0.10
Neurosurgery	0.01	0.01	0.01	0.01	0.01
Oncology—Medical, Surgical	0.19	0.19	0.16	0.16	0.16
Oncology—Radiation/Radiation Oncology	0.06	0.06	0.05	0.05	0.05
Ophthalmology	0.24	0.24	0.20	0.20	0.20
Orthopedic Surgery	0.20	0.20	0.17	0.17	0.17
Physiatry, Rehabilitative Medicine	0.04	0.04	0.03	0.03	0.03
Plastic Surgery	0.01	0.01	0.01	0.01	0.01
Podiatry	0.19	0.19	0.16	0.16	0.16

TABLE 2 TO PARAGRAPH (E)(3)(i)(C)—Continued

Minimum ratio	Large metro	Metro	Micro	Rural	CEAC
Psychiatry	0.14	0.14	0.12	0.12	0.12
Pulmonology	0.13	0.13	0.11	0.11	0.11
Rheumatology	0.07	0.07	0.06	0.06	0.06
Urology	0.12	0.12	0.10	0.10	0.10
Vascular Surgery	0.02	0.02	0.02	0.02	0.02
Cardiothoracic Surgery	0.01	0.01	0.01	0.01	0.01
Acute Inpatient Hospitals	12.2	12.2	12.2	12.2	12.2

(ii)(A) *Number of beneficiaries required to cover.* (*1*) The number of beneficiaries required to cover is calculated by multiplying the 95th percentile base population ratio by the total number of Medicare beneficiaries residing in a county.

(*2*) CMS uses its MA State/County Penetration data to calculate the total number of beneficiaries residing in a county.

(B) *95th percentile base population ratio.* (*1*) The 95th percentile base population ratio is:

(*i*) Calculated annually for each county type and varies over time as MA market penetration and plan enrollment change across markets; and

(*ii*) Represents the proportion of Medicare beneficiaries enrolled in the 95th percentile MA plan (that is, 95 percent of plans have enrollment lower than this level).

(*2*) CMS calculates the 95th percentile base population ratio as follows:

(*i*) Uses its most recent List of PFFS Network Counties to exclude any private-fee-for-service (PFFS) plans in non-networked counties from the calculation at the county-type level.

(*ii*) Uses its most recent MA State/County Penetration data to determine the number of eligible Medicare beneficiaries in each county.

(*iii*) Uses its Monthly MA Enrollment By State/County/Contract data to determine enrollment at the contract ID and county level, including only enrollment in regional preferred provider organization (RPPO), local preferred provider organization (LPPO), HMO, HMO/provider sponsored organization (POS), healthcare prepayment plans under section 1833 of the Act, and network PFFS plan types.

(*iv*) Calculates penetration at the contract ID and county level by dividing the number of enrollees for a given contract ID and county by the number of eligible beneficiaries in that county.

(*v*) Groups counties by county designation to determine the 95th percentile of penetration among MA plans for each county type.

(f) *Exception requests.* (1) An MA plan may request an exception to network adequacy criteria in paragraphs (b) through (e) of this section when both of the following occur:

(i) Certain providers or facilities are not available for the MA plan to meet the network adequacy criteria as shown in the Provider Supply file for the year for a given county and specialty type.

(ii) The MA plan has contracted with other providers and facilities that may be located beyond the limits in the time and distance criteria, but are currently available and accessible to most enrollees, consistent with the local pattern of care.

(2) In evaluating exception requests, CMS considers whether—

(i) The current access to providers and facilities is different from the HSD reference and Provider Supply files for the year;

(ii) There are other factors present, in accordance with § 422.112(a)(10)(v), that demonstrate that network access is consistent with or better than the original Medicare pattern of care; and

(iii) Approval of the exception is in the best interests of beneficiaries.

■ 13. Section 422.162 is amended in paragraph (a) by adding a definition for ''Tukey outer fence outliers'' in alphabetical order to read as follows:

§ 422.162 Medicare Advantage Quality Rating System.

(a) * * *

Tukey outer fence outliers are measure scores that are below a certain point (first quartile − 3.0 × (third quartile − first quartile)) or above a certain point (third quartile + 3.0 × (third quartile − first quartile)).

* * * * *

■ 14. Section 422.166 is amended—

■ a. By revising paragraph (a)(2)(i); and

■ b. In paragraphs (e)(1)(iii) and (iv) by removing the phrase ''weight of 2'' and adding in its place ''weight of 4''.

The revision reads as follows:

§ 422.166 Calculation of Star Ratings.

(a) * * *

(2) * * *

(i) The method maximizes differences across the star categories and minimizes the differences within star categories using mean resampling with the hierarchal clustering of the current year's data. Effective for the Star Ratings issued in October 2022 and subsequent years, CMS will add a guardrail so that the measure-threshold-specific cut points for non-CAHPS measures do not increase or decrease more than the value of the cap from 1 year to the next. Effective for the Star Ratings issued in October 2023 and subsequent years, prior to applying mean resampling with hierarchal clustering, Tukey outer fence outliers are removed. The cap is equal to 5 percentage points for measures having a 0 to 100 scale (absolute percentage cap) or 5 percent of the restricted range for measures not having a 0 to 100 scale (restricted range cap). New measures that have been in the Part C and D Star Rating program for 3 years or less use the hierarchal clustering methodology with mean resampling with no guardrail for the first 3 years in the program.

* * * * *

§ 422.258 [Amended]

■ 15. Section 422.258 is amended in paragraphs (d)(3), (d)(5) introductory text, (d)(5)(i) introductory text, (d)(5)(ii), and (d)(6)(i) by removing the reference ''§ 422.306(c)'' and adding in its place the reference '' § 422.306(c) and (d)''.

165. Section 422.306 is amended—

■ a. In the introductory text by:

■ i. Removing ''§§ 422.308(b) and 422.308(g)'' and adding in its place ''§ 422.308(b) and (g)''; and

■ ii. Removing the phrase ''year under paragraph (c) of this section'' and adding in its place the phrase ''year under paragraph (c) of this section and costs for kidney acquisitions in the area for the year under paragraph (d) of this section''; and

■ b. By adding paragraph (d).

The addition reads as follows:

§ 422.306 Annual MA capitation rates.

* * * * *

(d) *Exclusion of costs for kidney acquisitions from MA capitation rates.* Beginning with 2021, after the annual capitation rate for each MA local area is determined under paragraph (a) or (b) of

this section, the amount is adjusted in accordance with section 1853(k)(5) of the Act to exclude the Secretary's estimate of the standardized costs for payments for organ acquisitions for kidney transplants covered under this title (including expenses covered under section 1881(d) of the Act) in the area for the year.

§ 422.312 [Amended]

■ 17. Section 422.312 is amended—
■ a. In paragraph (b)(1) by removing the phrase ''45 days'' and adding in its place the phrase ''60 days''; and
■ b. In paragraph (b)(2) by removing the phrase ''15 days'' and adding in its place the phrase ''30 days''.

■ 18. Section 422.322 is amended by adding paragraph (d) to read as follows:

§ 422.322 Source of payment and effect of MA plan election on payment.

* * * * *

(d) *FFS payment for expenses for kidney acquisitions.* Paragraphs (b) and (c) of this section do not apply with respect to expenses for organ acquisitions for kidney transplants described in section 1852(a)(1)(B)(i) of the Act.

■ 19. Section 422.514 is amended by—
■ a. Revising the section heading and the heading for paragraph (a).
■ b. Adding paragraphs (d), (e), and (f).

The revisions and additions read as follows:

§ 422.514 Enrollment requirements.

(a) *Minimum enrollment rules.* * * *

* * * * *

(d) *Rule on dual eligible enrollment.* In any state where there is a dual eligible special needs plan or any other plan authorized by CMS to exclusively enroll individuals entitled to medical assistance under a state plan under title XIX, CMS does not:

(1) Enter into a contract under this subpart, for plan year 2022 and subsequent years, for a new MA plan that—

(i) Is not a specialized MA plan for special needs individuals as defined in § 422.2; and

(ii) Projects enrollment in its bid submitted under § 422.254 that 80 percent or more enrollees of the plan's total enrollment are enrollees entitled to medical assistance under a state plan under title XIX.

(2) Renew a contract under this subpart, for plan year 2023 and subsequent years, for an MA plan that—

(i) Is not a specialized MA plan for special needs individuals as defined in § 422.2; and

(ii) Has actual enrollment, as determined by CMS using the January enrollment of the current year, consisting of 80 percent or more of enrollees who are entitled to medical assistance under a state plan under title XIX, unless the MA plan has been active for less than 1 year and has enrollment of 200 or fewer individuals at the time of such determination.

(e) *Transition process and procedures.* (1) For coverage effective January 1 of the next year, and subject to the disclosure requirements described in paragraph (e)(2) of this section, an MA organization may transition enrollees in a plan specified in paragraph (d)(2) of this section into another MA plan or plans (including into a dual eligible special needs plan for enrollees who are eligible for such a plan) offered by the MA organization, or another MA organization that shares the same parent organization as the MA organization, for which the individual is eligible in accordance with §§ 422.50 through 422.53 if the MA plan or plans receiving such enrollment—

(i) Would not meet the criteria in paragraph (d)(2)(ii) of this section, as determined in the procedures described in paragraph (e)(3) of this section, with the addition of the newly enrolled individuals (unless such plan is a Specialized MA plan for Special Needs Individuals as defined in § 422.2);

(ii) Is an MA–PD plan described at § 422.2;

(iii) Has a combined Part C and Part D premium of $0.00 for individuals eligible for the premium subsidy for full subsidy eligible individuals described in § 423.780(a) of this chapter; and

(iv) Is of the same plan type (for example, HMO or PPO) as the plan specified in paragraph (d)(2) of this section.

(2) An MA organization may transition individuals under paragraph (e)(1) of this section without requiring the individual to file the election form under § 422.66(a) if—

(i) The enrolled individual is eligible to enroll in the MA plan; and

(ii) The MA–PD plan into which individuals are transitioned describes changes to MA–PD benefits and provides information about the MA–PD plan in the Annual Notice of Change, which must be sent consistent with § 422.111(a), (d), and (e).

(3) For the purpose of approving a MA organization to transition enrollment under this paragraph (e), CMS determines whether a non-SNP MA plan would meet the criteria in paragraph (d)(2) of this section by adding the cohort of individuals identified by the MA organization for enrollment in a non-SNP MA plan to the April enrollment of such plan and calculating the resulting percentage of dual eligible enrollment.

(4) In cases where an MA organization does not transition current enrollees under paragraph (e)(1) of this section, the MA organization must send a written notice to enrollees who are not transitioned, consistent with § 422.506(a)(2).

(f) *Special considerations.* Actions taken pursuant to paragraph (d) of this section warrant special consideration to exempt affected MA organizations from the denial of an application for a new contract or service area expansion in accordance with §§ 422.502(b)(3) and (4), 422.503(b)(6) and (7), 422.506(a)(3) and (4), 422.508(c) and (d), and 422.512(e)(1) and (2).

■ 20. Section 422.2420 is amended by revising paragraph (b)(2)(i) to read as follows:

§ 422.2420 Calculation of the medical loss ratio.

* * * * *

(b) * * *

(2) * * *

(i) Amounts that the MA organization pays (including under capitation contracts) for covered services, described at paragraph (a)(2) of this section, provided to all enrollees under the contract.

* * * * *

■ 21. Section 422.2440 is revised to read as follows:

§ 422.2440 Credibility adjustment.

(a) An MA organization may add the credibility adjustment specified under paragraph (e) of this section to a contract's MLR if the contract's experience is partially credible, as defined in paragraph (d)(1) of this section.

(b) An MA organization may not add a credibility adjustment to a contract's MLR if the contract's experience is fully credible, as defined in paragraph (d)(2) of this section.

(c) For those contract years for which a contract has non-credible experience, as defined in paragraph (d)(3) of this section, sanctions under § 422.2410(b) through (d) will not apply.

(d)(1) A contract's experience is partially credible if it is based on the experience of at least 2,400 member months and fewer than or equal to 180,000 member months.

(2) A contract's experience is fully credible if it is based on the experience of more than 180,000 member months.

(3) A contract's experience is non-credible if it is based on the experience of fewer than 2,400 member months.

(e)(1) The credibility adjustment for a partially credible MA contract, other

than an MSA contract, is equal to the base credibility factor determined under paragraph (f) of this section.

(2) The credibility adjustment for a partially credible MA MSA contract is the product of the base credibility factor, as determined under paragraph (f) of this section, multiplied by the deductible factor, as determined under paragraph (g) of this section.

(f) The base credibility factor for partially credible experience is determined based on the number of member months for all enrollees under the contract and the factors shown in Table 1 of this section. When the number of member months used to determine credibility exactly matches a member month category listed in Table 1 of this section, the value associated with that number of member months is the base credibility factor. The base credibility factor for a number of member months between the values shown in Table 1 of this section is determined by linear interpolation.

(g) The deductible factor is based on the enrollment-weighted average deductible for all MSA plans under the MA MSA contract, where the deductible for each plan under the contract is weighted by the plan's portion of the total number of member months for all plans under the contract. When the weighted average deductible exactly matches a deductible category listed in Table 2 of this section, the value associated with that deductible is the deductible factor. The deductible factor for a weighted average deductible between the values shown in Table 2 of section is determined by linear interpolation.

TABLE 1 TO § 422.2440—BASE CREDIBILITY FACTORS FOR MA CONTRACTS

Member months	Base credibility factor (additional percentage points)
<2,400	N/A (Non-credible).
2,400	8.4%.
6,000	5.3%.
12,000	3.7%.
24,000	2.6%.
60,000	1.7%.
120,000	1.2%.
180,000	1.0%.
>180,000	0.0% (Fully credible).

TABLE 2 TO § 422.2440—DEDUCTIBLE FACTORS FOR MA MSA CONTRACTS

Weighted average deductible	Deductible factor
<$2,500	1.000
$2,500	1.164
$5,000	1.402
≥$10,000	1.736

PART 423—VOLUNTARY MEDICARE PRESCRIPTION DRUG BENEFIT

■ 22. The authority citation for part 423 continues to read as follows:

Authority: 42 U.S.C. 1302, 1306, 1395w–101 through 1395w–152, and 1395hh.

■ 23. Section 423.38 is amended by revising paragraph (c)(8) and adding paragraphs (c)(11) through (34) to read as follows:

§ 423.38 Enrollment periods.

* * * * *

(c) * * *

(8) The individual demonstrates to CMS, in accordance with guidelines issued by CMS, that the PDP sponsor offering the PDP substantially violated a material provision of its contract under this part in relation to the individual, including, but not limited to any of the following:

(i) Failure to provide the individual on a timely basis benefits available under the plan.

(ii) Failure to provide benefits in accordance with applicable quality standards.

(iii) The PDP (or its agent, representative, or plan provider) materially misrepresented the plan's provisions in communications as outlined in subpart V of this part.

* * * * *

(11) The individual is making an enrollment request into or out of an employer sponsored Part D plan, is disenrolling from a Part D plan to take employer sponsored coverage of any kind, or is disenrolling from employer sponsored coverage (including Consolidated Omnibus Budget Reconciliation Act (COBRA) coverage) to elect a Part D plan.

(i) This special election period (SEP) is available to individuals who have (or are enrolling in) an employer or union sponsored Part D plan and ends 2 months after the month the employer or union coverage of any type ends.

(ii) The individual may choose an effective date that is not earlier than the first of the month following the month in which the election is made and no later than up to 3 months after the month in which the election is made.

(12) The individual is enrolled in a Part D plan offered by a Part D plan sponsor that has been sanctioned by CMS and elects to disenroll from that plan in connection with the matter(s) that gave rise to that sanction.

(i) Consistent with the disclosure requirements at § 423.128(f), CMS may require the sponsor to notify current enrollees that if the enrollees believe they are affected by the matter(s) that gave rise to the sanction, the enrollees are eligible for a SEP to elect another PDP.

(ii) The SEP starts with the imposition of the sanction and ends when the sanction ends or when the individual makes an election, whichever occurs first.

(13) The individual is enrolled in a section 1876 cost contract that is non-renewing its contract for the area in which the enrollee resides.

(i) Individuals eligible for this SEP must meet Part D plan eligibility requirements.

(ii) This SEP begins December 8 of the then-current contract year and ends on the last day of February of the following year.

(14) The individual is disenrolling from a PDP to enroll in a Program of All-inclusive Care for the Elderly (PACE) organization or is enrolling in a PDP after disenrolling from a PACE organization.

(i) An individual who disenrolls from PACE has a SEP for 2 months after the effective date of PACE disenrollment to elect a PDP.

(ii) An individual who disenrolls from a PDP has a SEP for 2 months after the effective date of PDP disenrollment to elect a PACE plan.

(15) The individual moves into, resides in, or moves out of an institution, as defined by CMS, and elects to enroll in, or disenroll from, a Part D plan.

(16) The individual is not entitled to premium free Part A and enrolls in Part B during the General Enrollment Period for Part B (January through March) for an effective date of July 1st are eligible to request enrollment in a Part D plan that begins April 1st and ends June 30th, with a Part D plan enrollment effective date of July 1st.

(17) The individual belongs to a qualified State Pharmaceutical Assistance Program (SPAP) and is requesting enrollment in a Part D plan.

(i) The individual is eligible to make one enrollment election per year.

(ii) This SEP is available while the individual is enrolled in the SPAP and, upon loss of eligibility for SPAP benefits, for an additional 2 calendar months after either the month of the loss of eligibility or notification of the loss, whichever is later.

(18) The individual is enrolled in a Part D plan and elects to disenroll from that Part D plan to enroll in or maintain other creditable prescription drug coverage.

(19)(i) The individual is enrolled in a section 1876 cost contract and an optional supplemental Part D benefit under that contract and elects a Part D plan upon disenrolling from the cost contract.

(ii) The SEP begins the month the individual requests disenrollment from the cost contract and ends when the individual makes an enrollment election or on the last day of the second month following the month the cost contract enrollment ended, whichever is earlier.

(20) The individual is requesting enrollment in a Part D plan offered by a Part D plan sponsor with a Star Rating of 5 Stars. An individual may use this SEP only once for the contract year in which the Part D plan was assigned a 5-star overall performance rating, beginning the December 8 before that contract year through November 30 of that contract year.

(21)(i) The individual is a non-U.S. citizen who becomes lawfully present in the United States.

(ii) This SEP begins the month the enrollee attains lawful presence status and ends the earlier of when the individual makes an enrollment election or 2 calendar months after the month the enrollee attains lawful presence status.

(22) The individual was adversely affected by having requested, but not received, required notices or information in an accessible format, as outlined in section 504 of the Rehabilitation Act of 1973, within the same timeframe that the Part D plan sponsor or CMS provided the same information to individuals who did not request an accessible format.

(i) The SEP begins at the end of the election period during which the individual was seeking to make an election and the length is at least as long as the time it takes for the information to be provided to the individual in an accessible format.

(ii) Part D plan sponsors may determine eligibility for this SEP when the criterion is met, ensuring adequate documentation of the situation, including records indicating the date of the individual's request, the amount of time taken to provide accessible versions of materials and the amount of time it takes for the same information to be provided to an individual who does not request an accessible format.

(23) Individuals affected by an emergency or major disaster declared by a federal, state or local government entity are eligible for a SEP to make a Part D enrollment or disenrollment election. The SEP starts as of the date the declaration is made, the incident start date or, if different, the start date identified in the declaration, whichever is earlier, and ends 2 full calendar months following the end date identified in the declaration or, if different, the date the end of the incident is announced, whichever is later. The individual is eligible for this SEP provided the individual—

(i)(A) Resides, or resided at the start of the SEP eligibility period described in this paragraph (c)(23), in an area for which a Federal, state or local government entity has declared an emergency or major disaster; or

(B) Does not reside in an affected area but relies on help making healthcare decisions from one or more individuals who reside in an affected area;

(ii) Was eligible for another election period at the time of SEP eligibility period described in this paragraph (c)(23); and

(iii) Did not make an election during that other election period due to the emergency or major disaster.

(24) The individual is using the SEP at § 422.62(b)(8) of this chapter to disenroll from a MA plan that includes Part D benefits.

(i) This SEP permits a one-time election to enroll in a Part D plan.

(ii) This SEP begins upon disenrollment from the MA plan and continues for 2 calendar months.

(25)(i) An individual using the MA Open Enrollment Period for Institutionalized Individuals (OEPI) to disenroll from a MA plan that includes Part D benefits plan is eligible for a SEP to request enrollment in a Part D plan.

(ii) The SEP begins with the month the individual requests disenrollment from the MA plan and ends on the last day of the second month following the month MA enrollment ended.

(26) An individual using the Medicare Advantage Open Enrollment Period (MA OEP) to elect original Medicare is eligible for a SEP to make a Part D enrollment election.

(27)(i) The individual is enrolled in a MA special needs plan (SNP) and is no longer eligible for the SNP because he or she no longer meets the specific special needs status.

(ii) The individual may request enrollment in a Part D plan that begins the month the individual's special needs status changes and ends the earlier of when he or she makes an election or 3 months after the effective date of involuntary disenrollment from the SNP.

(28) The individual is found, after enrollment into a Chronic Care SNP, not to have the required qualifying condition.

(i) This individual is eligible to enroll prospectively in a Part D plan.

(ii) This SEP begins when the MA organization notifies the individual of the lack of eligibility for the Chronic Care SNP and extends through the end of that month and the following 2 calendar months.

(iii) The SEP ends when the individual makes an enrollment election or on the last day of the second of the 2 calendar months following notification of the lack of eligibility, whichever occurs first.

(29) The individual uses the SEP at § 422.62(b)(15) of this chapter to enroll in a MA Private Fee-for-Service plan without Part D benefits, or enrolls in a section 1876 cost plan, is eligible to request enrollment in a PDP or the cost plan's optional supplemental Part D benefit, if offered.

(i) This SEP begins the month the individual uses the SEP at § 422.62(b)(15) of this chapter and continues for 2 additional months.

(ii) [Reserved]

(30) An individual who uses the SEP at § 422.62(b)(23) of this chapter to disenroll from a MA plan is eligible to request enrollment in a PDP.

(i) This SEP begins the month the individual is notified of eligibility for the SEP at § 422.62(b)(23) of this chapter and continues for an additional 2 calendar months.

(ii) This SEP permits one enrollment into a PDP.

(iii) This SEP ends when the individual has enrolled in the PDP.

(iv) An individual may use this SEP to request enrollment in a PDP subsequent to having submitted a disenrollment to the MA plan or may simply request enrollment in the PDP, resulting in automatic disenrollment from the MA plan.

(31) The individual is enrolled in a plan offered by a Part D plan sponsor that has been placed into receivership by a state or territorial regulatory authority. The SEP begins the month the receivership is effective and continues until it is no longer in effect or until the enrollee makes an election, whichever occurs first. When instructed by CMS, the MA plan that has been placed under receivership must notify its enrollees, in the form and manner directed by CMS, of the enrollees' eligibility for this SEP and how to use the SEP.

(32) The individual is enrolled in a plan that has been identified with the low performing icon in accordance with § 423.186(h)(1)(ii). This SEP exists while

the individual is enrolled in the low performing Part D plan.

(33) The individual was involuntarily disenrolled from an MA–PD plan due to loss of Part B but continues to be entitled to Part A. This SEP begins when the individual is advised of the loss of Part B and continues for 2 additional months.

(34) The individual meets other exceptional circumstances as CMS may provide.

* * * * *

■ 24. Section 423.40 is amended by revising paragraph (c) to read as follows:

§ 423.40 Effective dates.

* * * * *

(c) *Special enrollment periods.* For an enrollment or change of enrollment in Part D made during a special enrollment period specified in § 423.38(c), the coverage or change in coverage is effective the first day of the calendar month following the month in which the election is made, unless otherwise noted.

* * * * *

■ 25. Section 423.182 is amended in paragraph (a) by adding a definition for ''Tukey outer fence outliers'' in alphabetical order to read as follows:

§ 423.182 Part D Prescription Drug Plan Quality Rating System.

(a) * * *

Tukey outer fence outliers are measure scores that are below a certain point (first quartile − 3.0 × (third quartile − first quartile)) or above a certain point (third quartile + 3.0 × (third quartile − first quartile)).

* * * * *

■ 26. Section 423.186 is amended—

■ a. By revising paragraph (a)(2)(i); and

■ b. In paragraphs (e)(1)(iii) and (iv) by removing the phrase ''weight of 2'' and adding in its place ''weight of 4''.

The revision reads as follows:

§ 423.186 Calculation of Star Ratings.

(a) * * *

(2) * * *

(i) The method maximizes differences across the star categories and minimizes the differences within star categories using mean resampling with the hierarchal clustering of the current year's data. Effective for the Star Ratings issued in October 2022 and subsequent years, CMS will add a guardrail so that the measure-threshold-specific cut points for non-CAHPS measures do not increase or decrease more than the value of the cap from one year to the next. Effective for the Star Ratings issued in October 2023 and subsequent years, prior to applying mean resampling with hierarchal clustering, Tukey outer fence outliers are removed. The cap is equal to 5 percentage points for measures having a 0 to 100 scale (absolute percentage cap) or 5 percent of the restricted range for measures not having a 0 to 100 scale (restricted range cap). New measures that have been in the Part C and D Star Rating program for 3 years or less use the hierarchal clustering methodology with mean resampling with no guardrail for the first 3 years in the program.

* * * * *

■ 27. Section 423.329 is amended by revising paragraph (b)(4) to read as follows:

§ 423.329 Determination of payments.

* * * * *

(b) * * *

(4) *Publication.* CMS publishes the risk adjustment factors established under paragraph (b)(1) of this section for the upcoming calendar year in the Advance Notice and Rate Announcement publications specified under § 422.312 of this chapter.

* * * * *

■ 28. Section 423.2440 is revised to read as follows:

§ 423.2440 Credibility adjustment.

(a) A Part D sponsor may add the credibility adjustment specified under paragraph (e) of this section to a contract's MLR if the contract's experience is partially credible, as defined in paragraph (d)(1) of this section.

(b) A Part D sponsor may not add a credibility adjustment to a contract's MLR if the contract's experience is fully credible, as defined in paragraph (d)(2) of this section.

(c) For those contract years for which a contract has non-credible experience, as defined in paragraph (d)(3) of this section, sanctions under § 423.2410(b) through (d) will not apply.

(d)(1) A contract's experience is partially credible if it is based on the experience of at least 4,800 member months and fewer than or equal to 360,000 member months.

(2) A contract's experience is fully credible if it is based on the experience of more than 360,000 member months.

(3) A contract's experience is non-credible if it is based on the experience of fewer than 4,800 member months.

(e) The credibility adjustment for partially credible experience is determined based on the number of member months for all enrollees under the contract and the factors shown in Table 1 of this section. When the number of member months used to determine credibility exactly matches a member month category listed in Table 1 of this section, the value associated with that number of member months is the credibility adjustment. The credibility adjustment for a number of member months between the values shown in Table 1 of this section is determined by linear interpolation.

TABLE 1 TO § 423.2440—CREDIBILITY ADJUSTMENTS FOR PART D CONTRACTS

Member months	Credibility adjustment (additional percentage points)
<4,800	N/A (Non-credible).
4,800	8.4%.
12,000	5.3%.
24,000	3.7%.
48,000	2.6%.
120,000	1.7%.
240,000	1.2%.
360,000	1.0%.
>360,000	0.0% (Fully credible).

Dated: May 7, 2020.

Seema Verma,

Administrator, Centers for Medicare & Medicaid Services.

Dated: May 20, 2020.

Alex M. Azar II,

Secretary, Department of Health and Human Services.

[FR Doc. 2020–11342 Filed 5–22–20; 8:45 am]

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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 Northwest Training and Testing (NWTT) Study Area; Proposed Rule

DEPARTMENT OF COMMERCE

National Oceanic and Atmospheric Administration

50 CFR Part 218

[200417–0114]

RIN 0648–BJ30

Taking and Importing Marine Mammals; Taking Marine Mammals Incidental to the U.S. Navy Training and Testing Activities in the Northwest Training and Testing (NWTT) Study Area

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

ACTION: Proposed rule; request for comments and information.

SUMMARY: NMFS has received a request from the U.S. Navy (Navy) to take marine mammals incidental to training and testing activities conducted in the Northwest Training and Testing (NWTT) Study Area. Pursuant to the Marine Mammal Protection Act (MMPA), NMFS is requesting comments on its proposal to issue regulations and subsequent Letters of Authorization (LOAs) to the Navy to incidentally take marine mammals during the specified activities. NMFS will consider public comments prior to issuing any final rule and making final decisions on the issuance of the requested LOAs. Agency responses to public comments will be provided in the notice of the final decision. The Navy's activities qualify as military readiness activities pursuant to the MMPA, as amended by the National Defense Authorization Act for Fiscal Year 2004 (2004 NDAA).

DATES: Comments and information must be received no later than July 17, 2020.

ADDRESSES: You may submit comments on this document, identified by NOAA–NMFS–2020–0055, by any of the following methods:

- *Electronic submission:* Submit all electronic public comments via the Federal e-Rulemaking Portal. Go to *www.regulations.gov/#!docketDetail;D=NOAA-NMFS-2020-0055,* click the ''Comment Now!'' icon, complete the required fields, and enter or attach your comments.
- *Mail:* Submit written comments to Jolie Harrison, Chief, Permits and Conservation Division, Office of Protected Resources, National Marine Fisheries Service, 1315 East-West Highway, Silver Spring, MD 20910.

Instructions: Comments sent by any other method, to any other address or individual, or received after the end of the comment period, may not be considered by NMFS. All comments received are a part of the public record and will generally be posted for public viewing on *www.regulations.gov* without change. All personal identifying information (*e.g.,* name, address), confidential business information, or otherwise sensitive information submitted voluntarily by the sender will be publicly accessible. NMFS will accept anonymous comments (enter ''N/A'' in the required fields if you wish to remain anonymous). Attachments to electronic comments will be accepted in Microsoft Word, Excel, or Adobe PDF file formats only.

A copy of the Navy's application and other supporting documents and documents cited herein 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 use the contact listed here (see **FOR FURTHER INFORMATION CONTACT**).

FOR FURTHER INFORMATION CONTACT: Wendy Piniak, Office of Protected Resources, NMFS, (301) 427–8401.

SUPPLEMENTARY INFORMATION:

Purpose of Regulatory Action

These proposed regulations, issued under the authority of the MMPA (16 U.S.C. 1361 *et seq.*), would provide the framework for authorizing the take of marine mammals incidental to the Navy's training and testing activities (which qualify as military readiness activities) from the use of sonar and other transducers, in-water detonations, and potential vessel strikes based on Navy movement in the NWTT Study Area. The Study Area includes air and water space off the coast of Washington, Oregon, and northern California; in the Western Behm Canal, Alaska; and portions of waters of the Strait of Juan de Fuca and Puget Sound, including Navy pierside and harbor locations in Puget Sound (see Figure 1–1 of the Navy's rulemaking/LOA application).

NMFS received an application from the Navy requesting seven-year regulations and authorizations to incidentally take individuals of multiple species of marine mammals (''Navy's rulemaking/LOA application'' or ''Navy's application''). Take is anticipated to occur by Level A harassment 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.

Background

The MMPA prohibits the ''take'' of marine mammals, with certain exceptions. Sections 101(a)(5)(A) and (D) of the MMPA 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, the public is provided with notice of the proposed incidental take authorization and provided the opportunity to review and 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 stocks and will not have an unmitigable adverse impact on the availability of the species or stocks for taking for subsistence uses (where relevant). Further, NMFS must prescribe the permissible methods of taking and other means of effecting the least practicable adverse impact on the affected species or stocks and their habitat, paying particular attention to rookeries, mating grounds, and areas of similar significance, and on the availability of such species or stocks for taking for certain subsistence uses (referred to in this rule as ''mitigation measures''); and requirements pertaining to the monitoring and reporting of such takings. The MMPA defines ''take'' to mean to harass, hunt, capture, or kill, or attempt to harass, hunt, capture, or kill any marine mammal. The *Preliminary Analysis and Negligible Impact Determination* section below discusses the definition of ''negligible impact.''

The NDAA for Fiscal Year 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 applied to a ''military readiness activity.'' The definition of harassment for military readiness activities (Section 3(18)(B) of the MMPA) is (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). In addition, the 2004 NDAA amended the MMPA as it relates to military readiness activities such that the least practicable adverse impact analysis shall include consideration of personnel safety, practicality of implementation, and impact on the effectiveness of the military readiness activity.

More recently, Section 316 of the NDAA for Fiscal Year 2019 (2019 NDAA) (Pub. L. 115–232), signed on August 13, 2018, amended the MMPA to allow incidental take rules for military readiness activities under section 101(a)(5)(A) to be issued for up to seven years. Prior to this amendment, all incidental take rules under section 101(a)(5)(A) were limited to five years.

Summary and Background of Request

On March 11, 2019, NMFS received an application from the Navy for authorization to take marine mammals by Level A harassment and Level B harassment incidental to training and testing activities (which qualify as military readiness activities) from the use of sonar and other transducers and in-water detonations in the NWTT Study Area over a seven-year period beginning when the current authorization expires. In addition, the Navy requested incidental take authorization by serious injury or mortality for up to three takes of large whales from vessel strikes over the seven-year period. We received revised applications on June 6, 2019 and June 21, 2019 which provided revisions in the take number estimates and vessel strike analysis and Navy's rulemaking/LOA application was found to be adequate and complete. On August 6, 2019 (84 FR 38225), we published a notice of receipt (NOR) of application in the **Federal Register**, requesting comments and information related to the Navy's request for 30 days. We reviewed and considered all comments and information received on the NOR in development of this proposed rule. On October 4, 2019, the Navy submitted an amendment to its application which incorporated new Southern Resident killer whale offshore density information, and on December 19, 2019, the Navy submitted an amendment to its application which incorporated revised testing activity numbers.

The following types of training and testing, which are classified as military readiness activities pursuant to the MMPA, as amended by the 2004 NDAA, would be covered under the regulations and LOAs (if authorized): Anti-submarine warfare (sonar and other transducers, underwater detonations), mine warfare (sonar and other transducers, underwater detonations), surface warfare (underwater detonations), and other testing and training (sonar and other transducers). The activities would not include pile driving/removal or use of air guns.

This would be the third time NMFS has promulgated incidental take regulations pursuant to the MMPA relating to similar military readiness activities in the NWTT Study Area, following those effective from November 9, 2010 through November 8, 2015 (*75 FR 69275;* November 10, 2010) and from November 9, 2015 through November 8, 2020 (*80 FR 73555;* November 24, 2015).

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. 8062), which requires the readiness of the naval forces of the United States. The Navy executes this responsibility in part by training and testing at sea, often in designated operating areas (OPAREA) and testing and training ranges. The Navy must be able to access and utilize these areas and associated sea space and air space in order to develop and maintain skills for conducting naval operations. The Navy's testing activities ensure naval forces are equipped with well-maintained systems that take advantage of the latest technological advances. The Navy's research and acquisition community conducts military readiness activities that involve testing. The Navy tests ships, aircraft, weapons, combat systems, sensors, and related equipment, and conducts scientific research activities to achieve and maintain military readiness.

The Navy has been conducting training and testing activities in the NWTT Study Area for decades, with some activities dating back to at least the early 1900s. 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 (*e.g.,* organization of ships, submarines, aircraft, weapons, and personnel). Such developments influence the frequency, duration, intensity, and location of required training and testing activities, however the Navy's proposed activities for the period of this proposed rule would be largely a continuation of ongoing activities. In addition to ongoing activities, the Navy is proposing some new training activities such as torpedo exercise—submarine training and unmanned underwater vehicle training.[1] The Navy is also proposing some new testing activities, including: At-sea sonar testing, mine countermeasure and neutralization testing, mine detection and classification testing, kinetic energy weapon testing, propulsion testing, undersea warfare testing, vessel signature evaluation, acoustic and oceanographic research, radar and other system testing, and simulant testing.[2]

The Navy's rulemaking/LOA application reflects the most up-to-date compilation of training and testing activities deemed necessary by senior Navy leadership to accomplish military readiness requirements. The types and numbers of activities included in the proposed rule account for fluctuations in training and testing in order to meet evolving or emergent military readiness requirements. These proposed regulations would cover training and testing activities that would occur for a seven-year period following the expiration of the current MMPA authorization for the NWTT Study Area, which expires on November 8, 2020.

Description of the Specified Activity

The Navy requests authorization to take marine mammals incidental to conducting training and testing activities. The Navy has determined that acoustic and explosives stressors are most likely to result in impacts on marine mammals that could rise to the level of harassment, and NMFS concurs with this determination. Detailed descriptions of these activities are provided in Chapter 2 of the 2019 NWTT Draft Supplemental Environmental Impact Statement (SEIS)/Overseas EIS (OEIS) (2019 NWTT DSEIS/OEIS) (*https://www.nwtteis.com*) and in the Navy's rulemaking/LOA application (*https://www.fisheries.noaa.gov/national/marine-mammal-protection/incidental-take-authorizations-military-readiness-activities*) and are summarized here.

[1] Some of the activities included here are new to the 2019 NWTT DSEIS/OEIS, but are not new to the Study Area. TORPEX—SUB activity was previously analyzed in 2010 as part of the Sinking Exercise. The Sinking Exercise is no longer conducted in the NWTT Study Area and the TORPEX—SUB activity is now a separate activity included in the NWTT DSEIS/OEIS. Unmanned underwater vehicle activity was analyzed in 2010 as a testing activity, but is now being included as a training activity.

[2] Mine detection and classification testing was analyzed in 2010 in the Inland waters, but was not previously analyzed in the Offshore waters. Vessel signature evaluation testing was analyzed in 2010 as a component to other activities, but is included in the list of new activities because it was not previously identified as an independent activity.

Dates and Duration

The specified activities would occur at any time during the seven-year period of validity of the regulations. The proposed number of training and testing activities are described in the *Detailed Description of the Specified Activities* section (Tables 3 through 4).

Geographical Region

The NWTT Study Area is composed of established maritime operating and warning areas in the eastern North Pacific Ocean region, including areas of the Strait of Juan de Fuca, Puget Sound, and Western Behm Canal in southeastern Alaska. The Study Area includes air and water space within and outside Washington state waters, within Alaska state waters, and outside state waters of Oregon and Northern California (Figure 1). The eastern boundary of the Offshore Area portion of the Study Area is 12 nautical miles (nmi) off the coastline for most of the Study Area, including southern Washington, Oregon, and Northern California. The Offshore Area includes the ocean all the way to the coastline only along that part of the Washington coast that lies beneath the airspace of W–237 and the Olympic Military Operating Area (MOA) and the Washington coastline north of the Olympic MOA. The Study Area includes four existing range complexes and facilities: The Northwest Training Range Complex, the Keyport Range Complex, Carr Inlet Operations Area, and the Southeast Alaska Acoustic Measurement Facility (Western Behm Canal, Alaska). In addition to these range complexes, the Study Area also includes Navy pierside locations where sonar maintenance and testing occurs as part of overhaul, modernization, maintenance, and repair activities at Naval Base Kitsap, Bremerton; Naval Base Kitsap, Bangor; and Naval Station Everett. Additional detail can be found in Chapter 2 of the Navy's rulemaking/LOA application.

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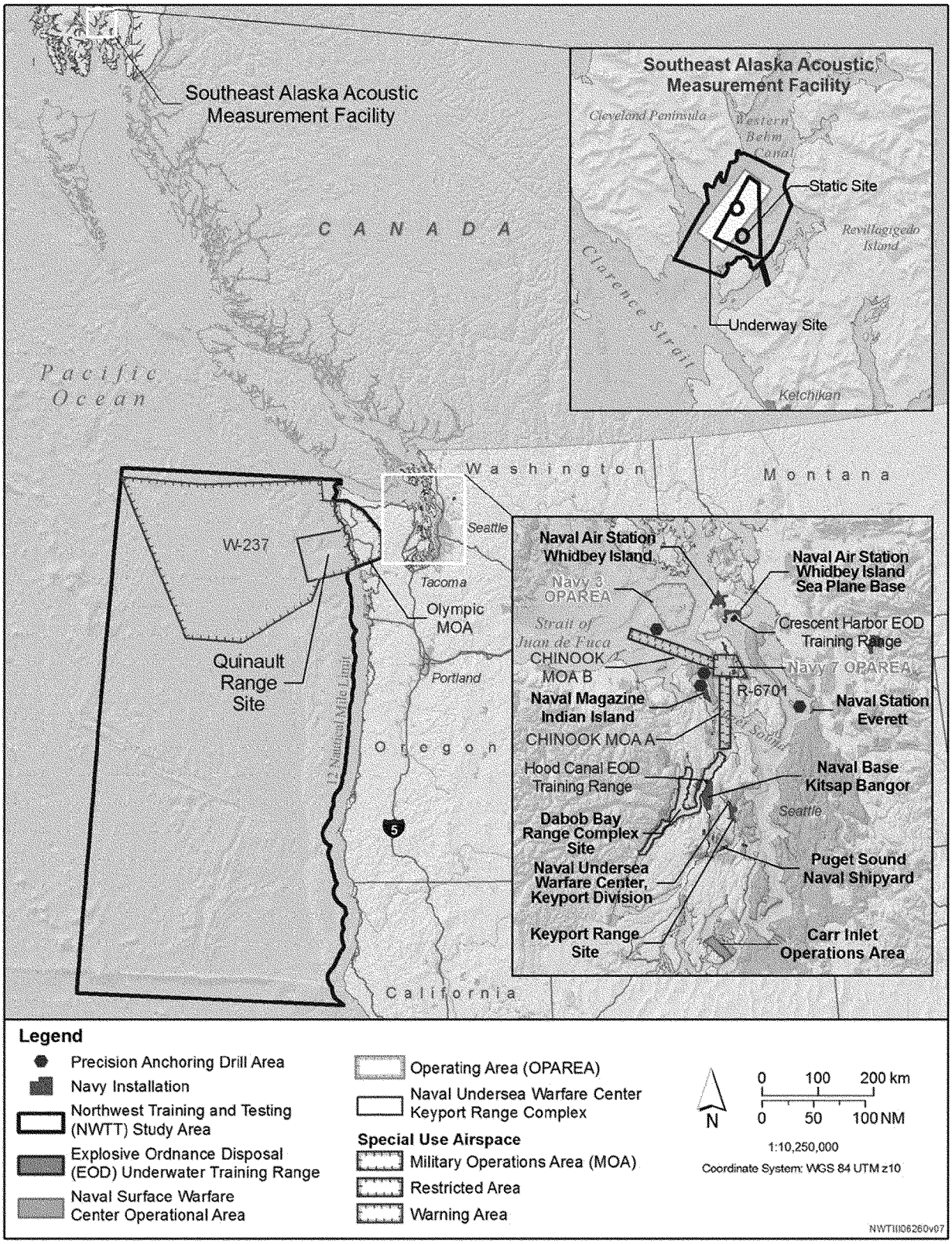

Figure 1 -- Map of the NWTT Study Area (a color version of this map can be found at *https://www.fisheries.noaa.gov/action/incidental-take-authorization-us-navy-northwest-training-and-testing-nwtt-2020*.

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Primary Mission Areas

The Navy categorizes many of its training and testing activities into functional warfare areas called primary mission areas. The Navy's proposed activities for NWTT generally fall into the following six primary mission areas: Air warfare; anti-submarine warfare; electronic warfare; expeditionary warfare; mine warfare; and surface warfare. Most activities conducted in NWTT are categorized under one of these primary mission areas; activities that do not fall within one of these areas are listed as ''other activities.'' Each warfare community (surface, subsurface, aviation, and expeditionary warfare) may train in some or all of these primary mission areas. The research and acquisition community also categorizes most, but not all, of its testing activities under these primary mission areas. A description of the sonar, munitions, targets, systems, and other material used during training and testing activities within these primary mission areas is provided in Appendix A (*Navy Activities Descriptions*) of the 2019 NWTT DSEIS/OEIS.

The Navy describes and analyzes the effects of its activities within the 2019 NWTT DSEIS/OEIS. In its assessment, the Navy concluded that sonar and other transducers and underwater detonations were the stressors most likely to result in impacts on marine mammals that could rise to the level of harassment as defined under the MMPA. Therefore, the Navy's 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. Those mission areas include the following:

- Anti-submarine warfare (sonar and other transducers, underwater detonations);
- expeditionary warfare;
- mine warfare (sonar and other transducers, underwater detonations);
- surface warfare (underwater detonations); and
- other (sonar and other transducers).

The Navy's training and testing activities in air warfare and electronic warfare do not involve sonar and other transducers, underwater detonations, or any other stressors that could result in harassment, serious injury, or mortality of marine mammals. Therefore, the activities in air warfare and electronic warfare are not discussed further in this proposed rule, but are analyzed fully in the 2019 NWTT DSEIS/OEIS.

Anti-Submarine Warfare

The mission of anti-submarine warfare is to locate, neutralize, and defeat hostile submarine forces that threaten Navy surface forces. Anti-submarine warfare can involve various assets such as aircraft, ships, and submarines which all search for hostile submarines. These forces operate together or independently to gain early warning and detection, and to localize, track, target, and attack submarine threats.

Anti-submarine warfare training addresses basic skills such as detecting and classifying submarines, as well as evaluating sounds to distinguish between enemy submarines and friendly submarines, ships, and marine life. More advanced training integrates the full spectrum of anti-submarine warfare, from detecting and tracking a submarine to attacking a target using either exercise torpedoes (*i.e.,* torpedoes that do not contain a warhead), or simulated weapons. These integrated anti-submarine warfare training exercises are conducted in coordinated, at-sea training events involving submarines, ships, and aircraft.

Testing of anti-submarine warfare systems is conducted to develop new technologies and assess weapon performance and operability with new systems and platforms, such as unmanned systems. Testing uses ships, submarines, and aircraft to demonstrate capabilities of torpedoes (exercise and explosive), missiles, countermeasure systems, and underwater surveillance and communications systems. Tests may be conducted as part of a large-scale training event involving submarines, ships, fixed-wing aircraft, and helicopters. These integrated training events offer opportunities to conduct research and acquisition activities and to train aircrew in the use of new or newly enhanced systems during a large-scale, complex exercise.

Expeditionary Warfare

The mission of expeditionary warfare is to provide security and surveillance in the littoral (at the shoreline), riparian (along a river), or coastal environments. Expeditionary warfare is wide ranging and includes defense of harbors, operation of remotely operated vehicles, defense against swimmers, and boarding/seizure operations. Expeditionary warfare training activities include underwater construction team training, dive and salvage operations, and insertion/extraction via air, surface, and subsurface platforms.

Mine Warfare

The mission of mine warfare is to detect, classify, and avoid or neutralize (disable) mines to protect Navy ships and submarines and to maintain free access to ports and shipping lanes. Mine warfare also includes training and testing in offensive mine laying to gain control of or deny the enemy access to sea space. Naval mines can be laid by ships, submarines, or aircraft.

Mine warfare training includes exercises in which ships, aircraft, submarines, underwater vehicles, unmanned vehicles, or marine mammal detection systems search for mine shapes. Personnel train to destroy or disable mines by attaching underwater explosives to or near the mine or using remotely operated vehicles to destroy the mine. Towed influence mine sweep systems mimic a particular ship's magnetic and acoustic signature, which would trigger a real mine, causing it to explode.

Testing and development of mine warfare systems is conducted to improve acoustic, optical, and magnetic detectors intended to hunt, locate, and record the positions of mines for avoidance or subsequent neutralization. Mine warfare testing and development falls into two primary categories: Mine detection and classification, and mine countermeasure and neutralization testing. Mine detection and classification testing involves the use of air, surface, and subsurface vessels; it uses sonar, including towed and side-scan sonar, and unmanned vehicles to locate and identify objects underwater. Mine detection and classification systems are sometimes used in conjunction with a mine neutralization system. Mine countermeasure and neutralization testing includes the use of air, surface, and subsurface units and uses tracking devices, countermeasure and neutralization systems, and general purpose bombs to evaluate the effectiveness of neutralizing mine threats. Most neutralization tests use mine shapes, or non-explosive practice mines, to accomplish the requirements of the activity. For example, during a mine neutralization test, a previously located mine is destroyed or rendered nonfunctional using a helicopter or manned/unmanned surface vehicle-based system that may involve the deployment of a towed neutralization system.

A small percentage of mine warfare activities require the use of high-explosives to evaluate and confirm the ability of the system or the crews conducting the training to neutralize a high-explosive mine under operational conditions. The majority of mine warfare systems are deployed by ships, helicopters, and unmanned vehicles. Tests may also be conducted in support of scientific research to support these new technologies.

Surface Warfare

The mission of surface warfare is to obtain control of sea space from which naval forces may operate, which entails offensive action against surface targets while also defending against aggressive actions by enemy forces. In the conduct of surface warfare, aircraft use guns, air-launched cruise missiles, or other precision-guided munitions; ships employ naval guns and surface-to-surface missiles; and submarines attack surface ships using torpedoes or submarine-launched, anti-ship cruise missiles.

Surface warfare training includes surface-to-surface gunnery and missile exercises, air-to-surface gunnery and missile exercises, submarine missile or torpedo launch events, and other munitions against surface targets.

Testing of weapons used in surface warfare is conducted to develop new technologies and to assess weapon performance and operability with new systems and platforms, such as unmanned systems. Tests include various air-to-surface guns and missiles, surface-to-surface guns and missiles, and bombing tests. Testing events may be integrated into training activities to test aircraft or aircraft systems in the delivery of munitions on a surface target. In most cases the tested systems are used in the same manner in which they are used for training activities.

Other Activities

The Navy conducts other training and testing activities in the Study Area that fall outside of the primary mission areas, but support overall readiness. Surface ship crews conduct Maritime Security Operations events, including maritime security escorts for Navy vessels such as Fleet Ballistic Missile Submarines; Visit, Board, Search, and Seizure; Maritime Interdiction Operations; Force Protection; Anti-Piracy Operations, Acoustic Component Testing, Cold Water Support, and Hydrodynamic and Maneuverability testing. Anti-terrorism/Force-protection training will occur as small boat attacks against moored ships at one of the Navy's piers inside Puget Sound. Pierside and at-sea maintenance of ship and submarine sonar is required for systems upkeep and systems evaluation.

Description of Stressors

The Navy uses a variety of sensors, platforms, weapons, and other devices, including ones used to ensure the safety of Sailors, to meet its mission. Training and testing with these systems may introduce acoustic (sound) energy or shock waves from explosives into the environment. The proposed training and testing activities were evaluated to identify 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 marine mammals and their habitat (including prey species) within the NWTT Study Area. Each description contains a list of activities that may generate the stressor. Stressor/resource interactions that were determined to have de minimis or no impacts (*e.g.,* vessel noise, aircraft noise, weapons noise, and explosions in air) were not carried forward for analysis in the Navy's rulemaking/LOA application. No Major Training Exercises (MTEs) or Sinking Exercise (SINKEX) events are proposed in the NWTT Study Area. NMFS reviewed the Navy's analysis and conclusions on de minimis sources 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, into sound waves), incidental sources of broadband sound produced as a byproduct of vessel movement, aircraft transits, and use of weapons or other deployed objects. Explosives also produce broadband sound but are characterized separately from other acoustic sources due to their unique hazardous characteristics. Characteristics of each of these sound sources are described in the following sections.

In order to better organize and facilitate the analysis of approximately 300 sources of underwater sound used in training and testing activities by the Navy, including sonar and other transducers and explosives, a series of source classifications, or source bins, were developed. The source classification bins do not include the broadband noise produced incidental to vessel and aircraft transits and weapons firing. Noise produced from vessel, aircraft, and weapons firing activities are not carried forward because those activities were found to have de minimis or no impacts, as stated above.

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 precautionary 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, navigate safely, 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. In this proposed rule, the terms sonar and other transducers will be used to indicate active sound sources unless otherwise specified.

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 (greater than 200 kilohertz (kHz)) doppler sonars used for navigation, like those used on commercial and private vessels. The characteristics of these sonars and other transducers, such as source level, beam width, directivity, and frequency, depend on the purpose of the source. Higher frequencies can carry more information or provide more information about objects off which they reflect, but attenuate more rapidly. Lower frequencies attenuate less rapidly, so they may detect objects over a longer distance, but with less detail.

Propagation of sound produced underwater is highly dependent on environmental characteristics such as bathymetry, bottom type, water depth, temperature, and salinity. The sound received at a particular location will be different than near the source due to the

interaction of many factors, including propagation loss; how the sound is reflected, refracted, or scattered; the potential for reverberation; and interference due to multi-path propagation. In addition, absorption greatly affects the distance over which higher-frequency sounds propagate. The effects of these factors are explained in Appendix D (*Acoustic and Explosive Concepts*) of the 2019 NWTT DSEIS/OEIS. 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 Study Area.

The sound sources and platforms typically used in naval activities analyzed in the Navy's rulemaking/LOA application are described in Appendix A (*Navy Activities Descriptions*) of the 2019 NWTT DSEIS/OEIS. Sonars and other transducers used to obtain and transmit information underwater during Navy training and testing activities generally fall into several categories of use described below.

Anti-Submarine Warfare

Sonar used during anti-submarine warfare training and testing would impart the greatest amount of acoustic energy of any category of sonar and other transducers analyzed in this proposed rule. Types of sonars used to detect potential enemy vessels include hull-mounted, towed, line array, sonobuoy, helicopter dipping, and torpedo sonars. In addition, acoustic targets and decoys (countermeasures) may be deployed to emulate the sound signatures of vessels or repeat received signals.

Most anti-submarine warfare sonars are mid-frequency (1–10 kHz) because mid-frequency sound balances sufficient resolution to identify targets with distance over which threats can be identified. However, some sources may use higher or lower frequencies. Duty cycles can vary widely, from rarely used to continuously active. Anti-submarine warfare sonars can be wide-ranging in a search mode or highly directional in a track mode.

Most anti-submarine warfare activities involving submarines or submarine targets would occur in waters greater than 600 feet (ft) deep due to safety concerns about running aground at shallower depths. Sonars used for anti-submarine warfare activities would typically be used beyond 12 nmi from shore. Exceptions include use of dipping sonar by helicopters, pierside testing and maintenance of systems while in port, and system checks while transiting to or from port.

Mine Warfare, Small Object Detection, and Imaging

Sonars used to locate mines and other small objects, as well as those used in imaging (*e.g.,* for hull inspections or imaging of the seafloor), are typically high frequency or very high frequency. Higher frequencies allow for greater resolution and, due to their greater attenuation, are most effective over shorter distances. Mine detection sonar can be deployed (towed or vessel hull-mounted) at variable depths on moving platforms (ships, helicopters, or unmanned vehicles) to sweep a suspected mined area. Hull-mounted anti-submarine sonars can also be used in an object detection mode known as ''Kingfisher'' mode. Sonars used for imaging are usually used in close proximity to the area of interest, such as pointing downward near the seafloor.

Mine detection sonar use would be concentrated in areas where practice mines are deployed, typically in water depths less than 200 ft, and at temporary minefields close to strategic ports and harbors, or at targets of opportunity such as navigation buoys. Kingfisher mode on vessels is most likely to be used when transiting to and from port. Sound sources used for imaging could be used throughout the NWTT Study Area.

Navigation and Safety

Similar to commercial and private vessels, Navy vessels employ navigational acoustic devices, including speed logs, Doppler sonars for ship positioning, and fathometers. These may be in use at any time for safe vessel operation. These sources are typically highly directional to obtain specific navigational data.

Communication

Sound sources used to transmit data (such as underwater modems), provide location (pingers), or send a single brief release signal to bottom-mounted devices (acoustic release) may be used throughout the NWTT Study Area. These sources typically have low duty cycles and are usually only used when it is desirable to send a detectable acoustic message.

Classification of Sonar and Other Transducers

Sonars and other transducers are grouped into classes that share an attribute, such as frequency range or purpose. As detailed below, 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. Unless stated otherwise, a reference distance of 1 meter (m) is used for sonar and other transducers.

- 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; and
  - Very-high-frequency sources operate above 100 kHz but below 200 kHz.
- Sound pressure level:
  - Greater than 160 decibels (dB) referenced to 1 micropascal (re: 1 μPa), but less than 180 dB re: 1 μPa;
  - Equal to 180 dB re: 1 μPa and up to 200 dB re: 1 μPa; and
  - 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 Study Area are shown in Table 1. While general parameters or source characteristics are shown in the table, actual source parameters are classified.

TABLE 1—SONAR AND OTHER TRANSDUCERS QUANTITATIVELY ANALYZED IN THE NWTT STUDY AREA

Source class category	Bin	Description
Low-Frequency (LF): Sources that produce signals less than 1 kHz.	LF4	LF sources equal to 180 dB and up to 200 dB.
	LF5	LF sources less than 180 dB.
Mid-Frequency (MF): Tactical and non-tactical sources that produce signals between 1 and 10 kHz.	MF1	Hull-mounted surface ship sonars (*e.g.,* AN/SQS–53C and AN/SQS–60).
	MF1K	Kingfisher mode associated with MF1 sonars.

TABLE 1—SONAR AND OTHER TRANSDUCERS QUANTITATIVELY ANALYZED IN THE NWTT STUDY AREA—Continued

Source class category	Bin	Description
	MF2	Hull-mounted surface ship sonars (*e.g.,* AN/SQS–56).
	MF3	Hull-mounted submarine sonars (*e.g.,* AN/BQQ–10).
	MF4	Helicopter-deployed dipping sonars (*e.g.,* AN/AQS–22).
	MF5	Active acoustic sonobuoys (*e.g.,* DICASS).
	MF6	Underwater sound signal devices (*e.g.,* MK 84 SUS).
	MF9	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%.
High-Frequency (HF): Tactical and non-tactical sources that produce signals between 10 and 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	Sources (equal to 180 dB and up to 200 dB) not otherwise binned.
	HF8	Hull-mounted surface ship sonars (*e.g.,* AN/SQS–61).
	HF9	Weapon-emulating sonar source.
Very High-Frequency (VHF): Tactical and non-tactical sources that produce signals greater than 100 kHz but less than 200 kHz.	VHF1	Active sources greater than 200 dB.
	VHF2	Active sources with a source level less than 200 dB.
Anti-Submarine Warfare (ASW): Tactical sources (*e.g.,* active sonobuoys and acoustic countermeasures 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 [1]	MF sonobuoys with high duty cycles.
Torpedoes (TORP): 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).
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): Sources used to transmit data	M3	MF acoustic modems (greater than 190 dB).
Synthetic Aperture Sonars (SAS): Sonars used to form high-resolution images of the seafloor.	SAS2	HF SAS systems.
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.

[1] Formerly ASW2 in the 2015–2020 (Phase II) rulemaking.

Explosive Stressors

The near-instantaneous rise from ambient to an extremely high peak pressure is what makes an explosive shock wave potentially damaging. Farther from an explosive, the peak pressures decay and the explosive waves propagate as an impulsive, broadband sound. Several parameters influence the effect of an explosive: The weight of the explosive in the warhead, the type of explosive material, the boundaries and characteristics of the propagation medium, and the detonation depth in water. The net explosive weight, which is the explosive power of a charge expressed as the equivalent weight of trinitrotoluene (TNT), accounts for the first two parameters. The effects of these factors are explained in Appendix D (*Acoustic and Explosive Concepts*) of the 2019 NWTT DSEIS/OEIS. The activities analyzed in the Navy's rulemaking/LOA application that use explosives are described in Appendix A (*Navy Activities Descriptions*) of the 2019 NWTT DSEIS/OEIS. Explanations of the terminology and metrics used when describing explosives are provided in Appendix D (*Acoustic and Explosive Concepts*) of the 2019 NWTT DSEIS/OEIS.

Explosives in Water

Explosive detonations during training and testing activities are associated with high-explosive munitions, including, but not limited to, bombs, missiles, 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 in the air or 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. Detonations would typically occur in waters greater than 200 ft in depth, and greater than 50 nmi from shore, with the exception of mine countermeasure and neutralization testing proposed in the Offshore Area, and existing mine warfare areas in Inland Waters (*i.e.,* Crescent Harbor and Hood Canal Explosive Ordnance Disposal Training Ranges). Mine countermeasure and neutralization testing is a new proposed testing activity that would occur closer to shore than other in-water explosive activities

analyzed in the 2015 NWTT Final EIS/OEIS for the Offshore Area of the NWTT Study Area. This activity would occur in waters 3 nmi or greater from shore in the Quinault Range Site (outside the Olympic Coast National Marine Sanctuary), or 12 nmi or greater from shore elsewhere in the Offshore Area. Two of the three events would involve the use of explosives, and would typically occur in water depths shallower than 1,000 ft. The two multi-day events (1–10 days per event) would include up to 36 E4 explosives (>2.5–5 lb net explosive weight) and 5 E7 explosives (>20–60 lb net explosive weight). 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. The use of explosive classification bins provides the same benefits discussed above and as described for acoustic source classification bins in Section 1.4.1 (Acoustic Stressors) of the Navy's rulemaking/LOA application.

Explosives detonated in water are binned by net explosive weight. The bins of explosives that are proposed for use in the Study Area are shown in Table 2 below.

TABLE 2—EXPLOSIVE SOURCES QUANTITATIVELY ANALYZED THAT COULD BE USED UNDERWATER OR AT THE WATER SURFACE IN THE STUDY AREA

Bin	Net explosive weight (lb)	Example explosive source	Modeled detonation depths (ft)
E1	0.1–0.25	Medium-caliber projectiles	0.3, 60.
E2	>0.25–0.5	Medium-caliber projectiles	0.3.
E3	>0.5–2.5	Explosive Ordnance Disposal Mine Neutralization	33, 60.
E4	>2.5–5	Mine Countermeasure and Neutralization	197, 262, 295, 394.
E5	>5–10	Large-caliber projectile	0.3.
E7	>20–60	Mine Countermeasure and Neutralization	33, 98, 230, 295.
E8	>60–100	Lightweight torpedo	150.
E10	>250–500	1,000 lb bomb	0.3.
E11	>500–650	Heavyweight torpedo	300, 656.

Notes: Net Explosive Weight refers to the equivalent amount of TNT, the actual weight of a munition may be larger due to other components; in = inch(es), lb = pound(s), ft = feet.

Propagation of explosive pressure waves in water is highly dependent on environmental characteristics such as bathymetry, bottom type, water depth, temperature, and salinity, which affect how the pressure waves are reflected, refracted, or scattered; the potential for reverberation; and interference due to multi-path propagation. In addition, absorption greatly affects the distance over which higher-frequency components of explosive broadband noise can propagate. Appendix D (*Acoustic and Explosive Concepts*) of the 2019 NWTT DSEIS/OEIS explains the characteristics of explosive detonations and how the above factors affect the propagation of explosive energy in the water. 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 Study Area.

Explosive Fragments

Marine mammals could be exposed to fragments from underwater explosions associated with the specified activities. When explosive ordnance *(e.g.,* bomb or missile) detonates, fragments of the weapon 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. Opposingly, the blast wave from an explosive detonation moves efficiently through the 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 ranges for assessing the likelihood of mortality and injury from a blast, which are also used to inform mitigation zones, are assumed to encompass risk due to fragmentation.

Other Stressor—Vessel Strike

NMFS also considered the chance that a vessel utilized in training or testing activities could strike a marine mammal. Vessel strikes have the potential to result in incidental take from serious injury and/or mortality. Vessel strikes are not specific to any particular training or testing activity, but rather are a limited, sporadic, and incidental result of Navy vessel movement during training and testing activities within a Study Area. Vessel strikes from commercial, recreational, and military vessels are known to seriously injure and occasionally kill cetaceans (Abramson *et al.,* 2011; Berman-Kowalewski *et al.,* 2010; Calambokidis, 2012; Douglas *et al.,* 2008; Laggner, 2009; Lammers *et al.,* 2003; Van der Hoop *et al.,* 2012; Van der Hoop *et al.,* 2013), although reviews of the literature on ship strikes mainly involve collisions between commercial vessels and whales (Jensen and Silber, 2003; Laist *et al.,* 2001). Vessel speed, size, and mass are all important factors in determining both the potential likelihood and impacts of a vessel strike to marine mammals (Conn and Silber, 2013; Gende *et al.,* 2011; Silber *et al.,* 2010; Vanderlaan and Taggart, 2007; Wiley *et al.,* 2016). For large vessels, speed and angle of approach can influence the severity of a strike.

Navy vessels transit at speeds that are optimal for fuel conservation and to meet training and testing requirements. Vessels used as part of the proposed Specified Activities include ships, submarines, unmanned vessels, 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). The average speed of large Navy ships ranges between 10 and 15 knots (kn) and submarines generally operate at speeds in the range of 8 to 13 kn, while a few specialized vessels can travel at faster speeds. Small craft (for

purposes of this analysis, less than 60 ft (18 m) in length) have much more variable speeds (0 to 50+ kn, dependent on the activity), but generally range from 10 to 14 kn. From unpublished Navy data, average median speed for large Navy ships in the other Navy ranges from 2011–2015 varied from 5 to 10 kn with variations by ship class and location (*i.e.,* slower speeds close to the coast). Similar patterns would occur in the NWTT Study Area. A full description of Navy vessels that are used during training and testing activities can be found in Chapter 2 (*Description of Proposed Action and Alternatives*) of the 2019 NWTT DSEIS/OEIS.

While these speeds are representative of most events, some vessels need to temporarily operate outside of these parameters for certain times or during certain activities. For example, to produce the required relative wind speed over the flight deck, an aircraft carrier engaged in flight operations must adjust its speed through the water accordingly. Conversely, there are other instances, such as launch and recovery of a small rigid hull inflatable boat; vessel boarding, search, and seizure training events; or retrieval of a target when vessels will be dead in the water or moving slowly ahead to maintain steerage.

Large Navy vessels (greater than 60 ft (18 m) in length) within the offshore areas of range complexes and testing ranges operate differently from commercial vessels in ways that may reduce potential whale collisions. Surface ships operated by or for the Navy have multiple personnel assigned to stand watch at all times, when a ship or surfaced submarine is moving through the water (underway). A primary duty of personnel standing watch on surface ships is to detect and report all objects and disturbances sighted in the water that may indicate a threat to the vessel and its crew, such as debris, a periscope, surfaced submarine, or surface disturbance. Per vessel safety requirements, personnel standing watch also report any marine mammals sighted in the path of the vessel as a standard collision avoidance procedure. All vessels proceed at a safe speed so they can take proper and effective action to avoid a collision with any sighted object or disturbance, and can be stopped within a distance appropriate to the prevailing circumstances and conditions.

Detailed Description of Proposed Activities

Proposed Training and Testing Activities

The training and testing activities that the Navy proposes to conduct in the NWTT Study Area are summarized in Table 3 (training) and Table 4 (testing). The tables are organized according to primary mission areas and include the activity name, associated stressor(s) of Navy's activities, description and duration of the activity, sound source bin, the areas where the activities are conducted in the NWTT Study Area, and the number of activities. Under the ''Annual # of Events'' column, events show either a single number or a range of numbers to indicate the maximum number of times that activity could occur during any single year. The ''7-Year # of Events'' is the maximum number of times an activity would occur over the 7-year period of proposed regulations. For further information regarding the primary platform used (*e.g.,* ship or aircraft type) see Appendix A (*Training and Testing Activities Descriptions*) of the 2019 NWTT DSEIS/OEIS.

The Navy's proposed activities reflect a representative year of training and testing to account for the natural fluctuation of training and testing cycles and deployment schedules that generally prevents the maximum level of activities from occurring year after year in any 7-year period. As shown in the tables of activities, the number of some activities may vary from year to year, and the level of variability can differ by activity. Still, the annual analysis assumes a ''maximum'' year. For the purposes of this request, the Navy assumes that some unit-level training would be conducted using synthetic means (*e.g.,* simulators). Additionally, the request assumes that some unit-level active sonar training and some testing will be completed during other scheduled activities.

TABLE 3—PROPOSED TRAINING ACTIVITIES ANALYZED FOR THE SEVEN-YEAR PERIOD IN THE NWTT STUDY AREA

Stressor category	Activity	Description	Typical duration	Source bin	Location	Annual # of events	7-Year # of events
Anti-Submarine Warfare							
Acoustic; Explosive	Torpedo Exercise—Submarine (TORPEX—Sub).	Submarine crews search for, track, and detect submarines. Event would include one MK–48 torpedo used during this event.	8 hours	TORP2	Offshore Area >12 nmi from land.	0–2	5
Acoustic	Tracking Exercise—Helicopter (TRACKEX—Helo).	Helicopter crews search for, track, and detect submarines.	2–4 hours	MF4, MF5	Offshore Area >12 nmi from land.	0–2	5
Acoustic	Tracking Exercise—Maritime Patrol Aircraft (TRACKEX—MPA).	Maritime patrol aircraft crews search for, track, and detect submarines.	2–8 hours	ASW2, ASW5, MF5, TORP1.	Offshore Area >12 nmi from land.	373	2,611
Acoustic	Tracking Exercise—Ship (TRACKEX—Ship).	Surface ship crews search for, track, and detect submarines.	2–4 hours	ASW3, MF1, MF11.	Offshore Area	62	434
Acoustic	Tracking Exercise—Submarine (TRACKEX—Sub).	Submarine crews search for, track, and detect submarines.	8 hours	HF1, MF3	Offshore Area	75–100	595
Mine Warfare							
Acoustic	Civilian Port Defense—Homeland Security Anti-Terrorism/Force Protection Exercises.	Maritime security personnel train to protect civilian ports and harbors against enemy efforts to interfere with access to those ports.	Multiple days	HF4, SAS2.	Inland Waters	0–1	5

TABLE 3—PROPOSED TRAINING ACTIVITIES ANALYZED FOR THE SEVEN-YEAR PERIOD IN THE NWTT STUDY AREA—Continued

Stressor category	Activity	Description	Typical duration	Source bin	Location	Annual # of events	7-Year # of events
Explosive	Mine Neutralization—Explosive Ordnance Disposal (EOD).	Personnel disable threat mines using explosive charges.	Up to 4 hours	E3	Crescent Harbor EOD Training Range, Hood Canal EOD Training Range.	12	84
Surface Warfare							
Explosive	Bombing Exercise (Air-to-Surface) (BOMBEX [A–S]).	Fixed-wing aircrews deliver bombs against surface targets.	1 hour	E10	Offshore Area (W–237) >50 nmi from land.	*0–2	5
Explosive	Gunnery Exercise (Surface-to-Surface)—Ship (GUNEX [S–S]—Ship).	Surface ship crews fire large- and medium-caliber guns at surface targets.	Up to 3 hours	E1, E2, E5	Offshore Area >50 nmi from land.	*90	504
Explosive	Missile Exercise (Air-to-Surface) (MISSILEX [A–S]).	Fixed-wing aircrews simulate firing precision-guided missiles, using captive air training missiles (CATMs) against surface targets. Some activities include firing a missile with a high-explosive (HE) warhead.	2 hours	E10	Offshore Area (W–237) >50 nmi from land.	0–2	5
Other Training							
Acoustic	Submarine Sonar Maintenance.	Maintenance of submarine sonar and other system checks are conducted pierside or at sea.	Up to 1 hour	LF5, MF3	NBK Bangor, NBK Bremerton, and Offshore Area >12 nmi from land.	26	182
Acoustic	Surface Ship Sonar Maintenance.	Maintenance of surface ship sonar and other system checks are conducted pierside or at sea.	Up to 4 hours	MF1	NBK Bremerton, NS Everett, and Offshore Area >12 nmi from land.	25	175
Acoustic	Unmanned Underwater Vehicle Training.	Unmanned underwater vehicle certification involves training with unmanned platforms to ensure submarine crew proficiency. Tactical development involves training with various payloads for multiple purposes to ensure that the systems can be employed effectively in an operational environment.	Up to 24 hours.	FLS2, M3	Inland Waters, Offshore Area.	60	420

*(Counts only the explosive events).

TABLE 4—PROPOSED TESTING ACTIVITIES ANALYZED FOR THE SEVEN-YEAR PERIOD IN THE NWTT STUDY AREA

Stressor category	Activity	Description	Typical duration	Source bin	Location	Annual # of events	7-Year # of events
Naval Sea Systems Command Testing Activities							
Anti-Submarine Warfare:							
Acoustic	Anti-Submarine Warfare Testing.	Ships and their supporting platforms (rotary-wing aircraft and unmanned aerial systems) detect, localize, and prosecute submarines.	4–8 hours of active sonar use.	ASW1, ASW2, ASW3, ASW5, MF1K, MF4, MF5, MF10, MF11, MF12, TORP1.	Offshore Area	44	308
Acoustic	At-Sea Sonar Testing.	At-sea testing to ensure systems are fully functional in an open ocean environment.	From 4 hours to 11 days.	ASW3, HF1, HF5, M3, MF3. ASW3, HF5, TORP1.	Offshore Area Inland Waters (DBRC).	4 4–6	28 34
Acoustic	Countermeasure Testing.	Countermeasure testing involves the testing of systems that will detect, localize, and track incoming weapons, including marine vessel targets. Countermeasures may be systems to obscure the vessel's location or systems to rapidly detect, track, and counter incoming threats. Testing includes surface ship torpedo defense systems and marine vessel stopping payloads.	From 4 hours to 6 days.	ASW3, ASW4, HF8, MF1, TORP2. ASW3, ASW4 ASW4	Offshore Area (QRS). Inland Waters (DBRC, Keyport Range Site). Western Behm Canal, AK.	14 29 1	98 203 5

TABLE 4—PROPOSED TESTING ACTIVITIES ANALYZED FOR THE SEVEN-YEAR PERIOD IN THE NWTT STUDY AREA—Continued

Stressor category	Activity	Description	Typical duration	Source bin	Location	Annual # of events	7-Year # of events
Acoustic	Pierside-Sonar Testing.	Pierside testing to ensure systems are fully functional in a controlled pierside environment prior to at-sea test activities.	Up to 3 weeks	ASW3, HF3, MF1, MF2, MF3, MF9, MF10, MF12.	Inland Waters (NS Everett, NBK Bangor, NBK Bremerton).	88–99	635
Acoustic	Submarine Sonar Testing/Maintenance.	Pierside, moored, and underway testing of submarine systems occurs periodically following major maintenance periods and for routine maintenance.	Up to 3 weeks	HF6, MF9	Western Behm Canal, AK.	1–2	10
Acoustic; Explosive	Torpedo (Explosive) Testing.	Air, surface, or submarine crews employ explosive and non-explosive torpedoes against artificial targets.	1–2 hours during daylight only.	E8, E11, ASW3, HF1, HF6, MF1, MF3, MF4, MF5, MF6, TORP1, TORP2.	Offshore Area >50 nmi from land.	4	28
Acoustic	Torpedo (Non-explosive) Testing.	Air, surface, or submarine crews employ non-explosive torpedoes against targets, submarines, or surface vessels.	Up to 2 weeks	ASW3, ASW4, HF1, HF5, HF6, MF1, MF3, MF4, MF5, MF6, MF9, MF10, TORP1, TORP2.	Offshore Area	22	154
				HF6, LF4, TORP1, TORP2, TORP3.	Inland Waters (DBRC).	61	427
Mine Warfare:							
Acoustic; Explosive	Mine Countermeasure and Neutralization Testing.	Air, surface, and subsurface vessels neutralize threat mines and mine-like objects.	1–10 days	E4, E7, HF4	Offshore Area	3	15
				HF4	Inland Waters	3	13
Acoustic	Mine Detection and Classification Testing.	Air, surface, and subsurface vessels and systems detect and classify mines and mine-like objects. Vessels also assess their potential susceptibility to mines and mine-like objects.	Up to 24 days	BB1, BB2, LF4	Offshore Area (QRS).	1	7
				BB1, BB2, HF4, LF4.	Inland Waters (DBRC, Keyport Range Site).	42	294
Unmanned Systems:							
Acoustic	Unmanned Underwater Vehicle Testing.	Testing involves the production or upgrade of unmanned underwater vehicles. This may include testing of mission capabilities (*e.g.,* mine detection), evaluating the basic functions of individual platforms, or conducting complex events with multiple vehicles.	Typically 1–2 days, up to multiple months.	FLS2, HF5, TORP1, VHF1.	Offshore Area (QRS).	38–39	269
				DS3, FLS2, HF5, HF9, M3, SAS2, VHF1, TORP1.	Inland Waters (DBRC, Keyport Range Site, Carr Inlet).	371–379	2,615
Vessel Evaluation:							
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 undersea targets.	Up to 10 days	ASW3, ASW4, HF4, MF1, MF4, MF5, MF6, MF9, TORP1, TORP2.	Offshore Area	1–12	27
Other Testing:							
Acoustic	Acoustic and Oceanographic Research.	Research using active transmissions from sources deployed from ships, aircraft, and unmanned underwater vehicles. Research sources can be used as proxies for current and future Navy systems.	Up to 14 days	LF4, MF9	Offshore Area (QRS).	1	7
					Inland Waters (DBRC, Keyport Range Site).	3	21
Acoustic	Acoustic Component Testing.	Various surface vessels, moored equipment, and materials are tested to evaluate performance in the marine environment.	1 day to multiple months.	HF3, HF6, LF5, MF9.	Western Behm Canal, AK.	13–18	99
Acoustic	Cold Water Support	Fleet training for divers in a cold water environment, and other diver training related to Navy divers supporting range/test site operations and maintenance.	8 hours	HF6	Inland Waters (Keyport Range Site, DBRC, Carr Inlet).	4	28
					Western Behm Canal, AK.	1	7

TABLE 4—PROPOSED TESTING ACTIVITIES ANALYZED FOR THE SEVEN-YEAR PERIOD IN THE NWTT STUDY AREA—Continued

Stressor category	Activity	Description	Typical duration	Source bin	Location	Annual # of events	7-Year # of events
Acoustic	Post-Refit Sea Trial	Following periodic maintenance periods or repairs, sea trials are conducted to evaluate submarine propulsion, sonar systems, and other mechanical tests.	8 hours	HF9, M3, MF10	Inland Waters (DBRC).	30	210
Acoustic	Semi-Stationary Equipment Testing.	Semi-stationary equipment (*e.g.,* hydrophones) is deployed to determine functionality.	From 10 minutes to multiple days.	HF6, HF9, LF4, MF9, VHF2.	Inland Waters (DBRC, Keyport Range Site).	120	840
				HF6, HF9	Western Behm Canal, AK.	2–3	12
Naval Air Systems Command Testing Activities							
Anti-Submarine Warfare: Acoustic; Explosive	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.	4–8 flight hours.	E1, E3, ASW2, ASW5, MF5, MF6.	Offshore Area	8	56

Summary of Acoustic and Explosive Sources Analyzed for Training and Testing

Tables 5 through 8 show the acoustic and explosive source classes, bins, and quantity used in either hours or counts associated with the Navy's proposed training and testing activities over a seven-year period in the NWTT Study Area that were analyzed in the Navy's rulemaking/LOA application. Table 5 describes the acoustic source classes (*i.e.,* low-frequency (LF), mid-frequency (MF), and high-frequency (HF)) and numbers that could occur over seven years under the proposed training activities. Acoustic source bin use in the proposed activities would vary annually. The seven-year totals for the proposed training activities take into account that annual variability.

TABLE 5—ACOUSTIC SOURCE CLASS BINS ANALYZED AND NUMBERS USED FOR SEVEN-YEAR PERIOD FOR TRAINING ACTIVITIES IN THE NWTT STUDY AREA

Source class category	Bin	Description	Unit	Annual	7-Year total
Low-Frequency (LF): Sources that produce signals less than 1 kHz.	LF5	LF sources less than 180 dB	H	1	5
Mid-Frequency (MF): Tactical and non-tactical sources that produce signals between 1 and 10 kHz.	MF1	Hull-mounted surface ship sonars (*e.g.,* AN/SQS–53C and AN/SQS–61).	H	164	1,148
	MF3	Hull-mounted submarine sonars (*e.g.,* AN/BQQ–10).	H	70	490
	MF4	Helicopter-deployed dipping sonars (*e.g.,* AN/AQS–22 and AN/AQS–13).	H	0–1	1
	MF5	Active acoustic sonobuoys (*e.g.,* DICASS)	C	918–926	6,443
	MF11	Hull-mounted surface ship sonars with an active duty cycle greater than 80%.	H	16	112
High-Frequency (HF): Tactical and non-tactical sources that produce signals between 10 and 100 kHz.	HF1	Hull-mounted submarine sonars (*e.g.,* AN/BQQ–10).	H	48	336
	HF4	Mine detection, classification, and neutralization sonar (*e.g.,* AN/SQS–20).	H	0–65	269
Anti-Submarine Warfare (ASW): Tactical sources (*e.g.,* active sonobuoys and acoustic countermeasures systems) used during ASW training and testing activities.	ASW2	MF Multistatic Active Coherent sonobuoy (*e.g.,* AN/SSQ–125).	C	350	2,450
	ASW3	MF towed active acoustic countermeasure systems (*e.g.,* AN/SLQ–25).	H	86	602
	ASW5	MF sonobuoys with high duty cycles	H	50	350
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).	C	16	112
	TORP2	Heavyweight torpedo (*e.g.,* MK 48)	C	0–2	5
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	240	1,680

TABLE 5—ACOUSTIC SOURCE CLASS BINS ANALYZED AND NUMBERS USED FOR SEVEN-YEAR PERIOD FOR TRAINING ACTIVITIES IN THE NWTT STUDY AREA—Continued

Source class category	Bin	Description	Unit	Annual	7-Year total
Acoustic Modems (M): Systems used to transmit data through the water.	M3	MF acoustic modems (greater than 190 dB) ..	H	30	210
Synthetic Aperture Sonars (SAS): Sonars in which active acoustic signals are post-processed to form high-resolution images of the seafloor.	SAS2	HF SAS systems	H	0–561	2,353

Notes: H = hours; C = count.

Table 6 describes the acoustic source classes and numbers that could occur over seven years under the proposed testing activities. Acoustic source bin use in the proposed activities would vary annually. The seven-year totals for the proposed testing activities take into account that annual variability.

TABLE 6—ACOUSTIC SOURCE CLASS BINS ANALYZED AND NUMBERS USED FOR SEVEN-YEAR PERIOD FOR TESTING ACTIVITIES IN THE NWTT STUDY AREA

Source class category	Bin	Description	Unit	Annual	7-Year total
Low-Frequency (LF): Sources that produce signals less than 1 kHz.	LF4	LF sources equal to 180 dB and up to 200 dB	H	177	1,239
	LF5	LF sources less than 180 dB	H	0–18	23
Mid-Frequency (MF): Tactical and non-tactical sources that produce signals between 1 and 10 kHz.	MF1	Hull-mounted surface ship sonars (*e.g.,* AN/SQS–53C and AN/SQS–61).	H	20–169	398
	MF1K	Kingfisher mode associated with MF1 sonars	H	48	336
	MF2	Hull-mounted surface ship sonars (*e.g.,* AN/SQS–56).	H	32	224
	MF3	Hull-mounted submarine sonars (*e.g.,* AN/BQQ–10).	H	34–36	239
	MF4	Helicopter-deployed dipping sonars (*e.g.,* AN/AQS–22 and AN/AQS–13).	H	41–50	298
	MF5	Active acoustic sonobuoys (*e.g.,* DICASS)	C	300–673	2,782
	MF6	Active underwater sound signal devices (*e.g.,* MK 84 SUS).	C	60–232	744
	MF9	Active sources (equal to 180 dB and up to 200 dB) not otherwise binned.	H	644–959	5,086
	MF10	Active sources (greater than 160 dB, but less than 180 dB) not otherwise binned.	H	886	6,197
	MF11	Hull-mounted surface ship sonars with an active duty cycle greater than 80 percent.	H	48	336
	MF12	Towed array surface ship sonars with an active duty cycle greater than 80 percent.	H	100	700
High-Frequency (HF): Tactical and non-tactical sources that produce signals between 10 and 100 kHz.	HF1	Hull-mounted submarine sonars (*e.g.,* AN/BQQ–10).	H	10	68
	HF3	Other hull-mounted submarine sonars (classified).	H	1–19	30
	HF4	Mine detection, classification, and neutralization sonar (*e.g.,* AN/SQS–20).	H	1,860–1,868	11,235
	HF5	Active sources (greater than 200 dB) not otherwise binned.	H	352–400	2,608
	HF6	Active sources (equal to 180 dB and up to 200 dB) not otherwise binned.	H	1,705–1,865	12,377
	HF8	Hull-mounted surface ship sonars (*e.g.,* AN/SQS–61).	H	24	168
	HF9	Weapon emulating sonar source	H	257	1,772
Very High-Frequency (VHF): Tactical and non-tactical sources that produce signals greater than 100 kHz but less than 200 kHz.	VHF1	Very high frequency sources greater than 200 dB.	H	320	2,240
	VHF2	Active sources with a frequency greater than 100 kHz, up to 200 kHz with a source level less than 200 dB.	H	135	945
Anti-Submarine Warfare (ASW): Tactical sources (*e.g.,* active sonobuoys and acoustic countermeasures systems) used during ASW training and testing activities.	ASW1	MF systems operating above 200 dB	H	80	560
	ASW2	MF systems operating above 200 dB	C	240	1,680
	ASW3	MF towed active acoustic countermeasure systems (*e.g.,* AN/SLQ–25).	H	487–1,015	4,091

TABLE 6—ACOUSTIC SOURCE CLASS BINS ANALYZED AND NUMBERS USED FOR SEVEN-YEAR PERIOD FOR TESTING ACTIVITIES IN THE NWTT STUDY AREA—Continued

Source class category	Bin	Description	Unit	Annual	7-Year total
	ASW4	MF expendable active acoustic device countermeasures (*e.g.,* MK 3).	C	1,349–1,389	9,442
	ASW5	MF sonobuoys with high duty cycles	H	80	560
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).	C	298–360	2,258
	TORP2	Heavyweight torpedo (*e.g.,* MK 48)	C	332–372	2,324
	TORP3	Heavyweight torpedo test (*e.g.,* MK 48)	C	6	42
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	24	168
Acoustic Modems (M): Systems used to transmit data through the water.	M3	MF acoustic modems (greater than 190 dB)	H	1,088	7,616
Synthetic Aperture Sonars (SAS): Sonars in which active acoustic signals are post-processed to form high-resolution images of the seafloor.	SAS2	HF SAS systems	H	1,312	9,184
Broadband Sound Sources (BB): Sonar systems with large frequency spectra, used for various purposes.	BB1	MF to HF mine countermeasure sonar	H	48	336
	BB2	HF to VHF mine countermeasure sonar	H	48	336

Notes: H = hours; C = count.

Table 7 describes the explosive source classes and numbers that could occur over seven years under the proposed training activities. Under the proposed activities bin use would vary annually, and the seven-year totals for the proposed training activities take into account that annual variability.

TABLE 7—EXPLOSIVE SOURCE CLASS BINS ANALYZED AND NUMBERS USED FOR SEVEN-YEAR PERIOD FOR TRAINING ACTIVITIES IN THE NWTT STUDY AREA

Bin	Net explosive weight (lb)	Example explosive source	Annual	7-Year total
E1	0.1–0.25	Medium-caliber projectiles	60–120	672
E2	>0.25–0.5	Medium-caliber projectiles	65–130	728
E3	>0.5–2.5	Explosive Ordnance Disposal Mine Neutralization	6	42
E5	>5–10	Large-caliber projectile	56–112	628
E10	>250–500	1,000 lb bomb	0–4	9

Notes: (1) Net explosive weight refers to the equivalent amount of TNT. The actual weight of a munition may be larger due to other components. lb = pound(s), ft = feet.

Table 8 describes the explosive source classes and numbers that could occur over seven years under the proposed testing activities. Under the proposed activities bin use would vary annually, and the seven-year totals for the proposed testing activities take into account that annual variability.

TABLE 8—EXPLOSIVE SOURCE CLASS BINS ANALYZED AND NUMBERS USED FOR SEVEN-YEAR PERIOD FOR TESTING ACTIVITIES IN THE NWTT STUDY AREA

Bin	Net explosive weight (lb)	Example explosive source	Annual	7-Year total
E1	0.1–0.25	SUS buoy	8	56
E3	>0.5–2.5	Explosive sonobuoy	72	504
E4	>2.5–5	Mine Countermeasure and Neutralization	36	180
E7	>20–60	Mine Countermeasure and Neutralization	5	25
E8	>60–100	Lightweight torpedo	4	28
E11	>500–650	Heavyweight torpedo	4	28

Notes: (1) Net explosive weight refers to the equivalent amount of TNT. The actual weight of a munition may be larger due to other components. lb = pound(s), ft = feet.

Vessel Movement

Vessels used as part of the proposed activities include ships, submarines, unmanned vessels, and boats ranging in size from small, 22 ft rigid hull inflatable boats to aircraft carriers with lengths up to 1,092 ft. Large ships greater than 60 ft generally operate at speeds in the range of 10–15 kn for fuel conservation. Submarines generally operate at speeds in the range of 8–13 kn in transits and less than those speeds for certain tactical maneuvers. Small craft (for purposes of this discussion—less than 60 ft in length) have much more variable speeds (dependent on the mission). While these speeds are representative of most events, some vessels need to temporarily operate outside of these parameters. For example, to produce the required relative wind speed over the flight deck, an aircraft carrier engaged in flight operations must adjust its speed through the water accordingly. Conversely, there are other instances, such as launch and recovery of a small rigid hull inflatable boat; vessel boarding, search, and seizure training events; or retrieval of a target when vessels will be dead in the water or moving slowly ahead to maintain steerage.

The number of military vessels used in the NWTT Study Area varies based on military training and testing requirements, deployment schedules, annual budgets, and other unpredictable factors. Many training and testing activities involve the use of vessels. These activities could be widely dispersed throughout the NWTT Study Area, but would be typically conducted near naval ports, piers, and range areas. Training and testing activities involving vessel movements occur intermittently and are variable in duration, ranging from a few hours to up to two weeks. There is no seasonal differentiation in military vessel use. Large vessel movement primarily occurs with the majority of the traffic flowing between the installations and the Operating Areas (OPAREAS). Smaller support craft would be more concentrated in the coastal waters in the areas of naval installations, ports, and ranges. The number of activities that include the use of vessels for training events is lower (approximately 10 percent) than the number for testing activities. Testing can occur jointly with a training event, in which case that testing activity could be conducted from a training vessel.

Additionally, a variety of smaller craft will be operated within the NWTT Study Area. Small craft types, sizes, and speeds vary. During training and testing, speeds generally range from 10–14 kn; however, vessels can and will, on occasion, operate within the entire spectrum of their specific operational capabilities. In all cases, the vessels/craft will be operated in a safe manner consistent with the local conditions.

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 military missions and combat operations 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 benefits to environmental, socioeconomic, public health and safety, and cultural resources.

Navy standard operating procedures have been developed and refined over years of experience and are broadcast via numerous naval instructions and manuals, including, but not limited to the following materials:

- Ship, submarine, and aircraft safety manuals;
- Ship, submarine, and aircraft standard operating manuals;
- Fleet Area Control and Surveillance Facility range operating instructions;
- Fleet exercise publications and instructions;
- Naval Sea Systems Command test range safety and standard operating instructions;
- Navy-instrumented range operating procedures;
- Naval shipyard sea trial agendas;
- Research, development, test, and evaluation plans;
- Naval gunfire safety instructions;
- Navy planned maintenance system instructions and requirements;
- Federal Aviation Administration regulations; and
- International Regulations for Preventing Collisions at Sea.

Because standard operating procedures are essential to safety and mission success, the Navy considers them to be part of the proposed Specified Activities, and has included them in the environmental analysis. Standard operating procedures that are recognized as having a potential benefit to marine mammals during training and testing activities are noted below and discussed in more detail within the 2019 NWTT DSEIS/OEIS.

- Vessel Safety;
- Weapons Firing Procedures;
- Target Deployment Safety; and
- Towed In-Water Device Safety.

Standard operating procedures (which are implemented regardless of their secondary benefits) are different from mitigation measures (which are designed entirely for the purpose of avoiding or reducing environmental impacts). Information on mitigation measures is provided in the *Proposed Mitigation* section below. Additional information on standard operating procedures is presented in Section 2.3.3 (Standard Operating Procedures) in the 2019 NWTT DSEIS/OEIS.

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 NWTT Study Area are presented in Table 9 along with an abundance estimate, an associated coefficient of variation value, and best and minimum abundance estimates. The Navy requests authorization to take individuals of 29 marine mammal species by Level A harassment and Level B harassment incidental to training and testing activities from the use of sonar and other transducers and in-water detonations. In addition, the Navy requests authorization for three takes of large whales by serious injury or mortality from vessel strikes over the seven-year period. Currently, the Southern Resident killer whale has critical habitat designated under the Endangered Species Act (ESA) in the NWTT Study Area (described below). However, NMFS has recently published two proposed rules, proposing new or revised ESA-designated critical habitat for humpback whales (84 FR 54354; October 9, 2019) and Southern Resident killer whales (84 FR 49214; September 19, 2019).

Information on the status, distribution, abundance, population trends, habitat, and ecology of marine mammals in the NWTT Study Area may be found in Chapter 4 of the Navy's rulemaking/LOA application. NMFS has reviewed this information and found it to be accurate and complete. Additional information on the general biology and ecology of marine mammals is included in the 2019 NWTT DSEIS/OEIS. Table 9 incorporates data from the U.S. Pacific and the Alaska Marine Mammal Stock Assessment Reports (SARs; Carretta *et al.,* 2019; Muto *et al.,* 2019) and the most recent revised data in the draft SARs (see *https://www.fisheries.noaa.gov/national/marine-mammal-protection/draft-marine-mammal-stock-assessment-reports*); as well as incorporates the best available science, including monitoring data from the Navy's marine mammal research efforts.

Species Not Included in the Analysis

The species carried forward for analysis (and described in Table 9 below) are those likely to be found in the NWTT Study Area based on the most recent data available, and do not include species that may have once inhabited or transited the area but have not been sighted in recent years (*e.g.,* species which were extirpated from factors such as 19th and 20th century commercial exploitation). Several species that may be present in the northwest Pacific Ocean have an extremely low probability of presence in the NWTT Study Area. These species are considered extralimital (not anticipated to occur in the Study Area) or rare (occur in the Study Area sporadically, but sightings are rare). These species/stocks include the Eastern North Pacific stock of Bryde's whale (*Balaenoptera edeni*), Eastern North Pacific stock of North Pacific right whale (*Eubalaena japonica*), false killer whale (*Pseudorca crassidens*), long-beaked common dolphin (*Delphinus capensis*), Western U.S. stock of Steller sea lion (*Eumetopias jubatus*), and Alaska stock of Cuvier's beaked whale (*Ziphius cavirostris*). Despite rare stranding or sighting reports, the Study Area is outside the normal range of the Eastern North Pacific stock of Bryde's whale and the California stock of the long-beaked common dolphin. The Study Area is also outside the normal range of the false killer whale's distribution in the Pacific Ocean. The Eastern North Pacific stock of North Pacific right whale is estimated to have an abundance of 31 individuals (Muto *et al.,* 2020) and is anticipated to be extremely rare in the Study Area. The Western U.S. stock of Steller sea lions is considered rare in the Offshore Area of the Study Area, and is not expected to occur in the Inland Waters portion of the Study Area. In Western Behm Canal, there is a low probability of juvenile male Steller sea lion occurrence from the Western U.S. stock, however these individuals are anticipated to be very rare. Finally, the Alaska stock of Cuvier's beaked whales is not expected to occur in either the Offshore Area or Inland Waters of the NWTT Study Area, and are considered extralimital in Western Behm Canal as this area does not overlap with their range of distribution. NMFS agrees with the Navy's assessment that these species are unlikely to occur in the NWTT Study Area and they are not discussed further.

TABLE 9—MARINE MAMMAL OCCURRENCE WITHIN THE NWTT STUDY AREA

Common name	Scientific name	Stock	ESA/ MMPA status; strategic (Y/N) [1]	Stock abundance (CV, N_{min}, most recent abundance survey) [2]	PBR	Annual M/SI [3]	Occurrence		
							Offshore area	Inland waters	Western Behm Canal
Order Cetartiodactyla—Cetacea—Superfamily Mysticeti (baleen whales)									
Family Eschrichtiidae:									
Gray whale	*Eschrichtius robustus*	Eastern North Pacific	-, -, N	26,960 (0.05, 25,849, 2016).	801	139	Seasonal	Seasonal	
Family Balaenopteridae (rorquals):									
Blue whale	*Balaenoptera musculus*	Eastern North Pacific	E, D, S	1,496 (0.44, 1,050, 2014)	1.2	≥19.4	Seasonal.		
Fin whale	*Balaenoptera physalus*	Northeast Pacific	E, D, S	3,168 (0.26, 2,554, 2013) [4]	5.1	0.4			Rare.
		CA/OR/WA	E, D, S	9,029 (0.12, 8,127, 2014)	81	≥43.5	Seasonal	Rare	
Humpback whale	*Megaptera novaeangliae*	Central North Pacific	T/E,[5] D, S	10,103 (0.3, 7,891, 2006)	83	25	Regular	Regular	Regular.
		CA/OR/WA	T/E,[5] D, S	2,900 (0.05, 2,784, 2014)	16.7	≥42.1	Regular	Regular	Regular.
Minke whale	*Balaenoptera acutorostrata*	Alaska	-, -, N	UNK	UND	0			Rare.
		CA/OR/WA	-, -, N	636 (0.72, 369, 2014)	3.5	≥1.3	Regular	Seasonal.	
Sei whale	*Balaenoptera borealis*	Eastern North Pacific	E, D, S	519 (0.4, 374, 2014)	0.75	≥0.2	Regular		
Superfamily Odontoceti (toothed whales, dolphins, and porpoises)									
Family Physeteridae:									
Sperm whale	*Physeter macrocephalus*	CA/OR/WA	E, D, S	1.997 (0.57, 1,270, 2014)	2.5	0.4	Rare.		
Family Kogiidae:									
Dwarf sperm whale	*Kogia sima*	CA/OR/WA	-, -, N	UNK	UND	0	Rare.		
Pygmy sperm whale	*Kogia breviceps*	CA/OR/WA	-, -, N	4,111 (1.12, 1,924, 2014)	19.2	0	Regular.		
Family Ziphiidae (beaked whales):									
Baird's beaked whale	*Berardius bairdii*	CA/OR/WA	-, -, N	2,697 (0.6, 1,633, 2014)	16	0	Regular.		
Cuvier's beaked whale	*Ziphius cavirostris*	CA/OR/WA	-, -, N	3,274 (0.67, 2,059, 2014)	21	< 0.1	Regular.		
Mesoplodont beaked whales.	*Mesoplodon* species	CA/OR/WA	-, -, N	3,044 (0.54, 1,967, 2014)	20	0.1	Regular.		
Family Delphinidae:									
Common bottlenose dolphin.	*Tursiops truncatus*	CA/OR/WA Offshore	-, -, N	1,924 (0.54, 1,255, 2014)	11	≥1.6	Regular.		
Killer whale	*Orcinus orca*	Eastern North Pacific Alaskan Resident.	-, -, N	2,347 (UNK, 2,347, 2012) [6]	24	1			Regular.
		Eastern North Pacific Northern Resident.	-, -, N	302 (UNK, 302, 2018) [6]	2.2	0.2	Seasonal	Seasonal	
		West Coast Transient	-, -, N	243 (UNK, 243, 2009)	2.4	0	Regular	Regular	Regular.
		Eastern North Pacific Offshore.	-, -, N	300 (0.1, 276, 2012)	2.8	0	Regular		Regular.
		Eastern North Pacific Southern Resident.	E, D, Y	75 (NA, 75, 2018)	0.13	0	Seasonal	Regular	
Northern right whale dolphin.	*Lissodelphus borealis*	CA/OR/WA	-, -, N	26,556 (0.44, 18,608, 2014).	179	3.8	Regular.		
Pacific white-sided dolphin.	*Lagenorhynchus obliquidens.*	North Pacific	-, -, N	26,880 (UNK, NA, 1990)	UND	0			Regular.
		CA/OR/WA	-, -, N	26,814 (0.28, 21,195, 2014).	191	7.5	Regular	Regular	
Risso's dolphin	*Grampus griseus*	CA/OR/WA	-, -, N	6,336 (0.32, 4,817, 2014)	46	≥3.7	Regular	Rare	
Short-beaked common dolphin.	*Delphinus delphis*	CA/OR/WA	-, -, N	969,861 (0.17, 839,325, 2014).	8,393	ε40	Regular	Rare	
Short-finned pilot whale	*Globicephala macrorhynchus.*	CA/OR/WA	-, -, N	836 (0.79, 466, 2014)	4.5	1.2	Regular	Rare	
Striped dolphin	*Stenella coeruleoalba*	CA/OR/WA	-, -, N	29,211 (0.2, 24,782, 2014)	238	≥0.8	Regular.		
Family Phocoenidae (porpoises):									
Dall's porpoise	*Phocoenoides dalli*	Alaska	-, -, N	83,400 (0.097, NA, 1991)	UND	38			Regular.

TABLE 9—MARINE MAMMAL OCCURRENCE WITHIN THE NWTT STUDY AREA—Continued

Common name	Scientific name	Stock	ESA/MMPA status; strategic (Y/N)[1]	Stock abundance (CV, N_{min}, most recent abundance survey)[2]	PBR	Annual M/SI[3]	Occurrence		
							Offshore area	Inland waters	Western Behm Canal
		CA/OR/WA	-, -, N	25,750 (0.45, 17,954, 2014).	172	0.3	Regular	Regular	
Harbor porpoise	*Phocoena phocoena*	Southeast Alaska	-, -, Y	1,354 (0.12, 1,224, 2012)	12	34			Regular.
		Northern OR/WA Coast	-, -, N	21,487 (0.44, 15, 123, 2011).	151	≥3	Regular.		
		Northern CA/Southern OR	-, -, N	35,769 (0.52, 23,749, 2011).	475	≥0.6	Regular.		
		Washington Inland Waters	-, -, N	11,233 (0.37, 8,308, 2015)	66	≥7.2		Regular	
Order Carnivora—Superfamily Pinnipedia									
Family Otariidae (eared seals and sea lions):									
California sea lion	*Zalophus californianus*	U.S.	-, -, N	257,606 (NA, 233,515, 2014).	14,011	≥321	Seasonal	Regular	
Guadalupe fur seal	*Arctocephalus townsendi*	Mexico to California	T, D, Y	34,187 (NA, 31,109, 2013)	1,062	≥3.8	Seasonal.		
Northern fur seal	*Callorhinus ursinus*	Eastern Pacific	-, D, Y	620,660 (0.2, 525,333, 2016).	11,295	399	Regular		Seasonal.
		California	-, -, N	14,050 (NA, 7,524, 2013)	451	1.8	Regular.		
Steller sea lion	*Eumetopias jubatus*	Eastern U.S.	-, -, N	43,201 (NA, 43,201, 2017)[7].	2,592	113	Regular	Seasonal	Regular.
Family Phocidae (earless seals):									
Harbor seal	*Phoca vitulina*	Southeast Alaska (Clarence Strait).	-, -, N	27,659 (UNK, 24,854, 2015).	746	40			Regular.
		OR/WA Coast	-, -, N	UNK	UND	10.6	Regular	Seasonal	
		California	-, -, N	30,968 (0.157, 27,348, 2012).	1,641	43	Regular.		
		Washington Northern Inland Waters.	-, -, N	UNK	UND	9.8	Seasonal	Regular	
		Hood Canal	-, -, N	UNK	UND	0.2	Seasonal	Regular	
		Southern Puget Sound	-, -, N	UNK	UND	3.4	Seasonal	Regular	
Northern Elephant seal	*Mirounga angustirostris*	California	-, -, N	179,000 (NA, 81,368, 2010).	4,882	8.8	Regular	Regular	Seasonal.

[1] Endangered Species Act (ESA) status: Endangered (E), Threatened (T)/MMPA status: Depleted (D). A dash (-) indicates that the species is not listed under the ESA or designated as depleted under the MMPA. Under the MMPA, a strategic stock is one for which the level of direct human-caused mortality exceeds potential biological removal (PBR) or which is determined to be declining and likely to be listed under the ESA within the foreseeable future. Any species or stock listed under the ESA is automatically designated under the MMPA as depleted and as a strategic stock.

[2] NMFS marine mammal stock assessment reports online at: *https://www.fisheries.noaa.gov/national/marine-mammal-protection/marine-mammal-stock-assessments.* CV is coefficient of variation; N_{min} is the minimum estimate of stock abundance. In some cases, CV is not applicable. For the Eastern North Pacific Southern Resident stock of killer whales Nbest/N_{min} are based on a direct count of individually identifiable animals. The population size of the U.S. stock of California sea lion was estimated from a 1975–2014 time series of pup counts (Lowry *et al.* 2017), combined with mark-recapture estimates of survival rates (DeLong *et al.* 2017, Laake *et al.* 2018). The population size of the Mexico to California stock of Guadalupe fur seals was estimated from pup count data collected in 2013 and a range of correction factors applied to pup counts to account for uncounted age classes and pre-census pup mortality (Garcia-Aguilar *et al.* 2018). The population size of the California stock of Northern fur seals was estimated from pup counts multiplied by an expansion factor (San Miguel Island) and maximum pup, juvenile, and adult counts (Farrallon Islands) at rookeries. The population size of the Eastern U.S. stock of Steller sea lions was estimated from pup counts and non-pup counts at rookeries in Southeast Alaska, British Columbia, Oregon, and California. The population size of the California stock of Northern Elephant seals was estimated from pup counts at rookeries multiplied by the inverse of the expected ratio of pups to total animals (McCann, 1985; Lowry *et al.,* 2014).

[3] These values, found in NMFS' SARs, represent annual levels of human-caused mortality and serious injury (M/SI) from all sources combined (*e.g.,* commercial fisheries, ship strike). Annual M/SI often cannot be determined precisely and is in some cases presented as a minimum value or range. A CV associated with estimated mortality due to commercial fisheries is presented in some cases.

[4] SAR reports this stock abundance assessment as provisional and notes that it is an underestimate for the entire stock because it is based on surveys which covered only a small portion of the stock's range.

[5] Humpback whales in the Central North Pacific stock and the CA/OR/WA stock are from three Distinct Population Segments (DPSs) based on animals identified in breeding areas in Hawaii, Mexico, and Central America. Both stocks and all three DPSs co-occur in the NWTT Study Area.

[6] Stock abundance estimate is based on counts of individual animals identified from photo-identification catalogues. Surveys for abundance estimates of these stocks are conducted infrequently.

[7] Stock abundance estimate is the best estimate counts, which have not been corrected to account for animals at sea during abundance surveys.

Note—Unknown (UNK); Undetermined (UND); Not Applicable (NA); California (CA); Oregon (OR); Washington (WA).

Below, we include additional information about the marine mammals in the area of the Specified Activities that informs our analysis, such as identifying known areas of important habitat or behaviors, or where Unusual Mortality Events (UME) have been designated.

Critical Habitat

Currently, only the distinct population segment (DPS) of Southern Resident killer whale (SRKW) has ESA-designated critical habitat in the NWTT Study Area. NMFS has recently published two proposed rules, however, proposing new or revised ESA-designated critical habitat for SRKW (84 FR 49214; September 19, 2019) and humpback whales (84 FR 54354; October 9, 2019).

NMFS designated critical habitat for the SRKW DPS on November 29, 2006 (71 FR 69054) in inland waters of Washington State. Based on the natural history of the SRKWs and their habitat needs, NMFS identified physical or biological features essential to the conservation of the SRKW DPS: (1) Water quality to support growth and development; (2) prey species of sufficient quantity, quality, and availability to support individual growth, reproduction and development, as well as overall population growth; and (3) passage conditions to allow for migration, resting, and foraging. ESA-designated critical habitat consists of three areas: (1) The Summer Core Area in Haro Strait and waters around the San Juan Islands; (2) Puget Sound; and (3) the Strait of Juan de Fuca, which comprise approximately 2,560 square miles (mi^2) (6,630 square kilometers (km^2)) of marine habitat. In designating critical habitat, NMFS considered economic impacts and impacts to national security, and concluded the benefits of exclusion of 18 military sites, comprising approximately 112 mi^2 (291 km^2), outweighed the benefits of inclusion because of national security impacts.

On January 21, 2014, NMFS received a petition requesting revisions to the SRKW critical habitat designation. The petition requested NMFS revise critical habitat to include ''inhabited marine waters along the West Coast of the United States that constitute essential foraging and wintering areas,'' specifically the region between Cape Flattery, Washington and Point Reyes, California extending from the coast to a distance of 47.2 mi (76 km) offshore.

The petition also requested NMFS adopt a fourth essential habitat feature in both current and expanded critical habitat relating to in-water sound levels. On September 19, 2019 (84 FR 54354), NMFS published a proposed rule proposing to revise the critical habitat designation for the SRKW DPS by designating six new areas (using the same essential features determined in 2006) along the U.S. West Coast. Specific new areas proposed along the U.S. West Coast include 15,626.6 mi^2 (40,472.7 km^2) of marine waters between the 6.1 m (20 ft) depth contour and the 200 m (656.2 ft) depth contour from the U.S. international border with Canada south to Point Sur, California.

On March 15, 2018, several non-governmental organizations filed a lawsuit seeking court-ordered deadlines for the issuance of proposed and final rules to designate ESA critical habitat for the Central American, Mexico, and Western North Pacific DPSs of humpback whales. In 2018, NMFS convened a critical habitat review team to assess and evaluate information in support of critical habitat designation for these DPSs. On October 9, 2019 (84 FR 54354), NMFS published a proposed rule proposing ESA-designated critical habitat areas located off the coasts of California, Oregon, Washington, and Alaska, including areas within the NWTT Study Area. Based on consideration of national security and economic impacts, NMFS also proposed to exclude multiple areas from the designation for each DPS.

Biologically Important Areas

Biologically Important Areas (BIAs) include areas of known importance for reproduction, feeding, or migration, or areas where small and resident populations are known to occur (Van Parijs, 2015). Unlike ESA critical habitat, these areas are not formally designated pursuant to any statute or law, but are a compilation of the best available science intended to inform impact and mitigation analyses. An interactive map of the BIAs may be found here: *https://cetsound.noaa.gov/biologically-important-area-map.*

BIAs off the West Coast of the continental United States with the potential to overlap portions of the NWTT Study Area include the following feeding and migration areas: Northern Puget Sound Feeding Area for gray whales (March–May); Northwest Feeding Area for gray whales (May–November); Northbound Migration Phase A for gray whales (January–July); Northbound Migration Phase B for gray whales (March–July); Northern Washington Feeding Area for humpback whales (May–November); Stonewall and Heceta Bank Feeding Area for humpback whales (May–November); and Point St. George Feeding Area for humpback whales (July–November) (Calambokidis *et al.,* 2015).

When comparing the geographic area of the NWTT Study Area with the BIAs off the West Coast of the continental United States, there is no direct spatial overlap between the Study Area and four of the offshore gray whale feeding areas—Grays Harbor, WA; Depoe Bay, OR; Cape Blanco and Orford Reef, OR; and Pt. St. George, CA. The NWTT Study Area does overlap with the Northwest WA gray whale feeding area and the Northern Puget Sound gray whale feeding area. There is no overlap of the gray whale migration corridor BIAs and the NWTT Study Area, with the exception of a portion of the Northwest coast of Washington approximately from Pacific Beach and extending north to the Strait of Juan de Fuca. The offshore Northern WA humpback whale feeding area is located entirely within the NWTT Study Area boundaries. The humpback whale feeding area at Stonewall and Hecta Bank only partially overlaps with the Study Area, and the feeding area at Point St. George has extremely limited overlap with the Study Area. All proposed activities occurring in the Offshore Area of the Study Area could potentially occur in these BIAs, except activities limited to greater than 50 nmi from shore (as described in the *Proposed Mitigation Measures* section). To mitigate impacts to marine mammals in these BIAs, the Navy would implement several procedural mitigation measures and mitigation areas (described in the *Proposed Mitigation Measures* section).

National Marine Sanctuaries

Under Title III of the Marine Protection, Research, and Sanctuaries Act of 1972 (also known as the National Marine Sanctuaries Act (NMSA)), NOAA can establish as national marine sanctuaries (NMS), areas of the marine environment with special conservation, recreational, ecological, historical, cultural, archaeological, scientific, educational, or aesthetic qualities. Sanctuary regulations prohibit or regulate activities that could destroy, cause the loss of, or injure sanctuary resources pursuant to the regulations for that sanctuary and other applicable law (15 CFR part 922). NMSs are managed on a site-specific basis, and each sanctuary has site-specific regulations. Most, but not all, sanctuaries have site-specific regulatory exemptions from the prohibitions for certain military activities. Separately, section 304(d) of the NMSA requires Federal agencies to consult with the Office of National Marine Sanctuaries whenever their activities are likely to destroy, cause the loss of, or injure a sanctuary resource. One NMS, the Olympic Coast NMS managed by the Office of National Marine Sanctuaries, is located within the offshore portion of the NWTT Study Area (for a map of the location of this NMS see Chapter 6 of the 2019 NWTT DSEIS/OEIS and Figure 6–1).

The Olympic Coast NMS includes 3,188 mi^2 of marine waters and submerged lands off the Olympic Peninsula coastline. The sanctuary extends 25–50 mi. (40.2–80.5 km) seaward, covering much of the continental shelf and portions of three major submarine canyons. The boundaries of the sanctuary as defined in the Olympic Coast NMS regulations (15 CFR part 922, subpart O) extend from Koitlah Point, due north to the United States/Canada international boundary, and seaward to the 100-fathom isobath (approximately 180 m in depth). The seaward boundary of the sanctuary follows the 100-fathom isobath south to a point due west of Copalis River, and cuts across the tops of Nitinat, Juan de Fuca, and the Quinault Canyons. The shoreward boundary of the sanctuary is at the mean lower low-water line when adjacent to American Indian lands and state lands, and includes the intertidal areas to the mean higher high-water line when adjacent to federally managed lands. When adjacent to rivers and streams, the sanctuary boundary cuts across the mouths but does not extend up river or up stream. The Olympic Coast NMS includes many types of productive marine habitats including kelp forests, subtidal reefs, rocky and sand intertidal zones, submarine canyons, rocky deep-sea habitat, and plankton-rich upwelling zones. These habitats support the Sanctuary's rich biodiversity which includes 29 species of marine mammals that reside in or migrate through the Sanctuary (Office of National Marine Sanctuaries 2008). Additional information on the Olympic Coast NMS can be found at *https://olympiccoast.noaa.gov.*

Unusual Mortality Events (UMEs)

An 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. Three UMEs with ongoing investigations in the NWTT Study Area that inform our analysis are discussed below. The California sea lion UME in

California is still open, but will be closed soon. The Guadalupe fur seal UME in California and the gray whale UME along the west coast of North America are active and involve ongoing investigations.

California Sea Lion UME

From January 2013 through September 2016, a greater than expected number of young malnourished California sea lions (*Zalophus californianus*) stranded along the coast of California. Sea lions stranding from an early age (6–8 months old) through two years of age (hereafter referred to as juveniles) were consistently underweight without other disease processes detected. Of the 8,122 stranded juveniles attributed to the UME, 93 percent stranded alive (n = 7,587, with 3,418 of these released after rehabilitation) and 7 percent (n = 531) stranded dead. Several factors are hypothesized to have impacted the ability of nursing females and young sea lions to acquire adequate nutrition for successful pup rearing and juvenile growth. In late 2012, decreased anchovy and sardine recruitment (CalCOFI data, July 2013) may have led to nutritionally stressed adult females. Biotoxins were present at various times throughout the UME, and while they were not detected in the stranded juvenile sea lions (whose stomachs were empty at the time of stranding), biotoxins may have impacted the adult females' ability to support their dependent pups by affecting their cognitive function (*e.g.,* navigation, behavior towards their offspring). Therefore, the role of biotoxins in this UME, via its possible impact on adult females' ability to support their pups, is unclear. The proposed primary cause of the UME was malnutrition of sea lion pups and yearlings due to ecological factors. These factors included shifts in distribution, abundance and/or quality of sea lion prey items around the Channel Island rookeries during critical sea lion life history events (nursing by adult females, and transitioning from milk to prey by young sea lions). These prey shifts were most likely driven by unusual oceanographic conditions at the time due to the ''Warm Water Blob'' and El Niño. This investigation will soon be closed. Please refer to: *https://www.fisheries.noaa.gov/national/marine-life-distress/2013-2017-california-sea-lion-unusual-mortality-event-california* for more information on this UME.

Guadalupe Fur Seal UME

Increased strandings of Guadalupe fur seals began along the entire coast of California in January 2015 and were eight times higher than the historical average (approximately 10 seals/yr). Strandings have continued since 2015 and remained well above average through 2019. Numbers by year are as follows: 2015 (98), 2016 (76), 2017 (62), 2018 (45), 2019 (116), 2020 (3 as of March 6, 2020). The total number of Guadalupe fur seals stranding in California from January 1, 2015, through March 6, 2020, in the UME is 400. Additionally, strandings of Guadalupe fur seals became elevated in the spring of 2019 in Washington and Oregon; subsequently, strandings for seals in these two states have been added to the UME starting from January 1, 2019. The current total number of strandings in Washington and Oregon is 94 seals, including 91 in 2019 and 3 in 2020 of 3/6/2020. Strandings are seasonal and generally peak in April through June of each year. The Guadalupe fur seal strandings have been mostly weaned pups and juveniles (1–2 years old) with both live and dead strandings occurring. Current findings from the majority of stranded animals include primary malnutrition with secondary bacterial and parasitic infections. The California portion of this UME was occurring in the same area as the 2013–2016 California sea lion UME. This investigation is ongoing. Please refer to: *https://www.fisheries.noaa.gov/national/marine-life-distress/2015-2019-guadalupe-fur-seal-unusual-mortality-event-california* for more information on this UME.

Gray Whale UME

Since January 1, 2019, elevated gray whale strandings have occurred along the west coast of North America, from Mexico to Canada. As of March 13, 2020, there have been a total of 264 strandings along the coasts of the United States, Canada, and Mexico, with 129 of those strandings occurring along the U.S. coast. Of the strandings on the U.S. coast, 48 have occurred in Alaska, 35 in Washington, 6 in Oregon, and 40 in California. Partial necropsy examinations conducted on a subset of stranded whales have shown evidence of poor to thin body condition. 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. Please refer to: *https://www.fisheries.noaa.gov/national/marine-life-distress/2019-gray-whale-unusual-mortality-event-along-west-coast* for more information on this UME.

Marine Mammal Hearing

Hearing is the most important sensory modality for marine mammals underwater, and exposure to anthropogenic sound can have deleterious effects. To appropriately assess the potential effects of exposure to sound, it is necessary to understand the frequency ranges marine mammals are able to hear. Current data indicate that not all marine mammal species have equal hearing capabilities (*e.g.,* Richardson *et al.,* 1995; Wartzok and Ketten, 1999; Au and Hastings, 2008). To reflect this, Southall *et al.* (2007) recommended that marine mammals be divided into functional hearing groups based on directly measured or estimated hearing ranges on the basis of available behavioral response data, audiograms derived using auditory evoked potential techniques, anatomical modeling, and other data. Note that no direct measurements of hearing ability have been successfully completed for mysticetes (*i.e.,* low-frequency cetaceans). Subsequently, NMFS (2018) described generalized hearing ranges for these marine mammal hearing groups. Generalized hearing ranges were chosen based on the approximately 65 dB threshold from the normalized composite audiograms, with the exception for lower limits for low-frequency cetaceans where the lower bound was deemed to be biologically implausible and the lower bound from Southall *et al.* (2007) retained. The functional groups and the associated frequencies are indicated below (note that these frequency ranges correspond to the range for the composite group, with the entire range not necessarily reflecting the capabilities of every species within that group):

- Low-frequency cetaceans (mysticetes): Generalized hearing is estimated to occur between approximately 7 Hz and 35 kHz;
- Mid-frequency cetaceans (larger toothed whales, beaked whales, and most delphinids): Generalized hearing is estimated to occur between approximately 150 Hz and 160 kHz;
- High-frequency cetaceans (porpoises, river dolphins, and members of the genera Kogia and Cephalorhynchus; including two members of the genus Lagenorhynchus, on the basis of recent echolocation data and genetic data): Generalized hearing is estimated to occur between approximately 275 Hz and 160 kHz;
- Pinnipeds in water; Phocidae (true seals): Generalized hearing is estimated to occur between approximately 50 Hz to 86 kHz; and

• Pinnipeds in water; Otariidae (eared seals): Generalized hearing is estimated to occur between 60 Hz and 39 kHz.

The pinniped functional hearing group was modified from Southall *et al.* (2007) on the basis of data indicating that phocid species have consistently demonstrated an extended frequency range of hearing compared to otariids, especially in the higher frequency range (Hemilä *et al.,* 2006; Kastelein *et al.,* 2009; Reichmuth and Holt, 2013).

For more details concerning these groups and associated frequency ranges, please see NMFS (2018) for a review of the available information.

Potential Effects of Specified Activities on Marine Mammals and Their Habitat

This section includes a discussion of the ways that components of the specified activity may impact marine mammals and their habitat. The *Estimated Take of Marine Mammals* section later in this rule includes a quantitative analysis of the number of instances of take that could occur from these activities. The *Preliminary Analysis and Negligible Impact Determination* section considers the content of this section, the *Estimated Take of Marine Mammals* section, and the *Proposed Mitigation Measures* section to draw conclusions regarding the likely impacts of these activities on the reproductive success or survivorship of individuals and whether those impacts on individuals are likely to adversely affect the species through effects on annual rates of recruitment or survival.

The Navy has requested authorization for the take of marine mammals that may occur incidental to training and testing activities in the NWTT Study Area. The Navy analyzed potential impacts to marine mammals from acoustic and explosive sources and from vessel use in its rulemaking/LOA application. NMFS carefully reviewed the information provided by the Navy along with independently reviewing applicable scientific research and literature and other information to evaluate the potential effects of the Navy's activities on marine mammals, which are presented in this section.

Other potential impacts to marine mammals from training and testing activities in the NWTT Study Area were analyzed in the 2019 NWTT DSEIS/OEIS, in consultation with NMFS as a cooperating agency, and determined to be unlikely to result in marine mammal take. This includes serious injury or mortality from explosives. Therefore, the Navy has not requested authorization for take of marine mammals incidental to other components of their proposed Specified Activities, and we agree that incidental take is unlikely to occur from those components. In this proposed rule, NMFS analyzes the potential effects on marine mammals from the activity components that may cause the take of marine mammals: Exposure to acoustic or explosive stressors including non-impulsive (sonar and other transducers) and impulsive (explosives) stressors and vessel movement.

For the purpose of MMPA incidental take authorizations, NMFS' effects assessments serve four primary purposes: (1) To determine whether the specified activities would have a negligible impact on the affected species or stocks of marine mammals (based on whether it is likely that the activities would adversely affect the species or stocks through effects on annual rates of recruitment or survival); (2) to determine whether the specified activities would have an unmitigable adverse impact on the availability of the species or stocks for subsistence uses; (3) to prescribe the permissible methods of taking (*i.e.,* Level B harassment (behavioral harassment and temporary threshold shift (TTS)), Level A harassment (permanent threshold shift (PTS) and non-auditory injury), serious injury, or mortality), including identification of the number and types of take that could occur by harassment, serious injury, or mortality, and to prescribe other means of effecting the least practicable adverse impact on the species or stocks and their habitat (*i.e.,* mitigation measures); and (4) to prescribe requirements pertaining to monitoring and reporting.

In this section, NMFS provides a description of the ways marine mammals may be generally affected by these activities in the form of mortality, physical trauma, sensory impairment (permanent and temporary threshold shifts and acoustic masking), physiological responses (particular stress responses), behavioral disturbance, or habitat effects. Explosives and vessel strikes, which have the potential to result in incidental take from serious injury and/or mortality, will be discussed in more detail in the *Estimated Take of Marine Mammals* section. The *Estimated Take of Marine Mammals* section also discusses how the potential effects on marine mammals from non-impulsive and impulsive sources relate to the MMPA definitions of Level A Harassment and Level B Harassment, and quantifies those effects that rise to the level of a take. The *Preliminary Analysis and Negligible Impact Determination* section assesses whether the proposed authorized take would have a negligible impact on the affected species and stocks.

Potential Effects of Underwater Sound

Anthropogenic sounds cover a broad range of frequencies and sound levels and can have a range of highly variable impacts on marine life, from none or minor to potentially severe responses, depending on received levels, duration of exposure, behavioral context, and various other factors. The potential effects of underwater sound from active acoustic sources can possibly result in one or more of the following: Temporary or permanent hearing impairment, non-auditory physical or physiological effects, behavioral disturbance, stress, and masking (Richardson *et al.,* 1995; Gordon *et al.,* 2004; Nowacek *et al.,* 2007; Southall *et al.,* 2007; Götz *et al.,* 2009, Southall *et al.,* 2019a). The degree of effect is intrinsically related to the signal characteristics, received level, distance from the source, and duration of the sound exposure. In general, sudden, high level sounds can cause hearing loss, as can longer exposures to lower level sounds. Temporary or permanent loss of hearing can occur after exposure to noise, and occurs almost exclusively for noise within an animal's hearing range. Note that in the following discussion, we refer in many cases to a review article concerning studies of noise-induced hearing loss conducted from 1996–2015 (*i.e.,* Finneran, 2015). For study-specific citations, please see that work. We first describe general manifestations of acoustic effects before providing discussion specific to the Navy's activities.

Richardson *et al.* (1995) described zones of increasing intensity of effect that might be expected to occur, in relation to distance from a source and assuming that the signal is within an animal's hearing range. First is the area within which the acoustic signal would be audible (potentially perceived) to the animal, but not strong enough to elicit any overt behavioral or physiological response. The next zone corresponds with the area where the signal is audible to the animal and of sufficient intensity to elicit behavioral or physiological responsiveness. Third is a zone within which, for signals of high intensity, the received level is sufficient to potentially cause discomfort or tissue damage to auditory systems. Overlaying these zones to a certain extent is the area within which masking (*i.e.,* when a sound interferes with or masks the ability of an animal to detect a signal of interest that is above the absolute hearing threshold) may occur; the

masking zone may be highly variable in size.

We also describe more severe potential effects (*i.e.,* certain non-auditory physical or physiological effects). Potential effects from impulsive sound sources can range in severity from effects such as behavioral disturbance or tactile perception to physical discomfort, slight injury of the internal organs and the auditory system, or mortality (Yelverton *et al.,* 1973). Non-auditory physiological effects or injuries that theoretically might occur in marine mammals exposed to high level underwater sound or as a secondary effect of extreme behavioral reactions (*e.g.,* change in dive profile as a result of an avoidance reaction) caused by exposure to sound include neurological effects, bubble formation, resonance effects, and other types of organ or tissue damage (Cox *et al.,* 2006; Southall *et al.,* 2007; Zimmer and Tyack, 2007; Tal *et al.,* 2015).

Acoustic Sources

Direct Physiological Effects

Non-impulsive sources of sound can cause direct physiological effects including noise-induced loss of hearing sensitivity (or ''threshold shift''), nitrogen decompression, acoustically-induced bubble growth, and injury due to sound-induced acoustic resonance. Only noise-induced hearing loss is anticipated to occur due to the Navy's activities. Acoustically-induced (or mediated) bubble growth and other pressure-related physiological impacts are addressed briefly below, but are not expected to result from the Navy's activities. Separately, an animal's behavioral reaction to an acoustic exposure might lead to physiological effects that might ultimately lead to injury or death, which is discussed later in the *Stranding* subsection.

Hearing Loss—Threshold Shift

Marine mammals exposed to high-intensity sound, or to lower-intensity sound for prolonged periods, can experience hearing threshold shift, which is the loss of hearing sensitivity at certain frequency ranges after cessation of sound (Finneran, 2015). Threshold shift can be permanent (PTS), in which case the loss of hearing sensitivity is not fully recoverable, or temporary (TTS), in which case the animal's hearing threshold would recover over time (Southall *et al.,* 2007). TTS can last from minutes or hours to days (*i.e.,* there is recovery back to baseline/pre-exposure levels), can occur within a specific frequency range (*i.e.,* an animal might only have a temporary loss of hearing sensitivity within a limited frequency band of its auditory range), and can be of varying amounts (*e.g.,* an animal's hearing sensitivity might be reduced by only 6 dB or reduced by 30 dB). While there is no simple functional relationship between TTS and PTS or other auditory injury (*e.g.,* neural degeneration), as TTS increases, the likelihood that additional exposure sound pressure level (SPL) or duration will result in PTS or other injury also increases (see also the 2019 NWTT DSEIS/OEIS for additional discussion). Exposure thresholds for the occurrence of PTS or other auditory injury can therefore be defined based on a specific amount of TTS; that is, although an exposure has been shown to produce only TTS, we assume that any additional exposure may result in some PTS or other injury. The specific upper limit of TTS is based on experimental data showing amounts of TTS that have not resulted in PTS or injury. In other words, we do not need to know the exact functional relationship between TTS and PTS or other injury, we only need to know the upper limit for TTS before some PTS or injury is possible. In severe cases of PTS, there can be total or partial deafness, while in most cases the animal has an impaired ability to hear sounds in specific frequency ranges (Kryter, 1985).

When PTS occurs, there is physical damage to the sound receptors in the ear (*i.e.,* tissue damage), whereas TTS represents primarily tissue fatigue and is reversible (Southall *et al.,* 2007). PTS is permanent (*i.e.,* there is incomplete recovery back to baseline/pre-exposure levels), but also can occur in a specific frequency range and amount as mentioned above for TTS. In addition, other investigators have suggested that TTS is within the normal bounds of physiological variability and tolerance and does not represent physical injury (*e.g.,* Ward, 1997). Therefore, NMFS does not consider TTS to constitute auditory injury.

The following physiological mechanisms are thought to play a role in inducing auditory threshold shift: Effects to sensory hair cells in the inner ear that reduce their sensitivity; modification of the chemical environment within the sensory cells; residual muscular activity in the middle ear; displacement of certain inner ear membranes; increased blood flow; and post-stimulatory reduction in both efferent and sensory neural output (Southall *et al.,* 2007). The amplitude, duration, frequency, temporal pattern, and energy distribution of sound exposure all can affect the amount of associated threshold shift and the frequency range in which it occurs. Generally, the amount of threshold shift, and the time needed to recover from the effect, increase as amplitude and duration of sound exposure increases. Human non-impulsive noise exposure guidelines are based on the assumption that exposures of equal energy (the same sound exposure level (SEL)) produce equal amounts of hearing impairment regardless of how the sound energy is distributed in time (NIOSH, 1998). Previous marine mammal TTS studies have also generally supported this equal energy relationship (Southall *et al.,* 2007). However, some more recent studies concluded that for all noise exposure situations the equal energy relationship may not be the best indicator to predict TTS onset levels (Mooney *et al.,* 2009a and 2009b; Kastak *et al.,* 2007). These studies highlight the inherent complexity of predicting TTS onset in marine mammals, as well as the importance of considering exposure duration when assessing potential impacts. Generally, with sound exposures of equal energy, those that were quieter (lower SPL) with longer duration were found to induce TTS onset at lower levels than those of louder (higher SPL) and shorter duration. Less threshold shift will occur from intermittent sounds than from a continuous exposure with the same energy (some recovery can occur between intermittent exposures) (Kryter *et al.,* 1966; Ward, 1997; Mooney *et al.,* 2009a, 2009b; Finneran *et al.,* 2010). For example, one short but loud (higher SPL) sound exposure may induce the same impairment as one longer but softer (lower SPL) sound, which in turn may cause more impairment than a series of several intermittent softer sounds with the same total energy (Ward, 1997). Additionally, though TTS is temporary, very prolonged or repeated exposure to sound strong enough to elicit TTS, or shorter-term exposure to sound levels well above the TTS threshold can cause PTS, at least in terrestrial mammals (Kryter, 1985; Lonsbury-Martin *et al.,* 1987).

PTS is considered auditory injury (Southall *et al.,* 2007). Irreparable damage to the inner or outer cochlear hair cells may cause PTS; however, other mechanisms are also involved, such as exceeding the elastic limits of certain tissues and membranes in the middle and inner ears and resultant changes in the chemical composition of the inner ear fluids (Southall *et al.,* 2007).

The NMFS Acoustic Technical Guidance (NMFS, 2018), which was used in the assessment of effects for this rule, 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. More recently, Southall *et al.* (2019a) evaluated Southall *et al.* (2007) and used updated scientific information to propose revised noise exposure criteria to predict onset of auditory effects in marine mammals (*i.e.,* PTS and TTS onset). Southall *et al.* (2019a) note that the quantitative processes described and the resulting exposure criteria (*i.e.,* thresholds and auditory weighting functions) are largely identical to those in Finneran (2016) and NMFS (2018). They only differ in that the Southall *et al.* (2019a) exposure criteria are more broadly applicable as they include all marine mammal species (rather than only those under NMFS jurisdiction) for all noise exposures (both in air and underwater for amphibious species) and, while the hearing group compositions are identical, they renamed the hearing groups.

Many studies have examined noise-induced hearing loss in marine mammals (see Finneran (2015) and Southall *et al.* (2019a) for summaries), however for cetaceans, published data on the onset of TTS are limited to the captive bottlenose dolphin, beluga, harbor porpoise, and Yangtze finless porpoise, and for pinnipeds in water, measurements of TTS are limited to harbor seals, elephant seals, and California sea lions. These studies examine hearing thresholds measured in marine mammals before and after exposure to intense sounds. The difference between the pre-exposure and post-exposure thresholds can then be used to determine the amount of threshold shift at various post-exposure times. NMFS has reviewed the available studies, which are summarized below (see also the 2019 NWTT DSEIS/OEIS which includes additional discussion on TTS studies related to sonar and other transducers).

- The method used to test hearing may affect the resulting amount of measured TTS, with neurophysiological measures producing larger amounts of TTS compared to psychophysical measures (Finneran *et al.,* 2007; Finneran, 2015).
- The amount of TTS varies with the hearing test frequency. As the exposure SPL increases, the frequency at which the maximum TTS occurs also increases (Kastelein *et al.,* 2014b). For high-level exposures, the maximum TTS typically occurs one-half to one octave above the exposure frequency (Finneran *et al.,* 2007; Mooney *et al.,* 2009a; Nachtigall *et al.,* 2004; Popov *et al.,* 2011; Popov *et al.,* 2013; Schlundt *et al.,* 2000). The overall spread of TTS from tonal exposures can therefore extend over a large frequency range (*i.e.,* narrowband exposures can produce broadband (greater than one octave) TTS).
- The amount of TTS increases with exposure SPL and duration and is correlated with SEL, especially if the range of exposure durations is relatively small (Kastak *et al.,* 2007; Kastelein *et al.,* 2014b; Popov *et al.,* 2014). As the exposure duration increases, however, the relationship between TTS and SEL begins to break down. Specifically, duration has a more significant effect on TTS than would be predicted on the basis of SEL alone (Finneran *et al.,* 2010a; Kastak *et al.,* 2005; Mooney *et al.,* 2009a). This means if two exposures have the same SEL but different durations, the exposure with the longer duration (thus lower SPL) will tend to produce more TTS than the exposure with the higher SPL and shorter duration. In most acoustic impact assessments, the scenarios of interest involve shorter duration exposures than the marine mammal experimental data from which impact thresholds are derived; therefore, use of SEL tends to over-estimate the amount of TTS. Despite this, SEL continues to be used in many situations because it is relatively simple, more accurate than SPL alone, and lends itself easily to scenarios involving multiple exposures with different SPL.
- Gradual increases of TTS may not be directly observable with increasing exposure levels, before the onset of PTS (Reichmuth *et al.,* 2019). Similarly, PTS can occur without measurable behavioral modifications (Reichmuth *et al.,* 2019).
- The amount of TTS depends on the exposure frequency. Sounds at low frequencies, well below the region of best sensitivity, are less hazardous than those at higher frequencies, near the region of best sensitivity (Finneran and Schlundt, 2013). The onset of TTS—defined as the exposure level necessary to produce 6 dB of TTS (*i.e.,* clearly above the typical variation in threshold measurements)—also varies with exposure frequency. At low frequencies, onset-TTS exposure levels are higher compared to those in the region of best sensitivity.
- TTS can accumulate across multiple exposures, but the resulting TTS will be less than the TTS from a single, continuous exposure with the same SEL (Finneran *et al.,* 2010a; Kastelein *et al.,* 2014b; Kastelein *et al.,* 2015b; Mooney *et al.,* 2009b). This means that TTS predictions based on the total, cumulative SEL will overestimate the amount of TTS from intermittent exposures such as sonars and impulsive sources.
- The amount of observed TTS tends to decrease with increasing time following the exposure; however, the relationship is not monotonic (*i.e.,* increasing exposure does not always increase TTS). The time required for complete recovery of hearing depends on the magnitude of the initial shift; for relatively small shifts recovery may be complete in a few minutes, while large shifts (*e.g.,* approximately 40 dB) may require several days for recovery. Under many circumstances TTS recovers linearly with the logarithm of time (Finneran *et al.,* 2010a, 2010b; Finneran and Schlundt, 2013; Kastelein *et al.,* 2012a; Kastelein *et al.,* 2012b; Kastelein *et al.,* 2013a; Kastelein *et al.,* 2014b; Kastelein *et al.,* 2014c; Popov *et al.,* 2011; Popov *et al.,* 2013; Popov *et al.,* 2014). This means that for each doubling of recovery time, the amount of TTS will decrease by the same amount (*e.g.,* 6 dB recovery per doubling of time).

Nachtigall *et al.* (2018) and Finneran (2018) describe the measurements of hearing sensitivity of multiple odontocete species (bottlenose dolphin, harbor porpoise, beluga, and false killer whale) when a relatively loud sound was preceded by a warning sound. These captive animals were shown to reduce hearing sensitivity when warned of an impending intense sound. Based on these experimental observations of captive animals, the authors suggest that wild animals may dampen their hearing during prolonged exposures or if conditioned to anticipate intense sounds. Finneran recommends further investigation of the mechanisms of hearing sensitivity reduction in order to understand the implications for interpretation of existing TTS data obtained from captive animals, notably for considering TTS due to short duration, unpredictable exposures.

Marine mammal hearing plays a critical role in communication with conspecifics and in interpretation of environmental cues for purposes such as predator avoidance and prey capture. Depending on the degree (elevation of threshold in dB), duration (*i.e.,* recovery time), and frequency range of TTS, and the context in which it is experienced, TTS can have effects on marine mammals ranging from discountable to serious similar to those discussed in auditory masking, below. For example, a marine mammal may be able to readily compensate for a brief, relatively small amount of TTS in a non-critical frequency range that takes place during

a time where ambient noise is lower and there are not as many competing sounds present. Alternatively, a larger amount and longer duration of TTS sustained during a time when communication is critical for successful mother/calf interactions could have more serious impacts if it were in the same frequency band as the necessary vocalizations and of a severity that impeded communication. The fact that animals exposed to high levels of sound that would be expected to result in this physiological response would also be expected to have behavioral responses of a comparatively more severe or sustained nature is potentially more significant than simple existence of a TTS. However, it is important to note that TTS could occur due to longer exposures to sound at lower levels so that a behavioral response may not be elicited.

Depending on the degree and frequency range, the effects of PTS on an animal could also range in severity, although it is considered generally more serious than TTS because it is a permanent condition. Of note, reduced hearing sensitivity as a simple function of aging has been observed in marine mammals, as well as humans and other taxa (Southall *et al.,* 2007), so we can infer that strategies exist for coping with this condition to some degree, though likely not without some cost to the animal.

Acoustically-Induced Bubble Formation Due to Sonars and Other Pressure-Related Impacts

One theoretical cause of injury to marine mammals is rectified diffusion (Crum and Mao, 1996), the process of increasing the size of a bubble by exposing it to a sound field. This process could be facilitated if the environment in which the ensonified bubbles exist is supersaturated with gas. Repetitive diving by marine mammals can cause the blood and some tissues to accumulate gas to a greater degree than is supported by the surrounding environmental pressure (Ridgway and Howard, 1979). The deeper and longer dives of some marine mammals (for example, beaked whales) are theoretically predicted to induce greater supersaturation (Houser *et al.,* 2001b). If rectified diffusion were possible in marine mammals exposed to high-level sound, conditions of tissue supersaturation could theoretically speed the rate and increase the size of bubble growth. Subsequent effects due to tissue trauma and emboli would presumably mirror those observed in humans suffering from decompression sickness.

It is unlikely that the short duration (in combination with the source levels) of sonar pings would be long enough to drive bubble growth to any substantial size, if such a phenomenon occurs. However, an alternative but related hypothesis has also been suggested: Stable bubbles could be destabilized by high-level sound exposures such that bubble growth then occurs through static diffusion of gas out of the tissues. In such a scenario the marine mammal would need to be in a gas-supersaturated state for a long enough period of time for bubbles to become of a problematic size. Recent research with *ex vivo* supersaturated bovine tissues suggested that, for a 37 kHz signal, a sound exposure of approximately 215 dB referenced to (re) 1 μPa would be required before microbubbles became destabilized and grew (Crum *et al.,* 2005). Assuming spherical spreading loss and a nominal sonar source level of 235 dB re: 1 μPa at 1 m, a whale would need to be within 10 m (33 ft) of the sonar dome to be exposed to such sound levels. Furthermore, tissues in the study were supersaturated by exposing them to pressures of 400–700 kilopascals for periods of hours and then releasing them to ambient pressures. Assuming the equilibration of gases with the tissues occurred when the tissues were exposed to the high pressures, levels of supersaturation in the tissues could have been as high as 400–700 percent. These levels of tissue supersaturation are substantially higher than model predictions for marine mammals (Houser *et al.,* 2001; Saunders *et al.,* 2008). It is improbable that this mechanism is responsible for stranding events or traumas associated with beaked whale strandings because both the degree of supersaturation and exposure levels observed to cause microbubble destabilization are unlikely to occur, either alone or in concert.

Yet another hypothesis (decompression sickness) has speculated that rapid ascent to the surface following exposure to a startling sound might produce tissue gas saturation sufficient for the evolution of nitrogen bubbles (Jepson *et al.,* 2003; Fernandez *et al.,* 2005; Fernández *et al.,* 2012). In this scenario, the rate of ascent would need to be sufficiently rapid to compromise behavioral or physiological protections against nitrogen bubble formation. Alternatively, Tyack *et al.* (2006) studied the deep diving behavior of beaked whales and concluded that: ''Using current models of breath-hold diving, we infer that their natural diving behavior is inconsistent with known problems of acute nitrogen supersaturation and embolism.'' Collectively, these hypotheses can be referred to as ''hypotheses of acoustically mediated bubble growth.''

Although theoretical predictions suggest the possibility for acoustically mediated bubble growth, there is considerable disagreement among scientists as to its likelihood (Piantadosi and Thalmann, 2004; Evans and Miller, 2003; Cox *et al.,* 2006; Rommel *et al.,* 2006). Crum and Mao (1996) hypothesized that received levels would have to exceed 190 dB in order for there to be the possibility of significant bubble growth due to supersaturation of gases in the blood (*i.e.,* rectified diffusion). Work conducted by Crum *et al.* (2005) demonstrated the possibility of rectified diffusion for short duration signals, but at SELs and tissue saturation levels that are highly improbable to occur in diving marine mammals. To date, energy levels (ELs) predicted to cause in vivo bubble formation within diving cetaceans have not been evaluated (NOAA, 2002b). Jepson *et al.* (2003, 2005) and Fernandez *et al.* (2004, 2005, 2012) concluded that in vivo bubble formation, which may be exacerbated by deep, long-duration, repetitive dives may explain why beaked whales appear to be relatively vulnerable to MF/HF sonar exposures. It has also been argued that traumas from some beaked whale strandings are consistent with gas emboli and bubble-induced tissue separations (Jepson *et al.,* 2003); however, there is no conclusive evidence of this (Rommel *et al.,* 2006). Based on examination of sonar-associated strandings, Bernaldo de Quiros *et al.* (2019) list diagnostic features, the presence of all of which suggest gas and fat embolic syndrome for beaked whales stranded in association with sonar exposure.

As described in additional detail in the Nitrogen Decompression subsection of the 2019 NWTT DSEIS/OEIS, marine mammals generally are thought to deal with nitrogen loads in their blood and other tissues, caused by gas exchange from the lungs under conditions of high ambient pressure during diving, through anatomical, behavioral, and physiological adaptations (Hooker *et al.,* 2012). Although not a direct injury, variations in marine mammal diving behavior or avoidance responses have been hypothesized to result in nitrogen off-gassing in super-saturated tissues, possibly to the point of deleterious vascular and tissue bubble formation (Hooker *et al.,* 2012; Jepson *et al.,* 2003; Saunders *et al.,* 2008) with resulting symptoms similar to decompression sickness, however the process is still not well understood.

In 2009, Hooker *et al.* tested two mathematical models to predict blood and tissue tension N2 (P_{N2}) using field data from three beaked whale species: Northern bottlenose whales, Cuvier's beaked whales, and Blainville's beaked whales. The researchers aimed to determine if physiology (body mass, diving lung volume, and dive response) or dive behavior (dive depth and duration, changes in ascent rate, and diel behavior) would lead to differences in P_{N2} levels and thereby decompression sickness risk between species. In their study, they compared results for previously published time depth recorder data (Hooker and Baird, 1999; Baird *et al.,* 2006, 2008) from Cuvier's beaked whale, Blainville's beaked whale, and northern bottlenose whale. They reported that diving lung volume and extent of the dive response had a large effect on end-dive P_{N2}. Also, results showed that dive profiles had a larger influence on end-dive P_{N2} than body mass differences between species. Despite diel changes (*i.e.,* variation that occurs regularly every day or most days) in dive behavior, P_{N2} levels showed no consistent trend. Model output suggested that all three species live with tissue P_{N2} levels that would cause a significant proportion of decompression sickness cases in terrestrial mammals. The authors concluded that the dive behavior of Cuvier's beaked whale was different from both Blainville's beaked whale and northern bottlenose whale, and resulted in higher predicted tissue and blood N2 levels (Hooker *et al.,* 2009). They also suggested that the prevalence of Cuvier's beaked whales stranding after naval sonar exercises could be explained by either a higher abundance of this species in the affected areas or by possible species differences in behavior and/or physiology related to MF active sonar (Hooker *et al.,* 2009).

Bernaldo de Quiros *et al.* (2012) showed that, among stranded whales, deep diving species of whales had higher abundances of gas bubbles compared to shallow diving species. Kvadsheim *et al.* (2012) estimated blood and tissue P_{N2} levels in species representing shallow, intermediate, and deep diving cetaceans following behavioral responses to sonar and their comparisons found that deep diving species had higher end-dive blood and tissue N_2 levels, indicating a higher risk of developing gas bubble emboli compared with shallow diving species. Fahlmann *et al.* (2014) evaluated dive data recorded from sperm, killer, long-finned pilot, Blainville's beaked and Cuvier's beaked whales before and during exposure to low-frequency (1–2 kHz), as defined by the authors, and mid-frequency (2–7 kHz) active sonar in an attempt to determine if either differences in dive behavior or physiological responses to sonar are plausible risk factors for bubble formation. The authors suggested that CO_2 may initiate bubble formation and growth, while elevated levels of N_2 may be important for continued bubble growth. The authors also suggest that if CO_2 plays an important role in bubble formation, a cetacean escaping a sound source may experience increased metabolic rate, CO_2 production, and alteration in cardiac output, which could increase risk of gas bubble emboli. However, as discussed in Kvadsheim *et al.* (2012), the actual observed behavioral responses to sonar from the species in their study (sperm, killer, long-finned pilot, Blainville's beaked, and Cuvier's beaked whales) did not imply any significantly increased risk of decompression sickness due to high levels of N_2. Therefore, further information is needed to understand the relationship between exposure to stimuli, behavioral response (discussed in more detail below), elevated N_2 levels, and gas bubble emboli in marine mammals. The hypotheses for gas bubble formation related to beaked whale strandings is that beaked whales potentially have strong avoidance responses to MF active sonars because they sound similar to their main predator, the killer whale (Cox *et al.,* 2006; Southall *et al.,* 2007; Zimmer and Tyack, 2007; Baird *et al.,* 2008; Hooker *et al.,* 2009). Further investigation is needed to assess the potential validity of these hypotheses.

To summarize, while there are several hypotheses, there is little data directly connecting intense, anthropogenic underwater sounds with non-auditory physical effects in marine mammals. The available data do not support identification of a specific exposure level above which non-auditory effects can be expected (Southall *et al.,* 2007) or any meaningful quantitative predictions of the numbers (if any) of marine mammals that might be affected in these ways. In addition, such effects, if they occur at all, would be expected to be limited to situations where marine mammals were exposed to high powered sounds at very close range over a prolonged period of time, which is not expected to occur based on the speed of the vessels operating sonar in combination with the speed and behavior of marine mammals in the vicinity of sonar.

Injury Due to Sonar-Induced Acoustic Resonance

An object exposed to its resonant frequency will tend to amplify its vibration at that frequency, a phenomenon called acoustic resonance. Acoustic resonance has been proposed as a potential mechanism by which a sonar or sources with similar operating characteristics could damage tissues of marine mammals. In 2002, NMFS convened a panel of government and private scientists to investigate the potential for acoustic resonance to occur in marine mammals (National Oceanic and Atmospheric Administration, 2002). They modeled and evaluated the likelihood that Navy mid-frequency sonar (2–10 kHz) caused resonance effects in beaked whales that eventually led to their stranding. The workshop participants concluded that resonance in air-filled structures was not likely to have played a primary role in the Bahamas stranding in 2000. They listed several reasons supporting this finding including (among others): Tissue displacements at resonance are estimated to be too small to cause tissue damage; tissue-lined air spaces most susceptible to resonance are too large in marine mammals to have resonant frequencies in the ranges used by mid-frequency or low-frequency sonar; lung resonant frequencies increase with depth, and tissue displacements decrease with depth so if resonance is more likely to be caused at depth it is also less likely to have an affect there; and lung tissue damage has not been observed in any mass, multi-species stranding of beaked whales. The frequency at which resonance was predicted to occur in the animals' lungs was 50 Hz, well below the frequencies used by the mid-frequency sonar systems associated with the Bahamas event. The workshop participants focused on the March 2000 stranding of beaked whales in the Bahamas as high-quality data were available, but the workshop report notes that the results apply to other sonar-related stranding events. For the reasons given by the 2002 workshop participants, we do not anticipate injury due to sonar-induced acoustic resonance from the Navy's proposed activities.

Physiological Stress

There is growing interest in monitoring and assessing the impacts of stress responses to sound in marine animals. Classic stress responses begin when an animal's central nervous system perceives a potential threat to its homeostasis. That perception triggers stress responses regardless of whether a

stimulus actually threatens the animal; the mere perception of a threat is sufficient to trigger a stress response (Moberg, 2000; Sapolsky *et al.,* 2005; Seyle, 1950). Once an animal's central nervous system perceives a threat, it mounts a biological response or defense that consists of a combination of the four general biological defense responses: Behavioral responses, autonomic nervous system responses, neuroendocrine responses, or immune responses.

According to Moberg (2000), in the case of many stressors, an animal's first and sometimes most economical (in terms of biotic costs) response is behavioral avoidance of the potential stressor or avoidance of continued exposure to a stressor. An animal's second line of defense to stressors involves the sympathetic part of the autonomic nervous system and the classical ''fight or flight'' response which includes the cardiovascular system, the gastrointestinal system, the exocrine glands, and the adrenal medulla to produce changes in heart rate, blood pressure, and gastrointestinal activity that humans commonly associate with ''stress.'' These responses have a relatively short duration and may or may not have significant long-term effect on an animal's welfare.

An animal's third line of defense to stressors involves its neuroendocrine systems or sympathetic nervous systems; the system that has received the most study has been the hypothalmus-pituitary-adrenal system (also known as the HPA axis in mammals or the hypothalamus-pituitary-interrenal axis in fish and some reptiles). Unlike stress responses associated with the autonomic nervous system, virtually all neuro-endocrine functions that are affected by stress—including immune competence, reproduction, metabolism, and behavior—are regulated by pituitary hormones. Stress-induced changes in the secretion of pituitary hormones have been implicated in failed reproduction (Moberg, 1987; Rivier and Rivest, 1991), altered metabolism (Elasser *et al.,* 2000), reduced immune competence (Blecha, 2000), and behavioral disturbance (Moberg, 1987; Blecha, 2000). Increases in the circulation of glucocorticosteroids (cortisol, corticosterone, and aldosterone in marine mammals; see Romano *et al.,* 2004) have been equated with stress for many years.

The primary distinction between stress (which is adaptive and does not normally place an animal at risk) and distress is the biotic cost of the response. During a stress response, an animal uses glycogen stores that can be quickly replenished once the stress is alleviated. In such circumstances, the cost of the stress response would not pose serious fitness consequences. However, when an animal does not have sufficient energy reserves to satisfy the energetic costs of a stress response, energy resources must be diverted from other biotic functions, which impairs those functions that experience the diversion. For example, when a stress response diverts energy away from growth in young animals, those animals may experience stunted growth. When a stress response diverts energy from a fetus, an animal's reproductive success and its fitness will suffer. In these cases, the animals will have entered a pre-pathological or pathological state which is called ''distress'' (Seyle, 1950) or ''allostatic loading'' (McEwen and Wingfield, 2003). This pathological state of distress will last until the animal replenishes its energetic reserves sufficiently to restore normal function. Note that these examples involved a long-term (days or weeks) stress response exposure to stimuli.

Relationships between these physiological mechanisms, animal behavior, and the costs of stress responses are well-studied through controlled experiments in both laboratory and free-ranging animals (for examples see, Holberton *et al.,* 1996; Hood *et al.,* 1998; Jessop *et al.,* 2003; Krausman *et al.,* 2004; Lankford *et al.,* 2005; Reneerkens *et al.,* 2002; Thompson and Hamer, 2000). However, it should be noted (and as is described in additional detail in the 2019 NWTT DSEIS/OEIS) that our understanding of the functions of various stress hormones (for example, cortisol), is based largely upon observations of the stress response in terrestrial mammals. Atkinson *et al.,* 2015 note that the endocrine response of marine mammals to stress may not be the same as that of terrestrial mammals because of the selective pressures marine mammals faced during their evolution in an ocean environment. For example, due to the necessity of breath-holding while diving and foraging at depth, the physiological role of epinephrine and norepinephrine (the catecholamines) in marine mammals might be different than in other mammals.

Marine mammals naturally experience stressors within their environment and as part of their life histories. Changing weather and ocean conditions, exposure to disease and naturally occurring toxins, lack of prey availability, and interactions with predators all contribute to the stress a marine mammal experiences (Atkinson *et al.,* 2015). Breeding cycles, periods of fasting, and social interactions with members of the same species are also stressors, although they are natural components of an animal's life history. Anthropogenic activities have the potential to provide additional stressors beyond those that occur naturally (Fair *et al.,* 2014; Meissner *et al.,* 2015; Rolland *et al.,* 2012). Anthropogenic stressors potentially include such things as fishery interactions, pollution, tourism, and ocean noise.

Acoustically induced stress in marine mammals is not well understood. There are ongoing efforts to improve our understanding of how stressors impact marine mammal populations (*e.g.,* King *et al.,* 2015; New *et al.,* 2013a; New *et al.,* 2013b; Pirotta *et al.,* 2015a), however little data exist on the consequences of sound-induced stress response (acute or chronic). Factors potentially affecting a marine mammal's response to a stressor include the individual's life history stage, sex, age, reproductive status, overall physiological and behavioral plasticity, and whether they are naïve or experienced with the sound (*e.g.,* prior experience with a stressor may result in a reduced response due to habituation (Finneran and Branstetter, 2013; St. Aubin and Dierauf, 2001a)). Stress responses due to exposure to anthropogenic sounds or other stressors and their effects on marine mammals have been reviewed (Fair and Becker, 2000; Romano *et al.,* 2002b) and, more rarely, studied in wild populations (*e.g.,* Romano *et al.,* 2002a). For example, Rolland *et al.* (2012) found that noise reduction from reduced ship traffic in the Bay of Fundy was associated with decreased stress in North Atlantic right whales. These and other studies lead to a reasonable expectation that some marine mammals will experience physiological stress responses upon exposure to acoustic stressors and that it is possible that some of these would be classified as ''distress.'' In addition, any animal experiencing TTS would likely also experience stress responses (NRC, 2003).

Other research has also investigated the impact from vessels (both whale-watching and general vessel traffic noise), and demonstrated impacts do occur (Bain, 2002; Erbe, 2002; Lusseau, 2006; Williams *et al.,* 2006; Williams *et al.,* 2009; Noren *et al.,* 2009; Read *et al.,* 2014; Rolland *et al.,* 2012; Skarke *et al.,* 2014; Williams *et al.,* 2013; Williams *et al.,* 2014a; Williams *et al.,* 2014b; Pirotta *et al.,* 2015). This body of research has generally investigated impacts associated with the presence of chronic stressors, which differ significantly from the proposed Navy training and testing

vessel activities in the NWTT Study Area. For example, in an analysis of energy costs to killer whales, Williams *et al.* (2009) suggested that whale-watching in Canada's Johnstone Strait resulted in lost feeding opportunities due to vessel disturbance, which could carry higher costs than other measures of behavioral change might suggest. Ayres *et al.* (2012) reported on research in the Salish Sea (Washington state) involving the measurement of southern resident killer whale fecal hormones to assess two potential threats to the species recovery: Lack of prey (salmon) and impacts to behavior from vessel traffic. Ayres *et al.* (2012) suggested that the lack of prey overshadowed any population-level physiological impacts on southern resident killer whales from vessel traffic. In a conceptual model developed by the Population Consequences of Acoustic Disturbance (PCAD) working group, serum hormones were identified as possible indicators of behavioral effects that are translated into altered rates of reproduction and mortality (NRC, 2005). The Office of Naval Research hosted a workshop (Effects of Stress on Marine Mammals Exposed to Sound) in 2009 that focused on this topic (ONR, 2009). Ultimately, the PCAD working group issued a report (Cochrem, 2014) that summarized information compiled from 239 papers or book chapters relating to stress in marine mammals and concluded that stress responses can last from minutes to hours and, while we typically focus on adverse stress responses, stress response is part of a natural process to help animals adjust to changes in their environment and can also be either neutral or beneficial.

Most sound-induced stress response studies in marine mammals have focused on acute responses to sound either by measuring catecholamines or by measuring heart rate as an assumed proxy for an acute stress response. Belugas demonstrated no catecholamine response to the playback of oil drilling sounds (Thomas *et al.,* 1990) but showed a small but statistically significant increase in catecholamines following exposure to impulsive sounds produced from a seismic water gun (Romano *et al.,* 2004). A bottlenose dolphin exposed to the same seismic water gun signals did not demonstrate a catecholamine response, but did demonstrate a statistically significant elevation in aldosterone (Romano *et al.,* 2004), albeit the increase was within the normal daily variation observed in this species (St. Aubin *et al.,* 1996). Increases in heart rate were observed in bottlenose dolphins to which known calls of other dolphins were played, although no increase in heart rate was observed when background tank noise was played back (Miksis *et al.,* 2001). Unfortunately, in this study, it cannot be determined whether the increase in heart rate was due to stress or an anticipation of being reunited with the dolphin to which the vocalization belonged. Similarly, a young beluga's heart rate was observed to increase during exposure to noise, with increases dependent upon the frequency band of noise and duration of exposure, and with a sharp decrease to normal or below normal levels upon cessation of the exposure (Lyamin *et al.,* 2011). Spectral analysis of heart rate variability corroborated direct measures of heart rate (Bakhchina *et al.,* 2017). This response might have been in part due to the conditions during testing, the young age of the animal, and the novelty of the exposure; a year later the exposure was repeated at a slightly higher received level and there was no heart rate response, indicating the beluga whale may have acclimated to the noise exposure. Kvadsheim *et al.* (2010) measured the heart rate of captive hooded seals during exposure to sonar signals and found an increase in the heart rate of the seals during exposure periods versus control periods when the animals were at the surface. When the animals dove, the normal dive-related bradycardia (decrease in heart rate) was not impacted by the sonar exposure. Similarly, Thompson *et al.* (1998) observed a rapid but short-lived decrease in heart rates in harbor and grey seals exposed to seismic air guns (cited in Gordon *et al.,* 2003). Williams *et al.* (2017) recently monitored the heart rates of narwhals released from capture and found that a profound dive bradycardia persisted, even though exercise effort increased dramatically as part of their escape response following release. Thus, although some limited evidence suggests that tachycardia might occur as part of the acute stress response of animals that are at the surface, the dive bradycardia persists during diving and might be enhanced in response to an acute stressor.

Despite the limited amount of data available on sound-induced stress responses for marine mammals exposed to anthropogenic sounds, studies of other marine animals and terrestrial animals would also lead us to expect that some marine mammals experience physiological stress responses and, perhaps, physiological responses that would be classified as ''distress'' upon exposure to high-frequency, mid-frequency, and low-frequency sounds. For example, Jansen (1998) reported on the relationship between acoustic exposures and physiological responses that are indicative of stress responses in humans (*e.g.,* elevated respiration and increased heart rates). Jones (1998) reported on reductions in human performance when faced with acute, repetitive exposures to acoustic disturbance. Trimper *et al.* (1998) reported on the physiological stress responses of osprey to low-level aircraft noise while Krausman *et al.* (2004) reported on the auditory and physiological stress responses of endangered Sonoran pronghorn to military overflights. However, take due to aircraft noise is not anticipated as a result of the Navy's activities. Smith *et al.* (2004a, 2004b) identified noise-induced physiological transient stress responses in hearing-specialist fish (*i.e.,* goldfish) that accompanied short- and long-term hearing losses. Welch and Welch (1970) reported physiological and behavioral stress responses that accompanied damage to the inner ears of fish and several mammals.

Auditory Masking

Sound can disrupt behavior through masking, or interfering with, an animal's ability to detect, recognize, or discriminate between acoustic signals of interest (*e.g.,* those used for intraspecific communication and social interactions, prey detection, predator avoidance, or navigation) (Richardson *et al.,* 1995; Erbe and Farmer, 2000; Tyack, 2000; Erbe *et al.,* 2016). Masking occurs when the receipt of a sound is interfered with by another coincident sound at similar frequencies and at similar or higher intensity, and may occur whether the sound is natural (*e.g.,* snapping shrimp, wind, waves, precipitation) or anthropogenic (*e.g.,* shipping, sonar, seismic exploration) in origin. As described in detail in the 2019 NWTT DSEIS/OEIS, the ability of a noise source to mask biologically important sounds depends on the characteristics of both the noise source and the signal of interest (*e.g.,* signal-to-noise ratio, temporal variability, direction), in relation to each other and to an animal's hearing abilities (*e.g.,* sensitivity, frequency range, critical ratios, frequency discrimination, directional discrimination, age, or TTS hearing loss), and existing ambient noise and propagation conditions. Masking these acoustic signals can disturb the behavior of individual animals, groups of animals, or entire populations. Masking can lead to behavioral changes including vocal changes (*e.g.,* Lombard effect, increasing amplitude, or changing frequency), cessation of

foraging, and leaving an area, to both signalers and receivers, in an attempt to compensate for noise levels (Erbe *et al.,* 2016).

In humans, significant masking of tonal signals occurs as a result of exposure to noise in a narrow band of similar frequencies. As the sound level increases, though, the detection of frequencies above those of the masking stimulus decreases also. This principle is expected to apply to marine mammals as well because of common biomechanical cochlear properties across taxa.

Under certain circumstances, marine mammals experiencing significant masking could also be impaired from maximizing their performance fitness in survival and reproduction. Therefore, when the coincident (masking) sound is man-made, it may be considered harassment when disrupting or altering critical behaviors. It is important to distinguish TTS and PTS, which persist after the sound exposure, from masking, which only occurs during the sound exposure. Because masking (without resulting in threshold shift) is not associated with abnormal physiological function, it is not considered a physiological effect, but rather a potential behavioral effect.

Richardson *et al.* (1995b) argued that the maximum radius of influence of an industrial noise (including broadband low-frequency sound transmission) on a marine mammal is the distance from the source to the point at which the noise can barely be heard. This range is determined by either the hearing sensitivity (including critical ratios, or the lowest signal-to-noise ratio in which animals can detect a signal, Finneran and Branstetter, 2013; Johnson *et al.,* 1989; Southall *et al.,* 2000) of the animal or the background noise level present. Industrial masking is most likely to affect some species' ability to detect communication calls and natural sounds (*i.e.,* surf noise, prey noise, *etc.;* Richardson *et al.,* 1995).

The frequency range of the potentially masking sound is important in determining any potential behavioral impacts. For example, low-frequency signals may have less effect on high-frequency echolocation sounds produced by odontocetes but are more likely to affect detection of mysticete communication calls and other potentially important natural sounds such as those produced by surf and some prey species. The masking of communication signals by anthropogenic noise may be considered as a reduction in the communication space of animals (*e.g.,* Clark *et al.,* 2009; Matthews *et al.,* 2016) and may result in energetic or other costs as animals change their vocalization behavior (*e.g.,* Miller *et al.,* 2000; Foote *et al.,* 2004; Parks *et al.,* 2007; Di Iorio and Clark, 2009; Holt *et al.,* 2009). Masking can be reduced in situations where the signal and noise come from different directions (Richardson *et al.,* 1995), through amplitude modulation of the signal, or through other compensatory behaviors (Houser and Moore, 2014). Masking can be tested directly in captive species (*e.g.,* Erbe, 2008), but in wild populations it must be either modeled or inferred from evidence of masking compensation. There are few studies addressing real-world masking sounds likely to be experienced by marine mammals in the wild (*e.g.,* Branstetter *et al.,* 2013).

The echolocation calls of toothed whales are subject to masking by high-frequency sound. Human data indicate low-frequency sound can mask high-frequency sounds (*i.e.,* upward masking). Studies on captive odontocetes by Au *et al.* (1974, 1985, 1993) indicate that some species may use various processes to reduce masking effects (*e.g.,* adjustments in echolocation call intensity or frequency as a function of background noise conditions). There is also evidence that the directional hearing abilities of odontocetes are useful in reducing masking at the high-frequencies these cetaceans use to echolocate, but not at the low-to-moderate frequencies they use to communicate (Zaitseva *et al.,* 1980). A study by Nachtigall and Supin (2008) showed that false killer whales adjust their hearing to compensate for ambient sounds and the intensity of returning echolocation signals.

Impacts on signal detection, measured by masked detection thresholds, are not the only important factors to address when considering the potential effects of masking. As marine mammals use sound to recognize conspecifics, prey, predators, or other biologically significant sources (Branstetter *et al.,* 2016), it is also important to understand the impacts of masked recognition thresholds (often called ''informational masking''). Branstetter *et al.,* 2016 measured masked recognition thresholds for whistle-like sounds of bottlenose dolphins and observed that they are approximately 4 dB above detection thresholds (energetic masking) for the same signals. Reduced ability to recognize a conspecific call or the acoustic signature of a predator could have severe negative impacts. Branstetter *et al.,* 2016 observed that if ''quality communication'' is set at 90 percent recognition the output of communication space models (which are based on 50 percent detection) would likely result in a significant decrease in communication range.

As marine mammals use sound to recognize predators (Allen *et al.,* 2014; Cummings and Thompson, 1971; Curé *et al.,* 2015; Fish and Vania, 1971), the presence of masking noise may also prevent marine mammals from responding to acoustic cues produced by their predators, particularly if it occurs in the same frequency band. For example, harbor seals that reside in the coastal waters off British Columbia are frequently targeted by mammal-eating killer whales. The seals acoustically discriminate between the calls of mammal-eating and fish-eating killer whales (Deecke *et al.,* 2002), a capability that should increase survivorship while reducing the energy required to attend to all killer whale calls. Similarly, sperm whales (Curé *et al.,* 2016; Isojunno *et al.,* 2016), long-finned pilot whales (Visser *et al.,* 2016), and humpback whales (Curé *et al.,* 2015) changed their behavior in response to killer whale vocalization playbacks; these findings indicate that some recognition of predator cues could be missed if the killer whale vocalizations were masked. The potential effects of masked predator acoustic cues depends on the duration of the masking noise and the likelihood of a marine mammal encountering a predator during the time that detection and recognition of predator cues are impeded.

Redundancy and context can also facilitate detection of weak signals. These phenomena may help marine mammals detect weak sounds in the presence of natural or manmade noise. Most masking studies in marine mammals present the test signal and the masking noise from the same direction. The dominant background noise may be highly directional if it comes from a particular anthropogenic source such as a ship or industrial site. Directional hearing may significantly reduce the masking effects of these sounds by improving the effective signal-to-noise ratio.

Masking affects both senders and receivers of acoustic signals and can potentially have long-term chronic effects on marine mammals at the population level as well as at the individual level. Low-frequency ambient sound levels have increased by as much as 20 dB (more than three times in terms of SPL) in the world's ocean from pre-industrial periods, with most of the increase from distant commercial shipping (Hildebrand, 2009). All anthropogenic sound sources, but especially chronic and lower-frequency signals (*e.g.,* from commercial vessel

traffic), contribute to elevated ambient sound levels, thus intensifying masking.

Impaired Communication

In addition to making it more difficult for animals to perceive and recognize acoustic cues in their environment, anthropogenic sound presents separate challenges for animals that are vocalizing. When they vocalize, animals are aware of environmental conditions that affect the ''active space'' (or communication space) of their vocalizations, which is the maximum area within which their vocalizations can be detected before it drops to the level of ambient noise (Brenowitz, 2004; Brumm *et al.,* 2004; Lohr *et al.,* 2003). Animals are also aware of environmental conditions that affect whether listeners can discriminate and recognize their vocalizations from other sounds, which is more important than simply detecting that a vocalization is occurring (Brenowitz, 1982; Brumm *et al.,* 2004; Dooling, 2004, Marten and Marler, 1977; Patricelli *et al.,* 2006). Most species that vocalize have evolved with an ability to make adjustments to their vocalizations to increase the signal-to-noise ratio, active space, and recognizability/distinguishability of their vocalizations in the face of temporary changes in background noise (Brumm *et al.,* 2004; Patricelli *et al.,* 2006). Vocalizing animals can make adjustments to vocalization characteristics such as the frequency structure, amplitude, temporal structure, and temporal delivery (repetition rate), or may cease to vocalize.

Many animals will combine several of these strategies to compensate for high levels of background noise. Anthropogenic sounds that reduce the signal-to-noise ratio of animal vocalizations, increase the masked auditory thresholds of animals listening for such vocalizations, or reduce the active space of an animal's vocalizations impair communication between animals. Most animals that vocalize have evolved strategies to compensate for the effects of short-term or temporary increases in background or ambient noise on their songs or calls. Although the fitness consequences of these vocal adjustments are not directly known in all instances, like most other trade-offs animals must make, some of these strategies probably come at a cost (Patricelli *et al.,* 2006). Shifting songs and calls to higher frequencies may also impose energetic costs (Lambrechts, 1996). For example, in birds, vocalizing more loudly in noisy environments may have energetic costs that decrease the net benefits of vocal adjustment and alter a bird's energy budget (Brumm, 2004; Wood and Yezerinac, 2006).

Marine mammals are also known to make vocal changes in response to anthropogenic noise. In cetaceans, vocalization changes have been reported from exposure to anthropogenic noise sources such as sonar, vessel noise, and seismic surveying (see the following for examples: Gordon *et al.,* 2003; Di Iorio and Clark, 2010; Hatch *et al.,* 2012; Holt *et al.,* 2008; Holt *et al.,* 2011; Lesage *et al.,* 1999; McDonald *et al.,* 2009; Parks *et al.,* 2007, Risch *et al.,* 2012, Rolland *et al.,* 2012), as well as changes in the natural acoustic environment (Dunlop *et al.,* 2014). Vocal changes can be temporary, or can be persistent. For example, model simulation suggests that the increase in starting frequency for the North Atlantic right whale upcall over the last 50 years resulted in increased detection ranges between right whales. The frequency shift, coupled with an increase in call intensity by 20 dB, led to a call detectability range of less than 3 km to over 9 km (Tennessen and Parks, 2016). Holt *et al.* (2008) measured killer whale call source levels and background noise levels in the one to 40 kHz band and reported that the whales increased their call source levels by one dB SPL for every one dB SPL increase in background noise level. Similarly, another study on St. Lawrence River belugas reported a similar rate of increase in vocalization activity in response to passing vessels (Scheifele *et al.,* 2005). Di Iorio and Clark (2010) showed that blue whale calling rates vary in association with seismic sparker survey activity, with whales calling more on days with surveys than on days without surveys. They suggested that the whales called more during seismic survey periods as a way to compensate for the elevated noise conditions.

In some cases, these vocal changes may have fitness consequences, such as an increase in metabolic rates and oxygen consumption, as observed in bottlenose dolphins when increasing their call amplitude (Holt *et al.,* 2015). A switch from vocal communication to physical, surface-generated sounds such as pectoral fin slapping or breaching was observed for humpback whales in the presence of increasing natural background noise levels, indicating that adaptations to masking may also move beyond vocal modifications (Dunlop *et al.,* 2010).

While these changes all represent possible tactics by the sound-producing animal to reduce the impact of masking, the receiving animal can also reduce masking by using active listening strategies such as orienting to the sound source, moving to a quieter location, or reducing self-noise from hydrodynamic flow by remaining still. The temporal structure of noise (*e.g.,* amplitude modulation) may also provide a considerable release from masking through comodulation masking release (a reduction of masking that occurs when broadband noise, with a frequency spectrum wider than an animal's auditory filter bandwidth at the frequency of interest, is amplitude modulated) (Branstetter and Finneran, 2008; Branstetter *et al.,* 2013). Signal type (*e.g.,* whistles, burst-pulse, sonar clicks) and spectral characteristics (*e.g.,* frequency modulated with harmonics) may further influence masked detection thresholds (Branstetter *et al.,* 2016; Cunningham *et al.,* 2014).

Masking Due to Sonar and Other Transducers

The functional hearing ranges of mysticetes, odontocetes, and pinnipeds underwater overlap the frequencies of the sonar sources used in the Navy's low-frequency active sonar (LFAS)/mid-frequency active sonar (MFAS)/high-frequency active sonar (HFAS) training and testing exercises. Additionally, almost all affected species' vocal repertoires span across the frequencies of these sonar sources used by the Navy. The closer the characteristics of the masking signal to the signal of interest, the more likely masking is to occur. Masking by low-frequency or mid-frequency active sonar (LFAS and MFAS) with relatively low-duty cycles is not anticipated (or would be of very short duration) for most cetaceans as sonar signals occur over a relatively short duration and narrow bandwidth (overlapping with only a small portion of the hearing range). LFAS could overlap in frequency with mysticete vocalizations, however LFAS does not overlap with vocalizations for most marine mammal species. For example, in the presence of LFAS, humpback whales were observed to increase the length of their songs (Fristrup *et al.,* 2003; Miller *et al.,* 2000), potentially due to the overlap in frequencies between the whale song and the LFAS. While dolphin whistles and MFAS are similar in frequency, masking is not anticipated (or would be of very short duration) due to the low-duty cycle of most sonars.

As described in additional detail the 2019 NWTT DSEIS/OEIS, newer high-duty cycle or continuous active sonars have more potential to mask vocalizations. These sonars transmit more frequently (greater than 80 percent duty cycle) than traditional sonars, but at a substantially lower source level. HFAS, such as pingers that operate at

higher repetition rates (*e.g.,* 2–10 kHz with harmonics up to 19 kHz, 76 to 77 pings per minute) (Culik *et al.,* 2001), also operate at lower source levels and have faster attenuation rates due to the higher frequencies used. These lower source levels limit the range of impacts, however compared to traditional sonar systems, individuals close to the source are likely to experience masking at longer time scales. The frequency range at which high-duty cycle systems operate overlaps the vocalization frequency of many mid-frequency cetaceans. Continuous noise at the same frequency of communicative vocalizations may cause disruptions to communication, social interactions, acoustically mediated cooperative behaviors, and important environmental cues. There is also the potential for the mid-frequency sonar signals to mask important environmental cues (*e.g.,* predator or conspectic acoustic cues), possibly affecting survivorship for targeted animals. While there are currently no available studies of the impacts of high-duty cycle sonars on marine mammals, masking due to these systems is likely analogous to masking produced by other continuous sources (*e.g.,* vessel noise and low-frequency cetaceans), and would likely have similar short-term consequences, though longer in duration due to the duration of the masking noise. These may include changes to vocalization amplitude and frequency (Brumm and Slabbekoorn, 2005; Hotchkin and Parks, 2013) and behavioral impacts such as avoidance of the area and interruptions to foraging or other essential behaviors (Gordon *et al.,* 2003). Long-term consequences could include changes to vocal behavior and vocalization structure (Foote *et al.,* 2004; Parks *et al.,* 2007), abandonment of habitat if masking occurs frequently enough to significantly impair communication (Brumm and Slabbekoorn, 2005), a potential decrease in survivorship if predator vocalizations are masked (Brumm and Slabbekoorn, 2005), and a potential decrease in recruitment if masking interferes with reproductive activities or mother-calf communication (Gordon *et al.,* 2003).

Masking Due to Vessel Noise

Masking is more likely to occur in the presence of broadband, relatively continuous noise sources such as vessels. Several studies have shown decreases in marine mammal communication space and changes in behavior as a result of the presence of vessel noise. For example, right whales were observed to shift the frequency content of their calls upward while reducing the rate of calling in areas of increased anthropogenic noise (Parks *et al.,* 2007) as well as increasing the amplitude (intensity) of their calls (Parks, 2009; Parks *et al.,* 2011). Fournet *et al.* (2018) observed that humpback whales in Alaska responded to increasing ambient sound levels (natural and anthropogenic) by increasing the source levels of their calls (non-song vocalizations). Clark *et al.* (2009) also observed that right whales communication space decreased by up to 84 percent in the presence of vessels (Clark *et al.,* 2009). Cholewiak *et al.* (2018) also observed loss in communication space in Stellwagen National Marine Sanctuary for North Atlantic right whales, fin whales, and humpback whales with increased ambient noise and shipping noise. Gabriele *et al.* (2018) modeled the effects of vessel traffic sound on communication space in Glacier Bay National Park in Alaska and found that typical summer vessel traffic in the Park causes losses of communication space to singing whales (reduced by 13–28 percent), calling whales (18–51 percent), and roaring seals (32–61 percent), particularly during daylight hours and even in the absence of cruise ships. Dunlop (2019) observed that an increase in vessel noise reduced modelled communication space and resulted in significant reduction in group social interactions in Australian humpback whales. However, communication signal masking did not fully explain this change in social behavior in the model, indicating there may also be an additional effect of the physical presence of the vessel on social behavior (Dunlop, 2019). Although humpback whales off Australia did not change the frequency or duration of their vocalizations in the presence of ship noise, their source levels were lower than expected based on source level changes to wind noise, potentially indicating some signal masking (Dunlop, 2016). Multiple delphinid species have also been shown to increase the minimum or maximum frequencies of their whistles in the presence of anthropogenic noise and reduced communication space (for examples see: Holt *et al.,* 2008; Holt *et al.,* 2011; Gervaise *et al.,* 2012; Williams *et al.,* 2013; Hermannsen *et al.,* 2014; Papale *et al.,* 2015; Liu *et al.,* 2017).

Behavioral Response/Disturbance

Behavioral responses to sound are highly variable and context-specific. Many different variables can influence an animal's perception of and response to (nature and magnitude) an acoustic event. An animal's prior experience with a sound or sound source affects whether it is less likely (habituation) or more likely (sensitization) to respond to certain sounds in the future (animals can also be innately predisposed to respond to certain sounds in certain ways) (Southall *et al.,* 2007). Related to the sound itself, the perceived nearness of the sound, bearing of the sound (approaching vs. retreating), the similarity of a sound to biologically relevant sounds in the animal's environment (*i.e.,* calls of predators, prey, or conspecifics), and familiarity of the sound may affect the way an animal responds to the sound (Southall *et al.,* 2007, DeRuiter *et al.,* 2013). Individuals (of different age, gender, reproductive status, *etc.*) among most populations will have variable hearing capabilities, and differing behavioral sensitivities to sounds that will be affected by prior conditioning, experience, and current activities of those individuals. Often, specific acoustic features of the sound and contextual variables (*i.e.,* proximity, duration, or recurrence of the sound or the current behavior that the marine mammal is engaged in or its prior experience), as well as entirely separate factors such as the physical presence of a nearby vessel, may be more relevant to the animal's response than the received level alone. For example, Goldbogen *et al.* (2013) demonstrated that individual behavioral state was critically important in determining response of blue whales to sonar, noting that some individuals engaged in deep (≤50 m) feeding behavior had greater dive responses than those in shallow feeding or non-feeding conditions. Some blue whales in the Goldbogen *et al.* (2013) study that were engaged in shallow feeding behavior demonstrated no clear changes in diving or movement even when received levels (RLs) were high (~160 dB re: 1µPa) for exposures to 3–4 kHz sonar signals, while others showed a clear response at exposures at lower received levels of sonar and pseudorandom noise.

Studies by DeRuiter *et al.* (2012) indicate that variability of responses to acoustic stimuli depends not only on the species receiving the sound and the sound source, but also on the social, behavioral, or environmental contexts of exposure. Another study by DeRuiter *et al.* (2013) examined behavioral responses of Cuvier's beaked whales to MF sonar and found that whales responded strongly at low received levels (RL of 89–127 dB re: 1µPa) by ceasing normal fluking and echolocation, swimming rapidly away, and extending both dive duration and subsequent non-foraging intervals when

the sound source was 3.4–9.5 km away. Importantly, this study also showed that whales exposed to a similar range of received levels (78–106 dB re: 1 µPa) from distant sonar exercises (118 km away) did not elicit such responses, suggesting that context may moderate reactions.

Ellison *et al.* (2012) outlined an approach to assessing the effects of sound on marine mammals that incorporates contextual-based factors. The authors recommend considering not just the received level of sound, but also the activity the animal is engaged in at the time the sound is received, the nature and novelty of the sound (*i.e.,* is this a new sound from the animal's perspective), and the distance between the sound source and the animal. They submit that this ''exposure context,'' as described, greatly influences the type of behavioral response exhibited by the animal. Forney *et al.* (2017) also point out that an apparent lack of response (*e.g.,* no displacement or avoidance of a sound source) may not necessarily mean there is no cost to the individual or population, as some resources or habitats may be of such high value that animals may choose to stay, even when experiencing stress or hearing loss. Forney *et al.* (2017) recommend considering both the costs of remaining in an area of noise exposure such as TTS, PTS, or masking, which could lead to an increased risk of predation or other threats or a decreased capability to forage, and the costs of displacement, including potential increased risk of vessel strike, increased risks of predation or competition for resources, or decreased habitat suitable for foraging, resting, or socializing. This sort of contextual information is challenging to predict with accuracy for ongoing activities that occur over large spatial and temporal expanses. However, distance is one contextual factor for which data exist to quantitatively inform a take estimate, and the method for predicting Level B harassment in this rule does consider distance to the source. Other factors are often considered qualitatively in the analysis of the likely consequences of sound exposure, where supporting information is available.

Friedlaender *et al.* (2016) provided the first integration of direct measures of prey distribution and density variables incorporated into across-individual analyses of behavior responses of blue whales to sonar, and demonstrated a five-fold increase in the ability to quantify variability in blue whale diving behavior. These results illustrate that responses evaluated without such measurements for foraging animals may be misleading, which again illustrates the context-dependent nature of the probability of response.

Exposure of marine mammals to sound sources can result in, but is not limited to, no response or any of the following observable responses: Increased alertness; orientation or attraction to a sound source; vocal modifications; cessation of feeding; cessation of social interaction; alteration of movement or diving behavior; habitat abandonment (temporary or permanent); and, in severe cases, panic, flight, stampede, or stranding, potentially resulting in death (Southall *et al.,* 2007). A review of marine mammal responses to anthropogenic sound was first conducted by Richardson (1995). More recent reviews (Nowacek *et al.,* 2007; DeRuiter *et al.,* 2012 and 2013; Ellison *et al.,* 2012; Gomez *et al.,* 2016) address studies conducted since 1995 and focused on observations where the received sound level of the exposed marine mammal(s) was known or could be estimated. Gomez *et al.* (2016) conducted a review of the literature considering the contextual information of exposure in addition to received level and found that higher received levels were not always associated with more severe behavioral responses and vice versa. Southall *et al.* (2016) states that results demonstrate that some individuals of different species display clear yet varied responses, some of which have negative implications, while others appear to tolerate high levels, and that responses may not be fully predictable with simple acoustic exposure metrics (*e.g.,* received sound level). Rather, the authors state that differences among species and individuals along with contextual aspects of exposure (*e.g.,* behavioral state) appear to affect response probability. The following subsections provide examples of behavioral responses that provide an idea of the variability in behavioral responses that would be expected given the differential sensitivities of marine mammal species to sound and the wide range of potential acoustic sources to which a marine mammal may be exposed. Behavioral responses that could occur for a given sound exposure should be determined from the literature that is available for each species, or extrapolated from closely related species when no information exists, along with contextual factors.

Flight Response

A flight response is a dramatic change in normal movement to a directed and rapid movement away from the perceived location of a sound source. The flight response differs from other avoidance responses in the intensity of the response (*e.g.,* directed movement, rate of travel). Relatively little information on flight responses of marine mammals to anthropogenic signals exist, although observations of flight responses to the presence of predators have occurred (Connor and Heithaus, 1996). The result of a flight response could range from brief, temporary exertion and displacement from the area where the signal provokes flight to, in extreme cases, being a component of marine mammal strandings associated with sonar activities (Evans and England, 2001). If marine mammals respond to Navy vessels that are transmitting active sonar in the same way that they might respond to a predator, their probability of flight responses should increase when they perceive that Navy vessels are approaching them directly, because a direct approach may convey detection and intent to capture (Burger and Gochfeld, 1981, 1990; Cooper, 1997, 1998). There are limited data on flight response for marine mammals in water; however, there are examples of this response in species on land. For instance, the probability of flight responses in Dall's sheep *Ovis dalli dalli* (Frid, 2001), hauled-out ringed seals *Phoca hispida* (Born *et al.,* 1999), Pacific brant (*Branta bernicl nigricans*), and Canada geese (*B. canadensis*) increased as a helicopter or fixed-wing aircraft more directly approached groups of these animals (Ward *et al.,* 1999). Bald eagles (*Haliaeetus leucocephalus*) perched on trees alongside a river were also more likely to flee from a paddle raft when their perches were closer to the river or were closer to the ground (Steidl and Anthony, 1996).

Response to Predator

As discussed earlier, evidence suggests that at least some marine mammals have the ability to acoustically identify potential predators. For example, harbor seals that reside in the coastal waters off British Columbia are frequently targeted by certain groups of killer whales, but not others. The seals discriminate between the calls of threatening and non-threatening killer whales (Deecke *et al.,* 2002), a capability that should increase survivorship while reducing the energy required for attending to and responding to all killer whale calls. The occurrence of masking or hearing impairment provides a means by which marine mammals may be prevented from responding to the acoustic cues produced by their predators. Whether or not this is a

possibility depends on the duration of the masking/hearing impairment and the likelihood of encountering a predator during the time that predator cues are impeded.

Alteration of Diving or Movement

Changes in dive behavior can vary widely. They may consist of increased or decreased dive times and surface intervals as well as changes in the rates of ascent and descent during a dive (*e.g.,* Frankel and Clark, 2000; Ng and Leung, 2003; Nowacek *et al.;* 2004; Goldbogen *et al.,* 2013a, 2013b). Variations in dive behavior may reflect interruptions in biologically significant activities (*e.g.,* foraging) or they may be of little biological significance. Variations in dive behavior may also expose an animal to potentially harmful conditions (*e.g.,* increasing the chance of ship-strike) or may serve as an avoidance response that enhances survivorship. The impact of a variation in diving resulting from an acoustic exposure depends on what the animal is doing at the time of the exposure and the type and magnitude of the response.

Nowacek *et al.* (2004) reported disruptions of dive behaviors in foraging North Atlantic right whales when exposed to an alerting stimulus, an action, they noted, that could lead to an increased likelihood of ship strike. However, the whales did not respond to playbacks of either right whale social sounds or vessel noise, highlighting the importance of the sound characteristics in producing a behavioral reaction. Conversely, Indo-Pacific humpback dolphins have been observed to dive for longer periods of time in areas where vessels were present and/or approaching (Ng and Leung, 2003). In both of these studies, the influence of the sound exposure cannot be decoupled from the physical presence of a surface vessel, thus complicating interpretations of the relative contribution of each stimulus to the response. Indeed, the presence of surface vessels, their approach, and speed of approach, seemed to be significant factors in the response of the Indo-Pacific humpback dolphins (Ng and Leung, 2003). Low-frequency signals of the Acoustic Thermometry of Ocean Climate (ATOC) sound source were not found to affect dive times of humpback whales in Hawaiian waters (Frankel and Clark, 2000) or to overtly affect elephant seal dives (Costa *et al.,* 2003). They did, however, produce subtle effects that varied in direction and degree among the individual seals, illustrating the equivocal nature of behavioral effects and consequent difficulty in defining and predicting them. Lastly, as noted previously, DeRuiter *et al.* (2013) noted that distance from a sound source may moderate marine mammal reactions in their study of Cuvier's beaked whales, which showed the whales swimming rapidly and silently away when a sonar signal was 3.4–9.5 km away while showing no such reaction to the same signal when the signal was 118 km away even though the received levels were similar.

Foraging

Disruption of feeding behavior can be difficult to correlate with anthropogenic sound exposure, so it is usually inferred by observed displacement from known foraging areas, the appearance of secondary indicators (*e.g.,* bubble nets or sediment plumes), or changes in dive behavior. As for other types of behavioral response, the frequency, duration, and temporal pattern of signal presentation, as well as differences in species sensitivity, are likely contributing factors to differences in response in any given circumstance (*e.g.,* Croll *et al.,* 2001; Harris *et al.,* 2017; Madsen *et al.,* 2006a; Nowacek *et al.;* 2004; Yazvenko *et al.,* 2007). A determination of whether foraging disruptions incur fitness consequences would require information on or estimates of the energetic requirements of the affected individuals and the relationship between prey availability, foraging effort and success, and the life history stage of the animal.

Noise from seismic surveys was not found to impact the feeding behavior in western grey whales off the coast of Russia (Yazvenko *et al.,* 2007). Visual tracking, passive acoustic monitoring, and movement recording tags were used to quantify sperm whale behavior prior to, during, and following exposure to air gun arrays at received levels in the range 140–160 dB at distances of 7–13 km, following a phase-in of sound intensity and full array exposures at 1–13 km (Madsen *et al.,* 2006a; Miller *et al.,* 2009). Sperm whales did not exhibit horizontal avoidance behavior at the surface. However, foraging behavior may have been affected. The sperm whales exhibited 19 percent less vocal (buzz) rate during full exposure relative to post exposure, and the whale that was approached most closely had an extended resting period and did not resume foraging until the air guns had ceased firing. The remaining whales continued to execute foraging dives throughout exposure; however, swimming movements during foraging dives were six percent lower during exposure than control periods (Miller *et al.,* 2009). These data raise concerns that air gun surveys may impact foraging behavior in sperm whales, although more data are required to understand whether the differences were due to exposure or natural variation in sperm whale behavior (Miller *et al.,* 2009).

Balaenopterid whales exposed to moderate low-frequency signals similar to the ATOC sound source demonstrated no variation in foraging activity (Croll *et al.,* 2001), whereas five out of six North Atlantic right whales exposed to an acoustic alarm interrupted their foraging dives (Nowacek *et al.,* 2004). Although the received SPLs were similar in the latter two studies, the frequency, duration, and temporal pattern of signal presentation were different. These factors, as well as differences in species sensitivity, are likely contributing factors to the differential response. Blue whales exposed to mid-frequency sonar in the Southern California Bight were less likely to produce low frequency calls usually associated with feeding behavior (Melcón *et al.,* 2012). However, Melcón *et al.* (2012) were unable to determine if suppression of low frequency calls reflected a change in their feeding performance or abandonment of foraging behavior and indicated that implications of the documented responses are unknown. Further, it is not known whether the lower rates of calling actually indicated a reduction in feeding behavior or social contact since the study used data from remotely deployed, passive acoustic monitoring buoys. In contrast, blue whales increased their likelihood of calling when ship noise was present, and decreased their likelihood of calling in the presence of explosive noise, although this result was not statistically significant (Melcón *et al.,* 2012). Additionally, the likelihood of an animal calling decreased with the increased received level of mid-frequency sonar, beginning at a SPL of approximately 110–120 dB re: 1 μPa (Melcón *et al.,* 2012). Results from behavioral response studies in Southern California waters indicated that, in some cases and at low received levels, tagged blue whales responded to mid-frequency sonar but that those responses were were generally brief, of low to moderate severity, and highly dependent on exposure context (Southall *et al.,* 2011; Southall *et al.,* 2012b, Southall *et al.,* 2019b). Information on or estimates of the energetic requirements of the individuals and the relationship between prey availability, foraging effort and success, and the life history stage of the animal will help better inform a

determination of whether foraging disruptions incur fitness consequences. Surface feeding blue whales did not show a change in behavior in response to mid-frequency simulated and real sonar sources with received levels between 90 and 179 dB re: 1 µPa, but deep feeding and non-feeding whales showed temporary reactions including cessation of feeding, reduced initiation of deep foraging dives, generalized avoidance responses, and changes to dive behavior. The behavioral responses they observed were generally brief, of low to moderate severity, and highly dependent on exposure context (behavioral state, source-to-whale horizontal range, and prey availability) (DeRuiter *et al.,* 2017; Goldbogen *et al.,* 2013b; Sivle *et al.,* 2015). Goldbogen *et al.* (2013b) indicate that disruption of feeding and displacement could impact individual fitness and health. However, for this to be true, we would have to assume that an individual whale could not compensate for this lost feeding opportunity by either immediately feeding at another location, by feeding shortly after cessation of acoustic exposure, or by feeding at a later time. There is no indication this is the case, particularly since unconsumed prey would likely still be available in the environment in most cases following the cessation of acoustic exposure.

Similarly, while the rates of foraging lunges decrease in humpback whales due to sonar exposure, there was variability in the response across individuals, with one animal ceasing to forage completely and another animal starting to forage during the exposure (Sivle *et al.,* 2016). In addition, almost half of the animals that exhibited avoidance behavior were foraging before the exposure but the others were not; the animals that exhibited avoidance behavior while not feeding responded at a slightly lower received level and greater distance than those that were feeding (Wensveen *et al.,* 2017). These findings indicate that the behavioral state of the animal plays a role in the type and severity of a behavioral response. In fact, when the prey field was mapped and used as a covariate in similar models looking for a response in the same blue whales, the response in deep-feeding behavior by blue whales was even more apparent, reinforcing the need for contextual variables to be included when assessing behavioral responses (Friedlaender *et al.,* 2016).

Breathing

Respiration naturally varies with different behaviors and variations in respiration rate as a function of acoustic exposure can be expected to co-occur with other behavioral reactions, such as a flight response or an alteration in diving. However, respiration rates in and of themselves may be representative of annoyance or an acute stress response. Mean exhalation rates of gray whales at rest and while diving were found to be unaffected by seismic surveys conducted adjacent to the whale feeding grounds (Gailey *et al.,* 2007). Studies with captive harbor porpoises showed increased respiration rates upon introduction of acoustic alarms (Kastelein *et al.,* 2001; Kastelein *et al.,* 2006a) and emissions for underwater data transmission (Kastelein *et al.,* 2005). However, exposure of the same acoustic alarm to a striped dolphin under the same conditions did not elicit a response (Kastelein *et al.,* 2006a), again highlighting the importance in understanding species differences in the tolerance of underwater noise when determining the potential for impacts resulting from anthropogenic sound exposure.

Social Relationships

Social interactions between mammals can be affected by noise via the disruption of communication signals or by the displacement of individuals. Disruption of social relationships therefore depends on the disruption of other behaviors (*e.g.,* avoidance, masking, *etc.*). Sperm whales responded to military sonar, apparently from a submarine, by dispersing from social aggregations, moving away from the sound source, remaining relatively silent, and becoming difficult to approach (Watkins *et al.,* 1985). In contrast, sperm whales in the Mediterranean that were exposed to submarine sonar continued calling (J. Gordon pers. comm. cited in Richardson *et al.,* 1995). Long-finned pilot whales exposed to three types of disturbance—playbacks of killer whale sounds, naval sonar exposure, and tagging—resulted in increased group sizes (Visser *et al.,* 2016). In response to sonar, pilot whales also spent more time at the surface with other members of the group (Visser *et al.,* 2016). However, social disruptions must be considered in context of the relationships that are affected. While some disruptions may not have deleterious effects, others, such as long-term or repeated disruptions of mother/calf pairs or interruption of mating behaviors, have the potential to affect the growth and survival or reproductive effort/success of individuals.

Vocalizations (Also See *Auditory Masking* Section)

Vocal changes in response to anthropogenic noise can occur across the repertoire of sound production modes used by marine mammals, such as whistling, echolocation click production, calling, and singing. Changes in vocalization behavior that may result in response to anthropogenic noise can occur for any of these modes and may result from a need to compete with an increase in background noise or may reflect an increased vigilance or a startle response. For example, in the presence of potentially masking signals (low-frequency active sonar), humpback whales have been observed to increase the length of their songs (Miller *et al.,* 2000; Fristrup *et al.,* 2003). A similar compensatory effect for the presence of low-frequency vessel noise has been suggested for right whales; right whales have been observed to shift the frequency content of their calls upward while reducing the rate of calling in areas of increased anthropogenic noise (Parks *et al.,* 2007; Roland *et al.,* 2012). Killer whales off the northwestern coast of the United States have been observed to increase the duration of primary calls once a threshold in observing vessel density (*e.g.,* whale watching) was reached, which has been suggested as a response to increased masking noise produced by the vessels (Foote *et al.,* 2004; NOAA, 2014b). In contrast, both sperm and pilot whales potentially ceased sound production during the Heard Island feasibility test (Bowles *et al.,* 1994), although it cannot be absolutely determined whether the inability to acoustically detect the animals was due to the cessation of sound production or the displacement of animals from the area.

Cerchio *et al.* (2014) used passive acoustic monitoring to document the presence of singing humpback whales off the coast of northern Angola and to opportunistically test for the effect of seismic survey activity on the number of singing whales. Two recording units were deployed between March and December 2008 in the offshore environment; numbers of singers were counted every hour. Generalized Additive Mixed Models were used to assess the effect of survey day (seasonality), hour (diel variation), moon phase, and received levels of noise (measured from a single pulse during each ten-minute sampled period) on singer number. The number of singers significantly decreased with increasing received level of noise, suggesting that humpback whale communication was disrupted to some extent by the survey activity.

Castellote *et al.* (2012) reported acoustic and behavioral changes by fin whales in response to shipping and air gun noise. Acoustic features of fin

whale song notes recorded in the Mediterranean Sea and northeast Atlantic Ocean were compared for areas with different shipping noise levels and traffic intensities and during an air gun survey. During the first 72 hours of the survey, a steady decrease in song received levels and bearings to singers indicated that whales moved away from the acoustic source and out of a Navy study area. This displacement persisted for a time period well beyond the 10-day duration of air gun activity, providing evidence that fin whales may avoid an area for an extended period in the presence of increased noise. The authors hypothesize that fin whale acoustic communication is modified to compensate for increased background noise and that a sensitization process may play a role in the observed temporary displacement.

Seismic pulses at average received levels of 131 dB re: 1 micropascal squared per second (µPa2-s) caused blue whales to increase call production (Di Iorio and Clark, 2010). In contrast, McDonald *et al.* (1995) tracked a blue whale with seafloor seismometers and reported that it stopped vocalizing and changed its travel direction at a range of 10 km from the seismic vessel (estimated received level 143 dB re: 1 µPa peak-to-peak). Blackwell *et al.* (2013) found that bowhead whale call rates dropped significantly at onset of air gun use at sites with a median distance of 41–45 km from the survey. Blackwell *et al.* (2015) expanded this analysis to show that whales actually increased calling rates as soon as air gun signals were detectable before ultimately decreasing calling rates at higher received levels (*i.e.,* 10-minute cumulative sound exposure level (cSEL) of ~127 dB). Overall, these results suggest that bowhead whales may adjust their vocal output in an effort to compensate for noise before ceasing vocalization effort and ultimately deflecting from the acoustic source (Blackwell *et al.,* 2013, 2015). Captive bottlenose dolphins sometimes vocalized after an exposure to impulse sound from a seismic water gun (Finneran *et al.,* 2010a). These studies demonstrate that even low levels of noise received far from the noise source can induce changes in vocalization and/or behavioral responses.

Avoidance

Avoidance is the displacement of an individual from an area or migration path as a result of the presence of a sound or other stressors. Richardson *et al.* (1995) noted that avoidance reactions are the most obvious manifestations of disturbance in marine mammals. Avoidance is qualitatively different from the 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. Acute avoidance responses have been observed in captive porpoises and pinnipeds exposed to a number of different sound sources (Kastelein *et al.,* 2001; Finneran *et al.,* 2003; Kastelein *et al.,* 2006a; Kastelein *et al.,* 2006b). Short-term avoidance of seismic surveys, low frequency emissions, and acoustic deterrents have also been noted in wild populations of odontocetes (Bowles *et al.,* 1994; Goold, 1996; 1998; Stone *et al.,* 2000; Morton and Symonds, 2002) and to some extent in mysticetes (Gailey *et al.,* 2007). Longer-term displacement is possible, however, which may lead to changes in abundance or distribution patterns of the affected species in the affected region if habituation to the presence of the sound does not occur (*e.g.,* Blackwell *et al.,* 2004; Bejder *et al.,* 2006; Teilmann *et al.,* 2006). Longer term or repetitive/chronic displacement for some dolphin groups and for manatees has been suggested to be due to the presence of chronic vessel noise (Haviland-Howell *et al.,* 2007; Miksis-Olds *et al.,* 2007). Gray whales have been reported deflecting from customary migratory paths in order to avoid noise from air gun surveys (Malme *et al.,* 1984). Humpback whales showed avoidance behavior in the presence of an active air gun array during observational studies and controlled exposure experiments in western Australia (McCauley *et al.,* 2000a).

As discussed earlier, Forney *et al.* (2017) detailed the potential effects of noise on marine mammal populations with high site fidelity, including displacement and auditory masking, noting that a lack of observed response does not imply absence of fitness costs and that apparent tolerance of disturbance may have population-level impacts that are less obvious and difficult to document. Avoidance of overlap between disturbing noise and areas and/or times of particular importance for sensitive species may be critical to avoiding population-level impacts because (particularly for animals with high site fidelity) there may be a strong motivation to remain in the area despite negative impacts. Forney *et al.* (2017) stated that, for these animals, remaining in a disturbed area may reflect a lack of alternatives rather than a lack of effects. The authors discuss several case studies, including western Pacific gray whales, which are a small population of mysticetes believed to be adversely affected by oil and gas development off Sakhalin Island, Russia (Weller *et al.,* 2002; Reeves *et al.,* 2005). Western gray whales display a high degree of interannual site fidelity to the area for foraging purposes, and observations in the area during air gun surveys have shown the potential for harm caused by displacement from such an important area (Weller *et al.,* 2006; Johnson *et al.,* 2007). Forney *et al.* (2017) also discuss beaked whales, noting that anthropogenic effects in areas where they are resident could cause severe biological consequences, in part because displacement may adversely affect foraging rates, reproduction, or health, while an overriding instinct to remain could lead to more severe acute effects.

In 1998, the Navy conducted a Low Frequency Sonar Scientific Research Program (LFS SRP) specifically to study behavioral responses of several species of marine mammals to exposure to LF sound, including one phase that focused on the behavior of gray whales to low frequency sound signals. The objective of this phase of the LFS SRP was to determine whether migrating gray whales respond more strongly to received levels, sound gradient, or distance from the source, and to compare whale avoidance responses to an LF source in the center of the migration corridor versus in the offshore portion of the migration corridor. A single source was used to broadcast LFAS sounds at received levels of 170–178 dB re: 1 µPa. The Navy reported that the whales showed some avoidance responses when the source was moored one mile (1.8 km) offshore, and located within the migration path, but the whales returned to their migration path when they were a few kilometers beyond the source. When the source was moored two miles (3.7 km) offshore, responses were much less, even when the source level was increased to achieve the same received levels in the middle of the migration corridor as whales received when the source was located within the migration corridor (Clark *et al.,* 1999). In addition, the researchers noted that the offshore whales did not seem to avoid the louder offshore source.

Also during the LFS SRP, researchers sighted numerous odontocete and pinniped species in the vicinity of the sound exposure tests with LFA sonar. The MF and HF hearing specialists present in California and Hawaii showed no immediately obvious responses or changes in sighting rates as a function of source conditions. Consequently, the researchers

concluded that none of these species had any obvious behavioral reaction to LFA sonar signals at received levels similar to those that produced only minor short-term behavioral responses in the baleen whales (*i.e.,* LF hearing specialists). Thus, for odontocetes, the chances of injury and/or significant behavioral responses to LFA sonar would be low given the MF/HF specialists' observed lack of response to LFA sounds during the LFS SRP and due to the MF/HF frequencies to which these animals are adapted to hear (Clark and Southall, 2009).

Maybaum (1993) conducted sound playback experiments to assess the effects of MFAS on humpback whales in Hawaiian waters. Specifically, she exposed focal pods to sounds of a 3.3-kHz sonar pulse, a sonar frequency sweep from 3.1 to 3.6 kHz, and a control (blank) tape while monitoring behavior, movement, and underwater vocalizations. The two types of sonar signals differed in their effects on the humpback whales, but both resulted in avoidance behavior. The whales responded to the pulse by increasing their distance from the sound source and responded to the frequency sweep by increasing their swimming speeds and track linearity. In the Caribbean, sperm whales avoided exposure to mid-frequency submarine sonar pulses, in the range of 1,000 Hz to 10,000 Hz (IWC, 2005).

Kvadsheim *et al.* (2007) conducted a controlled exposure experiment in which killer whales fitted with D-tags were exposed to mid-frequency active sonar (Source A: A 1.0 second upsweep 209 dB at 1–2 kHz every 10 seconds for 10 minutes; Source B: with a 1.0 second upsweep 197 dB at 6–7 kHz every 10 seconds for 10 minutes). When exposed to Source A, a tagged whale and the group it was traveling with did not appear to avoid the source. When exposed to Source B, the tagged whales along with other whales that had been carousel feeding, where killer whales cooperatively herd fish schools into a tight ball towards the surface and feed on the fish which have been stunned by tailslaps, and subsurface feeding (Simila, 1997) ceased feeding during the approach of the sonar and moved rapidly away from the source. When exposed to Source B, Kvadsheim *et al.* (2007) reported that a tagged killer whale seemed to try to avoid further exposure to the sound field by the following behaviors: Immediately swimming away (horizontally) from the source of the sound; engaging in a series of erratic and frequently deep dives that seemed to take it below the sound field; or swimming away while engaged in a series of erratic and frequently deep dives. Although the sample sizes in this study are too small to support statistical analysis, the behavioral responses of the killer whales were consistent with the results of other studies.

Southall *et al.* (2007) reviewed the available literature on marine mammal hearing and physiological and behavioral responses to human-made sound with the goal of proposing exposure criteria for certain effects. This peer-reviewed compilation of literature is very valuable, though Southall *et al.* (2007) note that not all data are equal and some have poor statistical power, insufficient controls, and/or limited information on received levels, background noise, and other potentially important contextual variables. Such data were reviewed and sometimes used for qualitative illustration, but no quantitative criteria were recommended for behavioral responses. All of the studies considered, however, contain an estimate of the received sound level when the animal exhibited the indicated response.

In the Southall *et al.* (2007) publication, for the purposes of analyzing responses of marine mammals to anthropogenic sound and developing criteria, the authors differentiate between single pulse sounds, multiple pulse sounds, and non-pulse sounds. LFAS/MFAS/HFAS are considered non-pulse sounds. Southall *et al.* (2007) summarize the studies associated with low-frequency, mid-frequency, and high-frequency cetacean and pinniped responses to non-pulse sounds, based strictly on received level, in Appendix C of their article (referenced and summarized in the following paragraphs).

The studies that address responses of low-frequency cetaceans to non-pulse sounds include data gathered in the field and related to several types of sound sources (of varying similarity to active sonar) including: Vessel noise, drilling and machinery playback, low-frequency M-sequences (sine wave with multiple phase reversals) playback, tactical low-frequency active sonar playback, drill ships, ATOC source, and non-pulse playbacks. These studies generally indicate no (or very limited) responses to received levels in the 90 to 120 dB re: 1 µPa range and an increasing likelihood of avoidance and other behavioral effects in the 120 to 160 dB re: 1 µPa range. As mentioned earlier, though, contextual variables play a very important role in the reported responses and the severity of effects are not linear when compared to received level. Also, few of the laboratory or field datasets had common conditions, behavioral contexts, or sound sources, so it is not surprising that responses differ.

The studies that address responses of mid-frequency cetaceans to non-pulse sounds include data gathered both in the field and the laboratory and related to several different sound sources (of varying similarity to active sonar) including: Pingers, drilling playbacks, ship and ice-breaking noise, vessel noise, Acoustic Harassment Devices (AHDs), Acoustic Deterrent Devices (ADDs), MFAS, and non-pulse bands and tones. Southall *et al.* (2007) were unable to come to a clear conclusion regarding the results of these studies. In some cases, animals in the field showed significant responses to received levels between 90 and 120 dB re: 1 µPa, while in other cases these responses were not seen in the 120 to 150 dB re: 1 µPa range. The disparity in results was likely due to contextual variation and the differences between the results in the field and laboratory data (animals typically responded at lower levels in the field).

The studies that address responses of high-frequency cetaceans to non-pulse sounds include data gathered both in the field and the laboratory and related to several different sound sources (of varying similarity to active sonar) including: Pingers, AHDs, and various laboratory non-pulse sounds. All of these data were collected from harbor porpoises. Southall *et al.* (2007) concluded that the existing data indicate that harbor porpoises are likely sensitive to a wide range of anthropogenic sounds at low received levels (~90 to 120 dB re: 1 µPa), at least for initial exposures. All recorded exposures above 140 dB re: 1 µPa induced profound and sustained avoidance behavior in wild harbor porpoises (Southall *et al.,* 2007). Rapid habituation was noted in some but not all studies. There are no data to indicate whether other high frequency cetaceans are as sensitive to anthropogenic sound as harbor porpoises.

The studies that address the responses of pinnipeds in water to non-impulsive sounds include data gathered both in the field and the laboratory and related to several different sound sources including: AHDs, ATOC, various non-pulse sounds used in underwater data communication, underwater drilling, and construction noise. Few studies existed with enough information to include them in the analysis. The limited data suggested that exposures to non-pulse sounds between 90 and 140 dB re: 1 µPa generally do not result in strong behavioral responses in pinnipeds in water, but no data exist at higher received levels.

In 2007, the first in a series of behavioral response studies (BRS) on deep diving odontocetes conducted by NMFS, Navy, and other scientists showed one Blainville's beaked whale responding to an MFAS playback. Tyack *et al.* (2011) indicates that the playback began when the tagged beaked whale was vocalizing at depth (at the deepest part of a typical feeding dive), following a previous control with no sound exposure. The whale appeared to stop clicking significantly earlier than usual, when exposed to MF signals in the 130–140 dB (rms) received level range. After a few more minutes of the playback, when the received level reached a maximum of 140–150 dB, the whale ascended on the slow side of normal ascent rates with a longer than normal ascent, at which point the exposure was terminated. The results are from a single experiment and a greater sample size is needed before robust and definitive conclusions can be drawn. Tyack *et al.* (2011) also indicates that Blainville's beaked whales appear to be sensitive to noise at levels well below expected TTS (~160 dB re: 1µ Pa). This sensitivity was manifested by an adaptive movement away from a sound source. This response was observed irrespective of whether the signal transmitted was within the band width of MFAS, which suggests that beaked whales may not respond to the specific sound signatures. Instead, they may be sensitive to any pulsed sound from a point source in this frequency range of the MFAS transmission. The response to such stimuli appears to involve the beaked whale increasing the distance between it and the sound source. Overall the results from the 2007–2008 study showed a change in diving behavior of the Blainville's beaked whale to playback of MFAS and predator sounds (Boyd *et al.,* 2008; Southall *et al.,* 2009; Tyack *et al.,* 2011).

Stimpert *et al.* (2014) tagged a Baird's beaked whale, which was subsequently exposed to simulated MFAS. Received levels of sonar on the tag increased to a maximum of 138 dB re: 1 µPa, which occurred during the first exposure dive. Some sonar received levels could not be measured due to flow noise and surface noise on the tag.

Reaction to mid-frequency sounds included premature cessation of clicking and termination of a foraging dive, and a slower ascent rate to the surface. Results from a similar behavioral response study in southern California waters were presented for the 2010–2011 field season (Southall *et al.,* 2011; DeRuiter *et al.,* 2013b). DeRuiter *et al.* (2013b) presented results from two Cuvier's beaked whales that were tagged and exposed to simulated MFAS during the 2010 and 2011 field seasons of the southern California behavioral response study. The 2011 whale was also incidentally exposed to MFAS from a distant naval exercise. Received levels from the MFAS signals from the controlled and incidental exposures were calculated as 84–144 and 78–106 dB re: 1 µPa rms, respectively. Both whales showed responses to the controlled exposures, ranging from initial orientation changes to avoidance responses characterized by energetic fluking and swimming away from the source. 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. Specifically, this result suggests that caution is needed when using marine mammal response data collected from smaller, nearer sound sources to predict at what received levels animals may respond to larger sound sources that are significantly farther away—as the distance of the source appears to be an important contextual variable and animals may be less responsive to sources at notably greater distances. Cuvier's beaked whale responses suggested particular sensitivity to sound exposure as consistent with results for Blainville's beaked whale. Similarly, beaked whales exposed to sonar during British training exercises stopped foraging (DSTL, 2007), and preliminary results of controlled playback of sonar may indicate feeding/foraging disruption of killer whales and sperm whales (Miller *et al.,* 2011).

In the 2007–2008 Bahamas study, playback sounds of a potential predator—a killer whale—resulted in a similar but more pronounced reaction, which included longer inter-dive intervals and a sustained straight-line departure of more than 20 km from the area (Boyd *et al.,* 2008; Southall *et al.,* 2009; Tyack *et al.,* 2011). The authors noted, however, that the magnified reaction to the predator sounds could represent a cumulative effect of exposure to the two sound types since killer whale playback began approximately two hours after MF source playback. Pilot whales and killer whales off Norway also exhibited horizontal avoidance of a transducer with outputs in the mid-frequency range (signals in the 1–2 kHz and 6–7 kHz ranges) (Miller *et al.,* 2011). Additionally, separation of a calf from its group during exposure to MFAS playback was observed on one occasion (Miller *et al.,* 2011, 2012). Miller *et al.* (2012) noted that this single observed mother-calf separation was unusual for several reasons, including the fact that the experiment was conducted in an unusually narrow fjord roughly one km wide and that the sonar exposure was started unusually close to the pod including the calf. Both of these factors could have contributed to calf separation. In contrast, preliminary analyses suggest that none of the pilot whales or false killer whales in the Bahamas showed an avoidance response to controlled exposure playbacks (Southall *et al.,* 2009).

In the 2010 BRS study, researchers again used controlled exposure experiments to carefully measure behavioral responses of individual animals to sound exposures of MFAS and pseudo-random noise. For each sound type, some exposures were conducted when animals were in a surface feeding (approximately 164 ft (50 m) or less) and/or socializing behavioral state and others while animals were in a deep feeding (greater than 164 ft (50 m)) and/or traveling mode. The researchers conducted the largest number of controlled exposure experiments on blue whales (n=19) and of these, 11 controlled exposure experiments involved exposure to the MFAS sound type. For the majority of controlled exposure experiment transmissions of either sound type, they noted few obvious behavioral responses detected either by the visual observers or on initial inspection of the tag data. The researchers observed that throughout the controlled exposure experiment transmissions, up to the highest received sound level (absolute RMS value approximately 160 dB re: 1 µPa with signal-to-noise ratio values over 60 dB), two blue whales continued surface feeding behavior and remained at a range of around 3,820 ft (1,000 m) from the sound source (Southall *et al.,* 2011). In contrast, another blue whale (later in the day and greater than 11.5 mi (18.5 km; 10 nmi) from the first controlled exposure experiment location) exposed to the same stimulus (MFA) while engaged in a deep feeding/travel state exhibited a different response. In that case, the blue whale responded almost immediately following the start of sound transmissions when received sounds were just above ambient background levels (Southall *et al.,* 2011). The authors note that this kind of temporary avoidance behavior was not evident in any of the nine controlled exposure experiments involving blue whales

engaged in surface feeding or social behaviors, but was observed in three of the ten controlled exposure experiments for blue whales in deep feeding/travel behavioral modes (one involving MFA sonar; two involving pseudo-random noise) (Southall *et al.,* 2011). The results of this study, as well as the results of the DeRuiter *et al.* (2013) study of Cuvier's beaked whales discussed above, further illustrate the importance of behavioral context in understanding and predicting behavioral responses.

Through analysis of the behavioral response studies, a preliminary overarching effect of greater sensitivity to all anthropogenic exposures was seen in beaked whales compared to the other odontocetes studied (Southall *et al.,* 2009). Therefore, recent studies have focused specifically on beaked whale responses to active sonar transmissions or controlled exposure playback of simulated sonar on various military ranges (Defence Science and Technology Laboratory, 2007; Claridge and Durban, 2009; Moretti *et al.,* 2009; McCarthy *et al.,* 2011; Miller *et al.,* 2012; Southall *et al.,* 2011, 2012a, 2012b, 2013, 2014; Tyack *et al.,* 2011). In the Bahamas, Blainville's beaked whales located on the instrumented range will move off-range during sonar use and return only after the sonar transmissions have stopped, sometimes taking several days to do so (Claridge and Durban 2009; Moretti *et al.,* 2009; McCarthy *et al.,* 2011; Tyack *et al.,* 2011). Moretti *et al.* (2014) used recordings from seafloor-mounted hydrophones at the Atlantic Undersea Test and Evaluation Center (AUTEC) to analyze the probability of Blainsville's beaked whale dives before, during, and after Navy sonar exercises.

Southall *et al.* (2016) indicates that results from Tyack *et al.* (2011), Miller *et al.* (2015), Stimpert *et al.* (2014), and DeRuiter *et al.* (2013) beaked whale studies demonstrate clear, strong, and pronounced but varied behavioral changes including avoidance with associated energetic swimming and cessation of individual foraging dives at quite low received levels (~100 to 135 dB re: 1 Pa) for exposures to simulated or active MF military sonars (1–8 kHz) with sound sources approximately 2–5 km away. Similar responses by beaked whales to sonar have been documented by Stimpert *et al.,* 2014, Falcone *et al.,* 2017, DiMarzio *et al.,* 2018, and Joyce *et al.,* 2019. However, there are a number of variables influencing response or non-response including source distance (close vs. far), received sound levels, and other contextual variables such as other sound sources (*e.g.,* vessels, *etc.*) (Manzano-Roth *et al.,* 2016, Falcone *et al.,* 2017, Harris *et al.,* 2018). Wensveen *et al.* (2019) found northern bottlenose whales to avoid sonar out to distances of 28 km, but these distances are well in line with those observed on Navy ranges (Manzano-Roth *et al.,* 2016; Joyce *et al.,* 2019) where the animals return once the sonar has ceased. Furthermore, beaked whales have also shown response to other non-sonar anthropogenic sounds such as commercial shipping and echosounders (Soto *et al.,* 2006, Pirotta *et al.,* 2012, Cholewiak *et al.,* 2017). Pirotta *et al.* (2012) documented broadband ship noise causing a significant change in beaked whale behavior up to at least 5.2 km away from the vessel. Even though beaked whales appear to be sensitive to anthropogenic sounds, the level of response at the population level does not appear to be significant based on over a decade of research at two heavily used Navy training areas in the Pacific (Falcone *et al.,* 2012, Schorr *et al.,* 2014, DiMarzio *et al.,* 2018, Schorr *et al.,* 2019). With the exception of seasonal patterns, DiMarzio *et al.* (2018) did not detect any changes in annual Cuvier's beaked whale abundance estimates in Southern California derived from passive acoustic echolocation detections over nine years (2010–2018). Similar results for Blainville's beaked whales abundance estimates over several years was documented in Hawaii (Henderson *et al.,* 2016;, DiMarzio *et al.,* 2018). Visually, there have been documented repeated sightings in southern California of the same individual Cuvier's beaked whales over 10 years, sightings of mother-calf pairs, and recently sightings of the same mothers with their second calf (Falcone *et al.,* 2012; Schorr *et al.,* 2014; Schorr *et al.,* 2019; Schorr, unpublished data).

Baleen whales have shown a variety of responses to impulse sound sources, including avoidance, reduced surface intervals, altered swimming behavior, and changes in vocalization rates (Richardson *et al.,* 1995; Gordon *et al.,* 2003; Southall, 2007). While most bowhead whales did not show active avoidance until within 8 km of seismic vessels (Richardson *et al.,* 1995), some whales avoided vessels by more than 20 km at received levels as low as 120 dB re: 1 µPa rms. Additionally, Malme *et al.* (1988) observed clear changes in diving and respiration patterns in bowheads at ranges up to 73 km from seismic vessels, with received levels as low as 125 dB re: 1 µPa.

Gray whales migrating along the United States West Coast showed avoidance responses to seismic vessels by 10 percent of animals at 164 dB re: 1 µPa, and by 90 percent of animals at 190 dB re: 1 µPa, with similar results for whales in the Bering Sea (Malme, 1986; 1988). In contrast, noise from seismic surveys was not found to impact feeding behavior or exhalation rates while resting or diving in western gray whales off the coast of Russia (Yazvenko *et al.,* 2007; Gailey *et al.,* 2007).

Humpback whales showed avoidance behavior at ranges of five to eight km from a seismic array during observational studies and controlled exposure experiments in western Australia (McCauley, 1998; Todd *et al.,* 1996). Todd *et al.* (1996) found no clear short-term behavioral responses by foraging humpbacks to explosions associated with construction operations in Newfoundland, but did see a trend of increased rates of net entanglement and a shift to a higher incidence of net entanglement closer to the noise source.

The strongest baleen whale response in any behavioral response study was observed in a minke whale in the 3S2 study, which responded at 146 dB re: 1 µPa by strongly avoiding the sound source (Kvadsheim *et al.,* 2017; Sivle *et al.,* 2015). Although the minke whale increased its swim speed, directional movement, and respiration rate, none of these were greater than rates observed in baseline behavior, and its dive behavior remained similar to baseline dives. A minke whale tagged in the Southern California behavioral response study also responded by increasing its directional movement, but maintained its speed and dive patterns, and so did not demonstrate as strong of a response (Kvadsheim *et al.,* 2017). In addition, the 3S2 minke whale demonstrated some of the same avoidance behavior during the controlled ship approach with no sonar, indicating at least some of the response was to the vessel (Kvadsheim *et al.,* 2017). Martin *et al.* (2015) found that the density of calling minke whales was reduced during periods of Navy training involving sonar relative to the periods before training, and increased again in the days after training was completed. The responses of individual whales could not be assessed, so in this case it is unknown whether the decrease in calling animals indicated that the animals left the range, or simply ceased calling. Similarly, minke whale detections made using Marine Acoustic Recording Instruments off Jacksonville, FL, were reduced or ceased altogether during periods of sonar use (Simeone *et al.,* 2015; U.S. Department of the Navy, 2013b), especially with an increased ping rate (Charif *et al.,* 2015).

Orientation

A shift in an animal's resting state or an attentional change via an orienting response represent behaviors that would be considered mild disruptions if occurring alone. As previously mentioned, the responses may co-occur with other behaviors; for instance, an animal may initially orient toward a sound source, and then move away from it. Thus, any orienting response should be considered in context of other reactions that may occur.

Continued Pre-Disturbance Behavior and Habituation

Under some circumstances, some of the individual marine mammals that are exposed to active sonar transmissions will continue their normal behavioral activities. In other circumstances, individual animals will respond to sonar transmissions at lower received levels and move to avoid additional exposure or exposures at higher received levels (Richardson *et al.,* 1995).

It is difficult to distinguish between animals that continue their pre-disturbance behavior without stress responses, animals that continue their behavior but experience stress responses (that is, animals that cope with disturbance), and animals that habituate to disturbance (that is, they may have experienced low-level stress responses initially, but those responses abated over time). Watkins (1986) reviewed data on the behavioral reactions of fin, humpback, right, and minke whales that were exposed to continuous, broadband low-frequency shipping and industrial noise in Cape Cod Bay. He concluded that underwater sound was the primary cause of behavioral reactions in these species of whales and that the whales responded behaviorally to acoustic stimuli within their respective hearing ranges. Watkins also noted that whales showed the strongest behavioral reactions to sounds in the 15 Hz to 28 kHz range, although negative reactions (avoidance, interruptions in vocalizations, *etc.*) were generally associated with sounds that were either unexpected, too loud, suddenly louder or different, or perceived as being associated with a potential threat (such as an approaching ship on a collision course). In particular, whales seemed to react negatively when they were within 100 m of the source or when received levels increased suddenly in excess of 12 dB relative to ambient sounds. At other times, the whales ignored the source of the signal and all four species habituated to these sounds. Nevertheless, Watkins concluded that whales ignored most sounds in the background of ambient noise, including sounds from distant human activities even though these sounds may have had considerable energies at frequencies well within the whales' range of hearing. Further, he noted that of the whales observed, fin whales were the most sensitive of the four species, followed by humpback whales; right whales were the least likely to be disturbed and generally did not react to low-amplitude engine noise. By the end of his period of study, Watkins (1986) concluded that fin and humpback whales had generally habituated to the continuous and broad-band noise of Cape Cod Bay while right whales did not appear to change their response. As mentioned above, animals that habituate to a particular disturbance may have experienced low-level stress responses initially, but those responses abated over time. In most cases, this likely means a lessened immediate potential effect from a disturbance. However, there is cause for concern where the habituation occurs in a potentially more harmful situation. For example, animals may become more vulnerable to vessel strikes once they habituate to vessel traffic (Swingle *et al.,* 1993; Wiley *et al.,* 1995).

Aicken *et al.* (2005) monitored the behavioral responses of marine mammals to a new low-frequency active sonar system used by the British Navy (the United States Navy considers this to be a mid-frequency source as it operates at frequencies greater than 1,000 Hz). During those trials, fin whales, sperm whales, Sowerby's beaked whales, long-finned pilot whales, Atlantic white-sided dolphins, and common bottlenose dolphins were observed and their vocalizations were recorded. These monitoring studies detected no evidence of behavioral responses that the investigators could attribute to exposure to the low-frequency active sonar during these trials.

Explosive Sources

Underwater explosive detonations send a shock wave and sound energy through the water and can release gaseous by-products, create an oscillating bubble, or cause a plume of water to shoot up from the water surface. The shock wave and accompanying noise are of most concern to marine animals. Depending on the intensity of the shock wave and size, location, and depth of the animal, an animal can be injured, killed, suffer non-lethal physical effects, experience hearing related effects with or without behavioral responses, or exhibit temporary behavioral responses or tolerance from hearing the blast sound. Generally, exposures to higher levels of impulse and pressure levels would result in greater impacts to an individual animal.

Injuries resulting from a shock wave take place at boundaries between tissues of different densities. Different velocities are imparted to tissues of different densities, and this can lead to their physical disruption. Blast effects are greatest at the gas-liquid interface (Landsberg, 2000). Gas-containing organs, particularly the lungs and gastrointestinal tract, are especially susceptible (Goertner, 1982; Hill, 1978; Yelverton *et al.,* 1973). Intestinal walls can bruise or rupture, with subsequent hemorrhage and escape of gut contents into the body cavity. Less severe gastrointestinal tract injuries include contusions, petechiae (small red or purple spots caused by bleeding in the skin), and slight hemorrhaging (Yelverton *et al.,* 1973).

Because the ears are the most sensitive to pressure, they are the organs most sensitive to injury (Ketten, 2000). Sound-related damage associated with sound energy from detonations can be theoretically distinct from injury from the shock wave, particularly farther from the explosion. If a noise is audible to an animal, it has the potential to damage the animal's hearing by causing decreased sensitivity (Ketten, 1995). Lethal impacts are those that result in immediate death or serious debilitation in or near an intense source and are not, technically, pure acoustic trauma (Ketten, 1995). Sublethal impacts include hearing loss, which is caused by exposures to perceptible sounds. Severe damage (from the shock wave) to the ears includes tympanic membrane rupture, fracture of the ossicles, damage to the cochlea, hemorrhage, and cerebrospinal fluid leakage into the middle ear. Moderate injury implies partial hearing loss due to tympanic membrane rupture and blood in the middle ear. Permanent hearing loss also can occur when the hair cells are damaged by one very loud event, as well as by prolonged exposure to a loud noise or chronic exposure to noise. The level of impact from blasts depends on both an animal's location and, at outer zones, on its sensitivity to the residual noise (Ketten, 1995).

Further Potential Effects of Behavioral Disturbance on Marine Mammal Fitness

The different ways that marine mammals respond to sound are sometimes indicators of the ultimate effect that exposure to a given stimulus will have on the well-being (survival, reproduction, *etc.*) of an animal. There

are few quantitative marine mammal data relating the exposure of marine mammals to sound to effects on reproduction or survival, though data exists for terrestrial species to which we can draw comparisons for marine mammals. Several authors have reported that disturbance stimuli may cause animals to abandon nesting and foraging sites (Sutherland and Crockford, 1993); may cause animals to increase their activity levels and suffer premature deaths or reduced reproductive success when their energy expenditures exceed their energy budgets (Daan *et al.,* 1996; Feare, 1976; Mullner *et al.,* 2004); or may cause animals to experience higher predation rates when they adopt risk-prone foraging or migratory strategies (Frid and Dill, 2002). Each of these studies addressed the consequences of animals shifting from one behavioral state (*e.g.,* resting or foraging) to another behavioral state (*e.g.,* avoidance or escape behavior) because of human disturbance or disturbance stimuli.

One consequence of behavioral avoidance results in the altered energetic expenditure of marine mammals because energy is required to move and avoid surface vessels or the sound field associated with active sonar (Frid and Dill, 2002). Most animals can avoid that energetic cost by swimming away at slow speeds or speeds that minimize the cost of transport (Miksis-Olds, 2006), as has been demonstrated in Florida manatees (Miksis-Olds, 2006).

Those energetic costs increase, however, when animals shift from a resting state, which is designed to conserve an animal's energy, to an active state that consumes energy the animal would have conserved had it not been disturbed. Marine mammals that have been disturbed by anthropogenic noise and vessel approaches are commonly reported to shift from resting to active behavioral states, which would imply that they incur an energy cost.

Morete *et al.* (2007) reported that undisturbed humpback whale cows that were accompanied by their calves were frequently observed resting while their calves circled them (milling). When vessels approached, the amount of time cows and calves spent resting and milling, respectively, declined significantly. These results are similar to those reported by Scheidat *et al.* (2004) for the humpback whales they observed off the coast of Ecuador.

Constantine and Brunton (2001) reported that bottlenose dolphins in the Bay of Islands, New Zealand engaged in resting behavior just 5 percent of the time when vessels were within 300 m, compared with 83 percent of the time when vessels were not present. However, Heenehan *et al.* (2016) report that results of a study of the response of Hawaiian spinner dolphins to human disturbance suggest that the key factor is not the sheer presence or magnitude of human activities, but rather the directed interactions and dolphin-focused activities that elicit responses from dolphins at rest. This information again illustrates the importance of context in regard to whether an animal will respond to a stimulus. Miksis-Olds (2006) and Miksis-Olds *et al.* (2005) reported that Florida manatees in Sarasota Bay, Florida, reduced the amount of time they spent milling and increased the amount of time they spent feeding when background noise levels increased. Although the acute costs of these changes in behavior are not likely to exceed an animal's ability to compensate, the chronic costs of these behavioral shifts are uncertain.

Attention is the cognitive process of selectively concentrating on one aspect of an animal's environment while ignoring other things (Posner, 1994). Because animals (including humans) have limited cognitive resources, there is a limit to how much sensory information they can process at any time. The phenomenon called ''attentional capture'' occurs when a stimulus (usually a stimulus that an animal is not concentrating on or attending to) ''captures'' an animal's attention. This shift in attention can occur consciously or subconsciously (for example, when an animal hears sounds that it associates with the approach of a predator) and the shift in attention can be sudden (Dukas, 2002; van Rij, 2007). Once a stimulus has captured an animal's attention, the animal can respond by ignoring the stimulus, assuming a ''watch and wait'' posture, or treat the stimulus as a disturbance and respond accordingly, which includes scanning for the source of the stimulus or ''vigilance'' (Cowlishaw *et al.,* 2004).

Vigilance is normally an adaptive behavior that helps animals determine the presence or absence of predators, assess their distance from conspecifics, or to attend cues from prey (Bednekoff and Lima, 1998; Treves, 2000). Despite those benefits, however, vigilance has a cost of time; when animals focus their attention on specific environmental cues, they are not attending to other activities such as foraging or resting. These effects have generally not been demonstrated for marine mammals, but studies involving fish and terrestrial animals have shown that increased vigilance may substantially reduce feeding rates (Saino, 1994; Beauchamp and Livoreil, 1997; Fritz *et al.,* 2002; Purser and Radford, 2011). Animals will spend more time being vigilant, which may translate to less time foraging or resting, when disturbance stimuli approach them more directly, remain at closer distances, have a greater group size (*e.g.,* multiple surface vessels), or when they co-occur with times that an animal perceives increased risk (*e.g.,* when they are giving birth or accompanied by a calf). An example of this concept with terrestrial species involved bighorn sheep and Dall's sheep, which dedicated more time being vigilant, and less time resting or foraging, when aircraft made direct approaches over them (Frid, 2001; Stockwell *et al.,* 1991). Vigilance has also been documented in pinnipeds at haul-out sites where resting may be disturbed when seals become alerted and/or flush into the water due to a variety of disturbances, which may be anthropogenic (noise and/or visual stimuli) or due to other natural causes such as other pinnipeds (Richardson *et al.,* 1995; Southall *et al.,* 2007; VanBlaricom, 2010; and Lozano and Hente, 2014).

Chronic disturbance can cause population declines through reduction of fitness (*e.g.,* decline in body condition) and subsequent reduction in reproductive success, survival, or both (*e.g.,* Harrington and Veitch, 1992; Daan *et al.,* 1996; Bradshaw *et al.,* 1998). For example, Madsen (1994) reported that pink-footed geese (*Anser brachyrhynchus*) in undisturbed habitat gained body mass and had about a 46 percent reproductive success rate compared with geese in disturbed habitat (being consistently scared off the fields on which they were foraging) which did not gain mass and had a 17 percent reproductive success rate. Similar reductions in reproductive success have been reported for mule deer (*Odocoileus hemionus*) disturbed by all-terrain vehicles (Yarmoloy *et al.,* 1988), caribou (*Rangifer tarandus caribou*) disturbed by seismic exploration blasts (Bradshaw *et al.,* 1998), and caribou disturbed by low-elevation military jet fights (Luick *et al.,* 1996, Harrington and Veitch, 1992). Similarly, a study of elk (*Cervus elaphus*) that were disturbed experimentally by pedestrians concluded that the ratio of young to mothers was inversely related to disturbance rate (Phillips and Alldredge, 2000). However, Ridgway *et al.* (2006) reported that increased vigilance in bottlenose dolphins exposed to sound over a five-day period in open-air, open-water enclosures in

San Diego Bay did not cause any sleep deprivation or stress effects such as changes in cortisol or epinephrine levels.

The primary mechanism by which increased vigilance and disturbance appear to affect the fitness of individual animals is by disrupting an animal's time budget and, as a result, reducing the time they might spend foraging and resting (which increases an animal's activity rate and energy demand while decreasing their caloric intake/energy). An example of this concept with terrestrial species involved a study of grizzly bears (*Ursus horribilis*) that reported that bears disturbed by hikers reduced their energy intake by an average of 12 kilocalories/min (50.2 × 103 kiloJoules/min), and spent energy fleeing or acting aggressively toward hikers (White *et al.,* 1999).

Lusseau and Bejder (2007) present data from three long-term studies illustrating the connections between disturbance from whale-watching boats and population-level effects in cetaceans. In Shark Bay Australia, the abundance of bottlenose dolphins was compared within adjacent control and tourism sites over three consecutive 4.5-year periods of increasing tourism levels. Between the second and third time periods, in which tourism doubled, dolphin abundance decreased by 15 percent in the tourism area and did not change significantly in the control area. In Fiordland, New Zealand, two populations (Milford and Doubtful Sounds) of bottlenose dolphins with tourism levels that differed by a factor of seven were observed and significant increases in travelling time and decreases in resting time were documented for both. Consistent short-term avoidance strategies were observed in response to tour boats until a threshold of disturbance was reached (average 68 minutes between interactions), after which the response switched to a longer-term habitat displacement strategy. For one population, tourism only occurred in a part of the home range. However, tourism occurred throughout the home range of the Doubtful Sound population and once boat traffic increased beyond the 68-minute threshold (resulting in abandonment of their home range/preferred habitat), reproductive success drastically decreased (increased stillbirths) and abundance decreased significantly (from 67 to 56 individuals in a short period). Last, in a study of northern resident killer whales off Vancouver Island, exposure to boat traffic was shown to reduce foraging opportunities and increase traveling time. A simple bioenergetics model was applied to show that the reduced foraging opportunities equated to a decreased energy intake of 18 percent, while the increased traveling incurred an increased energy output of 3–4 percent, which suggests that a management action based on avoiding interference with foraging might be particularly effective.

On a related note, many animals perform vital functions, such as feeding, resting, traveling, and socializing, on a diel cycle (24-hr cycle). Behavioral reactions to noise exposure (such as disruption of critical life functions, displacement, or avoidance of important habitat) are more likely to be significant for fitness if they last more than one diel cycle or recur on subsequent days (Southall *et al.,* 2007). Consequently, a behavioral response lasting less than one day and not recurring on subsequent days is not considered particularly severe unless it could directly affect reproduction or survival (Southall *et al.,* 2007). It is important to note the difference between behavioral reactions lasting or recurring over multiple days and anthropogenic activities lasting or recurring over multiple days. For example, just because at-sea exercises last for multiple days does not necessarily mean that individual animals will be either exposed to those activity-related stressors (*i.e.,* sonar) for multiple days or further, exposed in a manner that would result in sustained multi-day substantive behavioral responses.

Stone (2015a) reported data from at-sea observations during 1,196 airgun surveys from 1994 to 2010. When large arrays of airguns (considered to be 500 in^3 or more) were firing, lateral displacement, more localized avoidance, or other changes in behavior were evident for most odontocetes. However, significant responses to large arrays were found only for the minke whale and fin whale. Behavioral responses observed included changes in swimming or surfacing behavior, with indications that cetaceans remained near the water surface at these times. Cetaceans were recorded as feeding less often when large arrays were active. Monitoring of gray whales during an air gun survey included recording whale movements and respirations pre-, during-, and post-seismic survey (Gailey *et al.,* 2016). Behavioral state and water depth were the best 'natural' predictors of whale movements and respiration and, after considering natural variation, none of the response variables were significantly associated with survey or vessel sounds.

In order to understand how the effects of activities may or may not impact species and stocks of marine mammals, it is necessary to understand not only what the likely disturbances are going to be, but how those disturbances may affect the reproductive success and survivorship of individuals, and then how those impacts to individuals translate to population-level effects. Following on the earlier work of a committee of the U.S. National Research Council (NRC, 2005), New *et al.* (2014), in an effort termed the Potential Consequences of Disturbance (PCoD), outline an updated conceptual model of the relationships linking disturbance to changes in behavior and physiology, health, vital rates, and population dynamics. In this framework, behavioral and physiological changes can have direct (acute) effects on vital rates, such as when changes in habitat use or increased stress levels raise the probability of mother-calf separation or predation; they can have indirect and long-term (chronic) effects on vital rates, such as when changes in time/energy budgets or increased disease susceptibility affect health, which then affects vital rates; or they can have no effect to vital rates (New *et al.,* 2014). In addition to outlining this general framework and compiling the relevant literature that supports it, the authors chose four example species for which extensive long-term monitoring data exist (southern elephant seals, North Atlantic right whales, *Ziphidae* beaked whales, and bottlenose dolphins) and developed state-space energetic models that can be used to forecast longer-term, population-level impacts from behavioral changes. While these are very specific models with very specific data requirements that cannot yet be applied broadly to project-specific risk assessments for the majority of species, as well as requiring significant resources and time to conduct (more than is typically available to support regulatory compliance for one project), they are a critical first step towards being able to quantify the likelihood of a population level effect.

Since New *et al.* (2014), several publications have described models developed to examine the long-term effects of environmental or anthropogenic disturbance of foraging on various life stages of selected species (sperm whale, Farmer *et al.* (2018); California sea lion, McHuron *et al.* (2018); and blue whale, Pirotta, *et al.* (2018a)). These models continue to add to refinement to the approaches to the population consequences of disturbance (PCOD) framework. Such models also help identify what data inputs require further investigation. Pirotta *et al.*

(2018b) provides a review of the PCOD framework with details on each step of the process and approaches to applying real data or simulations to achieve each step.

Stranding and Mortality

The definition for a stranding under title IV of the MMPA is that (A) a marine mammal is dead and is (i) on a beach or shore of the United States; or (ii) in waters under the jurisdiction of the United States (including any navigable waters); or (B) a marine mammal is alive and is (i) on a beach or shore of the United States and is unable to return to the water; (ii) on a beach or shore of the United States and, although able to return to the water, is in need of apparent medical attention; or (iii) in the waters under the jurisdiction of the United States (including any navigable waters), but is unable to return to its natural habitat under its own power or without assistance (see MMPA section 410(3)). This definition is useful for considering stranding events even when they occur beyond lands and waters under the jurisdiction of the United States.

Marine mammal strandings have been linked to a variety of causes, such as illness from exposure to infectious agents, biotoxins, or parasites; starvation; unusual oceanographic or weather events; or anthropogenic causes including fishery interaction, ship strike, entrainment, entrapment, sound exposure, or combinations of these stressors sustained concurrently or in series. Historically, the cause or causes of most strandings have remained unknown (Geraci *et al.,* 1976; Eaton, 1979, Odell *et al.,* 1980; Best, 1982), but the development of trained, professional stranding response networks and improved analyses have led to a greater understanding of marine mammal stranding causes (Simeone and Moore 2017).

Numerous studies suggest that the physiology, behavior, habitat, social relationships, age, or condition of cetaceans may cause them to strand or might predispose them to strand when exposed to another phenomenon. These suggestions are consistent with the conclusions of numerous other studies that have demonstrated that combinations of dissimilar stressors commonly combine to kill an animal or dramatically reduce its fitness, even though one exposure without the other does not produce the same result (Bernaldo de Quiros *et al.,* 2019; Chroussos, 2000; Creel, 2005; DeVries *et al.,* 2003; Fair and Becker, 2000; Foley *et al.,* 2001; Moberg, 2000; Relyea, 2005a; 2005b, Romero, 2004; Sih *et al.,* 2004).

Historically, stranding reporting and response efforts have been inconsistent, although significant improvements have occurred over the last 25 years. Reporting forms for basic (''Level A'') information, rehabilitation disposition, and human interaction have been standardized nationally (available at *https://www.fisheries.noaa.gov/national/marine-mammal-protection/level-data-collection-marine-mammal-stranding-events*). However, data collected beyond basic information varies by region (and may vary from case to case), and are not standardized across the United States. Logistical conditions such as weather, time, location, and decomposition state may also affect the ability of the stranding network to thoroughly examine a specimen (Carretta *et al.,* 2016b; Moore *et al.,* 2013). While the investigation of stranded animals provides insight into the types of threats marine mammal populations face, full investigations are only possible and conducted on a small fraction of the total number of strandings that occur, limiting our understanding of the causes of strandings (Carretta *et al.,* 2016a). Additionally, and due to the variability in effort and data collected, the ability to interpret long-term trends in stranded marine mammals is complicated.

In the United States from 2006–2017, there were 19,430 cetacean strandings and 55,833 pinniped strandings (75,263 total) (P. Onens, NMFS, pers comm., 2019). Several mass strandings (strandings that involve two or more individuals of the same species, excluding a single mother-calf pair) that have occurred over the past two decades have been associated with anthropogenic activities that introduced sound into the marine environment such as naval operations and seismic surveys. An in-depth discussion of strandings is in the Navy's Technical Report on Marine Mammal Strandings Associated with U.S. Navy Sonar Activities (U.S. Navy Marine Mammal Program & Space and Naval Warfare Systems Command Center Pacific, 2017).

Worldwide, there have been several efforts to identify relationships between cetacean mass stranding events and military active sonar (Cox *et al.,* 2006, Hildebrand, 2004; IWC, 2005; Taylor *et al.,* 2004). For example, based on a review of mass stranding events around the world consisting of two or more individuals of Cuvier's beaked whales, records from the International Whaling Commission (IWC) (2005) show that a quarter (9 of 41) were associated with concurrent naval patrol, explosion, maneuvers, or MFAS. D'Amico *et al.* (2009) reviewed beaked whale stranding data compiled primarily from the published literature, which provides an incomplete record of stranding events, as many are not written up for publication, along with unpublished information from some regions of the world.

Most of the stranding events reviewed by the IWC involved beaked whales. A mass stranding of Cuvier's beaked whales in the eastern Mediterranean Sea occurred in 1996 (Frantzis, 1998), and mass stranding events involving Gervais' beaked whales, Blainville's beaked whales, and Cuvier's beaked whales occurred off the coast of the Canary Islands in the late 1980s (Simmonds and Lopez-Jurado, 1991). The stranding events that occurred in the Canary Islands and Kyparissiakos Gulf in the late 1990s and the Bahamas in 2000 have been the most intensively-studied mass stranding events and have been associated with naval maneuvers involving the use of tactical sonar. Other cetacean species with naval sonar implicated in stranding events include harbor porpoise (*Phocoena phocoena*) (Norman *et al.,* 2004, Wright *et al.,* 2013) and common dolphin (*Delphinus delphis*) (Jepson and Deaville 2009).

Strandings Associated With Impulsive Sound

Silver Strand

During a Navy training event on March 4, 2011 at the Silver Strand Training Complex in San Diego, California, three or possibly four dolphins were killed in an explosion. During an underwater detonation training event, a pod of 100 to 150 long-beaked common dolphins were observed moving towards the 700-yd (640.1 m) exclusion zone around the explosive charge, monitored by personnel in a safety boat and participants in a dive boat. Approximately five minutes remained on a time-delay fuse connected to a single 8.76 lb (3.97 kg) explosive charge (C–4 and detonation cord). Although the dive boat was placed between the pod and the explosive in an effort to guide the dolphins away from the area, that effort was unsuccessful and three long-beaked common dolphins near the explosion died. In addition to the three dolphins found dead on March 4, the remains of a fourth dolphin were discovered on March 7, 2011 near Oceanside, California (3 days later and approximately 68 km north of the detonation), which might also have been related to this event. Association of the

fourth stranding with the training event is uncertain because dolphins strand on a regular basis in the San Diego area. Details such as the dolphins' depth and distance from the explosive at the time of the detonation could not be estimated from the 250 yd (228.6 m) standoff point of the observers in the dive boat or the safety boat.

These dolphin mortalities are the only known occurrence of a U.S. Navy training or testing event involving impulsive energy (underwater detonation) that caused mortality or injury to a marine mammal. Despite this being a rare occurrence, the Navy reviewed training requirements, safety procedures, and possible mitigation measures and implemented changes to reduce the potential for this to occur in the future. Discussions of procedures associated with underwater explosives training and other training events are presented in the *Proposed Mitigation Measures* section.

Kyle of Durness, Scotland

On July 22, 2011 a mass stranding event involving long-finned pilot whales occurred at Kyle of Durness, Scotland. An investigation by Brownlow *et al.* (2015) considered unexploded ordnance detonation activities at a Ministry of Defense bombing range, conducted by the Royal Navy prior to and during the strandings, as a plausible contributing factor in the mass stranding event. While Brownlow *et al.* (2015) concluded that the serial detonations of underwater ordnance were an influential factor in the mass stranding event (along with the presence of a potentially compromised animal and navigational error in a topographically complex region), they also suggest that mitigation measures—which included observations from a zodiac only and by personnel not experienced in marine mammal observation, among other deficiencies—were likely insufficient to assess if cetaceans were in the vicinity of the detonations. The authors also cite information from the Ministry of Defense indicating ''an extraordinarily high level of activity'' (*i.e.,* frequency and intensity of underwater explosions) on the range in the days leading up to the stranding.

Gulf of California, Mexico

One stranding event was contemporaneous with and reasonably associated spatially with the use of seismic air guns. This event occurred in the Gulf of California, coincident with seismic reflection profiling by the R/V Maurice Ewing operated by Columbia University's Lamont-Doherty Earth Observatory and involved two Cuvier's beaked whales (Hildebrand, 2004). The vessel had been firing an array of 20 air guns with a total volume of 8,500 in^3 (Hildebrand, 2004; Taylor *et al.,* 2004).

Strandings Associated With Active Sonar

Over the past 21 years, there have been five stranding events coincident with U.S. Navy MF active sonar use in which exposure to sonar is believed to have been a contributing factor: Greece (1996); the Bahamas (2000); Madeira (2000); Canary Islands (2002); and Spain (2006) (Cox *et al.,* 2006; Fernandez, 2006; U.S. Navy Marine Mammal Program & Space and Naval Warfare Systems Command Center Pacific, 2017). These five mass strandings have resulted in about 40 known cetacean deaths consisting mostly of beaked whales and with close linkages to mid-frequency active sonar activity. In these circumstances, exposure to non-impulsive acoustic energy was considered a potential indirect cause of death of the marine mammals (Cox *et al.,* 2006). Only one of these stranding events, the Bahamas (2000), was associated with exercises conducted by the U.S. Navy. Additionally, in 2004, during the Rim of the Pacific (RIMPAC) exercises, between 150 and 200 usually pelagic melon-headed whales occupied the shallow waters of Hanalei Bay, Kauai, Hawaii for over 28 hours. NMFS determined that MFAS was a plausible, if not likely, contributing factor in what may have been a confluence of events that led to the Hanalei Bay stranding. A number of other stranding events coincident with the operation of MFAS, including the death of beaked whales or other species (minke whales, dwarf sperm whales, pilot whales), have been reported; however, the majority have not been investigated to the degree necessary to determine the cause of the stranding. Most recently, the Independent Scientific Review Panel investigating potential contributing factors to a 2008 mass stranding of melon-headed whales in Antsohihy, Madagascar released its final report suggesting that the stranding was likely initially triggered by an industry seismic survey (Southall *et al.,* 2013). This report suggests that the operation of a commercial high-powered 12 kHz multi-beam echosounder during an industry seismic survey was a plausible and likely initial trigger that caused a large group of melon-headed whales to leave their typical habitat and then ultimately strand as a result of secondary factors such as malnourishment and dehydration. The report indicates that the risk of this particular convergence of factors and ultimate outcome is likely very low, but recommends that the potential be considered in environmental planning. Because of the association between tactical mid-frequency active sonar use and a small number of marine mammal strandings, the Navy and NMFS have been considering and addressing the potential for strandings in association with Navy activities for years. In addition to the proposed mitigation measures intended to more broadly minimize impacts to marine mammals, the Navy will abide by the Notification and Reporting Plan, which sets out notification, reporting, and other requirements when dead, injured, or stranded marine mammals are detected in certain circumstances.

Greece (1996)

Twelve Cuvier's beaked whales stranded atypically (in both time and space) along a 38.2-km strand of the Kyparissiakos Gulf coast on May 12 and 13, 1996 (Frantzis, 1998). From May 11 through May 15, the North Atlantic Treaty Organization (NATO) research vessel Alliance was conducting sonar tests with signals of 600 Hz and 3 kHz and source levels of 228 and 226 dB re: 1µPa, respectively (D'Amico and Verboom, 1998; D'Spain *et al.,* 2006). The timing and location of the testing encompassed the time and location of the strandings (Frantzis, 1998).

Necropsies of eight of the animals were performed but were limited to basic external examination and sampling of stomach contents, blood, and skin. No ears or organs were collected, and no histological samples were preserved. No significant apparent abnormalities or wounds were found, however examination of photos of the animals, taken soon after their death, revealed that the eyes of at least four of the individuals were bleeding (Frantzis, 2004). Stomach contents contained the flesh of cephalopods, indicating that feeding had recently taken place (Frantzis, 1998).

All available information regarding the conditions associated with this stranding event was compiled, and many potential causes were examined including major pollution events, prominent tectonic activity, unusual physical or meteorological events, magnetic anomalies, epizootics, and conventional military activities (International Council for the Exploration of the Sea, 2005a). However, none of these potential causes coincided in time or space with the mass stranding, or could explain its characteristics (International Council for the Exploration of the Sea, 2005a). The robust condition of the animals, plus the

recent stomach contents, is inconsistent with pathogenic causes. In addition, environmental causes can be ruled out as there were no unusual environmental circumstances or events before or during this time period and within the general proximity (Frantzis, 2004).

Because of the rarity of this mass stranding of Cuvier's beaked whales in the Kyparissiakos Gulf (first one in historical records), the probability for the two events (the military exercises and the strandings) to coincide in time and location, while being independent of each other, was thought to be extremely low (Frantzis, 1998). However, because full necropsies had not been conducted, and no abnormalities were noted, the cause of the strandings could not be precisely determined (Cox *et al.,* 2006). A Bioacoustics Panel convened by NATO concluded that the evidence available did not allow them to accept or reject sonar exposures as a causal agent in these stranding events. The analysis of this stranding event provided support for, but no clear evidence for, the cause-and-effect relationship of tactical sonar training activities and beaked whale strandings (Cox *et al.,* 2006).

Bahamas (2000)

NMFS and the Navy prepared a joint report addressing the multi-species stranding in the Bahamas in 2000, which took place within 24 hrs of U.S. Navy ships using MFAS as they passed through the Northeast and Northwest Providence Channels on March 15–16, 2000. The ships, which operated both AN/SQS–53C and AN/SQS–56, moved through the channel while emitting sonar pings approximately every 24 seconds. Of the 17 cetaceans that stranded over a 36-hour period (Cuvier's beaked whales, Blainville's beaked whales, minke whales, and a spotted dolphin), seven animals died on the beach (five Cuvier's beaked whales, one Blainville's beaked whale, and the spotted dolphin), while the other 10 were returned to the water alive (though their ultimate fate is unknown). As discussed in the Bahamas report (DOC/DON, 2001), there is no likely association between the minke whale and spotted dolphin strandings and the operation of MFAS.

Necropsies were performed on five of the stranded beaked whales. All five necropsied beaked whales were in good body condition, showing no signs of infection, disease, ship strike, blunt trauma, or fishery related injuries, and three still had food remains in their stomachs. Auditory structural damage was discovered in four of the whales, specifically bloody effusions or hemorrhaging around the ears. Bilateral intracochlear and unilateral temporal region subarachnoid hemorrhage, with blood clots in the lateral ventricles, were found in two of the whales. Three of the whales had small hemorrhages in their acoustic fats (located along the jaw and in the melon).

A comprehensive investigation was conducted and all possible causes of the stranding event were considered, whether they seemed likely at the outset or not. Based on the way in which the strandings coincided with ongoing naval activity involving tactical MFAS use, in terms of both time and geography, the nature of the physiological effects experienced by the dead animals, and the absence of any other acoustic sources, the investigation team concluded that MFAS aboard U.S. Navy ships that were in use during the active sonar exercise in question were the most plausible source of this acoustic or impulse trauma to beaked whales. This sound source was active in a complex environment that included the presence of a surface duct, unusual and steep bathymetry, a constricted channel with limited egress, intensive use of multiple, active sonar units over an extended period of time, and the presence of beaked whales that appear to be sensitive to the frequencies produced by these active sonars. The investigation team concluded that the cause of this stranding event was the confluence of the Navy MFAS and these contributory factors working together, and further recommended that the Navy avoid operating MFAS in situations where these five factors would be likely to occur. This report does not conclude that all five of these factors must be present for a stranding to occur, nor that beaked whales are the only species that could potentially be affected by the confluence of the other factors. Based on this, NMFS believes that the operation of MFAS in situations where surface ducts exist, or in marine environments defined by steep bathymetry and/or constricted channels may increase the likelihood of producing a sound field with the potential to cause cetaceans (especially beaked whales) to strand, and therefore, suggests the need for increased vigilance while operating MFAS in these areas, especially when beaked whales (or potentially other deep divers) are likely present.

Madeira, Portugal (2000)

From May 10–14, 2000, three Cuvier's beaked whales were found atypically stranded on two islands in the Madeira archipelago, Portugal (Cox *et al.,* 2006). A fourth animal was reported floating in the Madeiran waters by fisherman but did not come ashore (Woods Hole Oceanographic Institution, 2005). Joint NATO amphibious training peacekeeping exercises involving participants from 17 countries and 80 warships, took place in Portugal during May 2–15, 2000.

The bodies of the three stranded whales were examined post mortem (Woods Hole Oceanographic Institution, 2005), though only one of the stranded whales was fresh enough (24 hours after stranding) to be necropsied (Cox *et al.,* 2006). Results from the necropsy revealed evidence of hemorrhage and congestion in the right lung and both kidneys (Cox *et al.,* 2006). There was also evidence of intercochlear and intracranial hemorrhage similar to that which was observed in the whales that stranded in the Bahamas event (Cox *et al.,* 2006). There were no signs of blunt trauma, and no major fractures (Woods Hole Oceanographic Institution, 2005). The cranial sinuses and airways were found to be clear with little or no fluid deposition, which may indicate good preservation of tissues (Woods Hole Oceanographic Institution, 2005).

Several observations on the Madeira stranded beaked whales, such as the pattern of injury to the auditory system, are the same as those observed in the Bahamas strandings. Blood in and around the eyes, kidney lesions, pleural hemorrhages, and congestion in the lungs are particularly consistent with the pathologies from the whales stranded in the Bahamas, and are consistent with stress and pressure related trauma. The similarities in pathology and stranding patterns between these two events suggest that a similar pressure event may have precipitated or contributed to the strandings at both sites (Woods Hole Oceanographic Institution, 2005).

Even though no definitive causal link can be made between the stranding event and naval exercises, certain conditions may have existed in the exercise area that, in their aggregate, may have contributed to the marine mammal strandings (Freitas, 2004): Exercises were conducted in areas of at least 547 fathoms (1,000 m) depth near a shoreline where there is a rapid change in bathymetry on the order of 547 to 3,281 fathoms (1,000 to 6,000 m) occurring across a relatively short horizontal distance (Freitas, 2004); multiple ships were operating around Madeira, though it is not known if MFAS was used, and the specifics of the sound sources used are unknown (Cox *et al.,* 2006, Freitas, 2004); and exercises took place in an area surrounded by landmasses separated by less than 35 nmi (65 km) and at least 10 nmi (19 km)

in length, or in an embayment. Exercises involving multiple ships employing MFAS near land may produce sound directed towards a channel or embayment that may cut off the lines of egress for marine mammals (Freitas, 2004).

Canary Islands, Spain (2002)

The southeastern area within the Canary Islands is well known for aggregations of beaked whales due to its ocean depths of greater than 547 fathoms (1,000 m) within a few hundred meters of the coastline (Fernandez *et al.,* 2005). On September 24, 2002, 14 beaked whales were found stranded on Fuerteventura and Lanzarote Islands in the Canary Islands (International Council for Exploration of the Sea, 2005a). Seven whales died, while the remaining seven live whales were returned to deeper waters (Fernandez *et al.,* 2005). Four beaked whales were found stranded dead over the next three days either on the coast or floating offshore. These strandings occurred within close proximity of an international naval exercise that utilized MFAS and involved numerous surface warships and several submarines. Strandings began about four hours after the onset of MFAS activity (International Council for Exploration of the Sea, 2005a; Fernandez *et al.,* 2005).

Eight Cuvier's beaked whales, one Blainville's beaked whale, and one Gervais' beaked whale were necropsied, 6 of them within 12 hours of stranding (Fernandez *et al.,* 2005). No pathogenic bacteria were isolated from the carcasses (Jepson *et al.,* 2003). The animals displayed severe vascular congestion and hemorrhage especially around the tissues in the jaw, ears, brain, and kidneys, displaying marked disseminated microvascular hemorrhages associated with widespread fat emboli (Jepson *et al.,* 2003; International Council for Exploration of the Sea, 2005a). Several organs contained intravascular bubbles, although definitive evidence of gas embolism in vivo is difficult to determine after death (Jepson *et al.,* 2003). The livers of the necropsied animals were the most consistently affected organ, which contained macroscopic gas-filled cavities and had variable degrees of fibrotic encapsulation. In some animals, cavitary lesions had extensively replaced the normal tissue (Jepson *et al.,* 2003). Stomachs contained a large amount of fresh and undigested contents, suggesting a rapid onset of disease and death (Fernandez *et al.,* 2005). Head and neck lymph nodes were enlarged and congested, and parasites were found in the kidneys of all animals (Fernandez *et al.,* 2005).

The association of NATO MFAS use close in space and time to the beaked whale strandings, and the similarity between this stranding event and previous beaked whale mass strandings coincident with sonar use, suggests that a similar scenario and causative mechanism of stranding may be shared between the events. Beaked whales stranded in this event demonstrated brain and auditory system injuries, hemorrhages, and congestion in multiple organs, similar to the pathological findings of the Bahamas and Madeira stranding events. In addition, the necropsy results of the Canary Islands stranding event lead to the hypothesis that the presence of disseminated and widespread gas bubbles and fat emboli were indicative of nitrogen bubble formation, similar to what might be expected in decompression sickness (Jepson *et al.,* 2003; Fernández *et al.,* 2005).

Hanalei Bay (2004)

On July 3 and 4, 2004, approximately 150 to 200 melon-headed whales occupied the shallow waters of Hanalei Bay, Kauai, Hawaii for over 28 hrs. Attendees of a canoe blessing observed the animals entering the Bay in a single wave formation at 7 a.m. on July 3, 2004. The animals were observed moving back into the shore from the mouth of the Bay at 9 a.m. The usually pelagic animals milled in the shallow bay and were returned to deeper water with human assistance beginning at 9:30 a.m. on July 4, 2004, and were out of sight by 10:30 a.m.

Only one animal, a calf, was known to have died following this event. The animal was noted alive and alone in the Bay on the afternoon of July 4, 2004, and was found dead in the Bay the morning of July 5, 2004. A full necropsy, magnetic resonance imaging, and computerized tomography examination were performed on the calf to determine the manner and cause of death. The combination of imaging, necropsy and histological analyses found no evidence of infectious, internal traumatic, congenital, or toxic factors. Cause of death could not be definitively determined, but it is likely that maternal separation, poor nutritional condition, and dehydration contributed to the final demise of the animal. Although it is not known when the calf was separated from its mother, the animals' movement into the Bay and subsequent milling and re-grouping may have contributed to the separation or lack of nursing, especially if the maternal bond was weak or this was an inexperienced mother with her first calf.

Environmental factors, abiotic and biotic, were analyzed for any anomalous occurrences that would have contributed to the animals entering and remaining in Hanalei Bay. The Bay's bathymetry is similar to many other sites within the Hawaiian Island chain and dissimilar to sites that have been associated with mass strandings in other parts of the United States. The weather conditions appeared to be normal for that time of year with no fronts or other significant features noted. There was no evidence of unusual distribution, occurrence of predator or prey species, or unusual harmful algal blooms, although Mobley *et al.* (2007) suggested that the full moon cycle that occurred at that time may have influenced a run of squid into the Bay. Weather patterns and bathymetry that have been associated with mass strandings elsewhere were not found to occur in this instance.

The Hanalei event was spatially and temporally correlated with RIMPAC. Official sonar training and tracking exercises in the Pacific Missile Range Facility (PMRF) warning area did not commence until approximately 8 a.m. on July 3 and were thus ruled out as a possible trigger for the initial movement into the bay. However, six naval surface vessels transiting to the operational area on July 2 intermittently transmitted active sonar (for approximately nine hours total from 1:15 p.m. to 12:30 a.m.) as they approached from the south. The potential for these transmissions to have triggered the whales' movement into Hanalei Bay was investigated. Analyses with the information available indicated that animals to the south and east of Kaua'i could have detected active sonar transmissions on July 2, and reached Hanalei Bay on or before 7 a.m. on July 3. However, data limitations regarding the position of the whales prior to their arrival in the Bay, the magnitude of sonar exposure, behavioral responses of melon-headed whales to acoustic stimuli, and other possible relevant factors preclude a conclusive finding regarding the role of sonar in triggering this event. Propagation modeling suggests that transmissions from sonar use during the July 3 exercise in the PMRF warning area may have been detectable at the mouth of the bay. If the animals responded negatively to these signals, it may have contributed to their continued presence in the bay. The U.S. Navy ceased all active sonar transmissions during exercises in this range on the afternoon of July 3. Subsequent to the cessation of sonar

use, the animals were herded out of the bay.

While causation of this stranding event may never be unequivocally determined, NMFS considers the active sonar transmissions of July 2–3, 2004, a plausible, if not likely, contributing factor in what may have been a confluence of events. This conclusion is based on the following: (1) The evidently anomalous nature of the stranding; (2) its close spatiotemporal correlation with wide-scale, sustained use of sonar systems previously associated with stranding of deep-diving marine mammals; (3) the directed movement of two groups of transmitting vessels toward the southeast and southwest coast of Kauai; (4) the results of acoustic propagation modeling and an analysis of possible animal transit times to the bay; and (5) the absence of any other compelling causative explanation. The initiation and persistence of this event may have resulted from an interaction of biological and physical factors. The biological factors may have included the presence of an apparently uncommon, deep-diving cetacean species (and possibly an offshore, non-resident group), social interactions among the animals before or after they entered the bay, and/or unknown predator or prey conditions. The physical factors may have included the presence of nearby deep water, multiple vessels transiting in a directed manner while transmitting active sonar over a sustained period, the presence of surface sound ducting conditions, and/or intermittent and random human interactions while the animals were in the bay.

A separate event involving melon-headed whales and rough-toothed dolphins took place over the same period of time in the Northern Mariana Islands (Jefferson *et al.,* 2006), which is several thousand miles from Hawaii. Some 500 to 700 melon-headed whales came into Sasanhaya Bay on July 4, 2004, near the island of Rota and then left of their own accord after 5.5 hours; no known active sonar transmissions occurred in the vicinity of that event. The Rota incident led to scientific debate regarding what, if any, relationship the event had to the simultaneous events in Hawaii and whether they might be related by some common factor (*e.g.,* there was a full moon on July 2, 2004, as well as during other melon-headed whale strandings and nearshore aggregations (Brownell *et al.,* 2009; Lignon *et al.,* 2007; Mobley *et al.,* 2007). Brownell *et al.* (2009) compared the two incidents, along with one other stranding incident at Nuka Hiva in French Polynesia and normal resting behaviors observed at Palmyra Island, in regard to physical features in the areas, melon-headed whale behavior, and lunar cycles. Brownell *et al.,* (2009) concluded that the rapid entry of the whales into Hanalei Bay, their movement into very shallow water far from the 100-m contour, their milling behavior (typical pre-stranding behavior), and their reluctance to leave the bay constituted an unusual event that was not similar to the events that occurred at Rota, which appear to be similar to observations of melon-headed whales resting normally at Palmyra Island. Additionally, there was no correlation between lunar cycle and the types of behaviors observed in the Brownell *et al.* (2009) examples.

Spain (2006)

The Spanish Cetacean Society reported an atypical mass stranding of four beaked whales that occurred January 26, 2006, on the southeast coast of Spain, near Mojácar (Gulf of Vera) in the Western Mediterranean Sea. According to the report, two of the whales were discovered the evening of January 26 and were found to be still alive. Two other whales were discovered during the day on January 27, but had already died. The first three animals were located near the town of Mojácar and the fourth animal was found dead, a few kilometers north of the first three animals. From January 25–26, 2006, Standing NATO Response Force Maritime Group Two (five of seven ships including one U.S. ship under NATO Operational Control) had conducted active sonar training against a Spanish submarine within 50 nmi (93 km) of the stranding site.

Veterinary pathologists necropsied the two male and two female Cuvier's beaked whales. According to the pathologists, the most likely primary cause of this type of beaked whale mass stranding event was anthropogenic acoustic activities, most probably anti-submarine MFAS used during the military naval exercises. However, no positive acoustic link was established as a direct cause of the stranding. Even though no causal link can be made between the stranding event and naval exercises, certain conditions may have existed in the exercise area that, in their aggregate, may have contributed to the marine mammal strandings (Freitas, 2004). Exercises were conducted in areas of at least 547 fathoms (1,000 m) depth near a shoreline where there is a rapid change in bathymetry on the order of 547 to 3,281 fathoms (1,000 to 6,000 m) occurring across a relatively short horizontal distance (Freitas, 2004). Multiple ships (in this instance, five) were operating MFAS in the same area over extended periods of time (in this case, 20 hours) in close proximity; and exercises took place in an area surrounded by landmasses, or in an embayment. Exercises involving multiple ships employing MFAS near land may have produced sound directed towards a channel or embayment that may have cut off the lines of egress for the affected marine mammals (Freitas, 2004).

Behaviorally Mediated Responses to MFAS That May Lead to Stranding

Although the confluence of Navy MFAS with the other contributory factors noted in the 2001 NMFS/Navy joint report was identified as the cause of the 2000 Bahamas stranding event, the specific mechanisms that led to that stranding (or the others) are not well understood, and there is uncertainty regarding the ordering of effects that led to the stranding. It is unclear whether beaked whales were directly injured by sound (*e.g.,* acoustically mediated bubble growth, as addressed above) prior to stranding or whether a behavioral response to sound occurred that ultimately caused the beaked whales to be injured and strand.

Although causal relationships between beaked whale stranding events and active sonar remain unknown, several authors have hypothesized that stranding events involving these species in the Bahamas and Canary Islands may have been triggered when the whales changed their dive behavior in a startled response to exposure to active sonar or to further avoid exposure (Cox *et al.,* 2006; Rommel *et al.,* 2006). These authors proposed three mechanisms by which the behavioral responses of beaked whales upon being exposed to active sonar might result in a stranding event. These include the following: Gas bubble formation caused by excessively fast surfacing; remaining at the surface too long when tissues are supersaturated with nitrogen; or diving prematurely when extended time at the surface is necessary to eliminate excess nitrogen. More specifically, beaked whales that occur in deep waters that are in close proximity to shallow waters (for example, the ''canyon areas'' that are cited in the Bahamas stranding event; see D'Spain and D'Amico, 2006), may respond to active sonar by swimming into shallow waters to avoid further exposures and strand if they were not able to swim back to deeper waters. Second, beaked whales exposed to active sonar might alter their dive behavior. Changes in their dive behavior might cause them to remain at the surface or at depth for extended periods

of time which could lead to hypoxia directly by increasing their oxygen demands or indirectly by increasing their energy expenditures (to remain at depth) and increase their oxygen demands as a result. If beaked whales are at depth when they detect a ping from an active sonar transmission and change their dive profile, this could lead to the formation of significant gas bubbles, which could damage multiple organs or interfere with normal physiological function (Cox *et al.,* 2006; Rommel *et al.,* 2006; Zimmer and Tyack, 2007). Baird *et al.* (2005) found that slow ascent rates from deep dives and long periods of time spent within 50 m of the surface were typical for both Cuvier's and Blainville's beaked whales, the two species involved in mass strandings related to naval sonar. These two behavioral mechanisms may be necessary to purge excessive dissolved nitrogen concentrated in their tissues during their frequent long dives (Baird *et al.,* 2005). Baird *et al.* (2005) further suggests that abnormally rapid ascents or premature dives in response to high-intensity sonar could indirectly result in physical harm to the beaked whales, through the mechanisms described above (gas bubble formation or non-elimination of excess nitrogen). In a review of the previously published data on the potential impacts of sonar on beaked whales, Bernaldo de Quirós *et al.* (2019) suggested that the effect of mid-frequency active sonar on beaked whales varies among individuals or populations, and that predisposing conditions such as previous exposure to sonar and individual health risk factors may contribute to individual outcomes (such as decompression sickness).

Because many species of marine mammals make repetitive and prolonged dives to great depths, it has long been assumed that marine mammals have evolved physiological mechanisms to protect against the effects of rapid and repeated decompressions. Although several investigators have identified physiological adaptations that may protect marine mammals against nitrogen gas supersaturation (alveolar collapse and elective circulation; Kooyman *et al.,* 1972; Ridgway and Howard, 1979), Ridgway and Howard (1979) reported that bottlenose dolphins that were trained to dive repeatedly had muscle tissues that were substantially supersaturated with nitrogen gas. Houser *et al.* (2001) used these data to model the accumulation of nitrogen gas within the muscle tissue of other marine mammal species and concluded that cetaceans that dive deep and have slow ascent or descent speeds would have tissues that are more supersaturated with nitrogen gas than other marine mammals. Based on these data, Cox *et al.* (2006) hypothesized that a critical dive sequence might make beaked whales more prone to stranding in response to acoustic exposures. The sequence began with (1) very deep (to depths as deep as 2 km) and long (as long as 90 minutes) foraging dives; (2) relatively slow, controlled ascents; and (3) a series of ''bounce'' dives between 100 and 400 m in depth (see also Zimmer and Tyack, 2007). They concluded that acoustic exposures that disrupted any part of this dive sequence (for example, causing beaked whales to spend more time at surface without the bounce dives that are necessary to recover from the deep dive) could produce excessive levels of nitrogen supersaturation in their tissues, leading to gas bubble and emboli formation that produces pathologies similar to decompression sickness.

Zimmer and Tyack (2007) modeled nitrogen tension and bubble growth in several tissue compartments for several hypothetical dive profiles and concluded that repetitive shallow dives (defined as a dive where depth does not exceed the depth of alveolar collapse, approximately 72 m for Cuvier's beaked whale), perhaps as a consequence of an extended avoidance reaction to sonar sound, could pose a risk for decompression sickness and that this risk should increase with the duration of the response. Their models also suggested that unrealistically rapid rates of ascent from normal dive behaviors are unlikely to result in supersaturation to the extent that bubble formation would be expected. Tyack *et al.* (2006) suggested that emboli observed in animals exposed to mid-frequency range sonar (Jepson *et al.,* 2003; Fernandez *et al.,* 2005; Fernández *et al.,* 2012) could stem from a behavioral response that involves repeated dives shallower than the depth of lung collapse. Given that nitrogen gas accumulation is a passive process (*i.e.,* nitrogen is metabolically inert), a bottlenose dolphin was trained to repetitively dive a profile predicted to elevate nitrogen saturation to the point that nitrogen bubble formation was predicted to occur. However, inspection of the vascular system of the dolphin via ultrasound did not demonstrate the formation of asymptomatic nitrogen gas bubbles (Houser *et al.,* 2007). Baird *et al.* (2008), in a beaked whale tagging study off Hawaii, showed that deep dives are equally common during day or night, but ''bounce dives'' are typically a daytime behavior, possibly associated with visual predator avoidance. This may indicate that ''bounce dives'' are associated with something other than behavioral regulation of dissolved nitrogen levels, which would be necessary day and night.

If marine mammals respond to a Navy vessel that is transmitting active sonar in the same way that they might respond to a predator, their probability of flight responses could increase when they perceive that Navy vessels are approaching them directly, because a direct approach may convey detection and intent to capture (Burger and Gochfeld, 1981, 1990; Cooper, 1997, 1998). The probability of flight responses could also increase as received levels of active sonar increase (and the ship is, therefore, closer) and as ship speeds increase (that is, as approach speeds increase). For example, the probability of flight responses in Dall's sheep (*Ovis dalli dalli*) (Frid 2001a, b), ringed seals (*Phoca hispida*) (Born *et al.,* 1999), Pacific brant (*Branta bernic nigricans*) and Canada geese (*B. canadensis*) increased as a helicopter or fixed-wing aircraft approached groups of these animals more directly (Ward *et al.,* 1999). Bald eagles (*Haliaeetus leucocephalus*) perched on trees alongside a river were also more likely to flee from a paddle raft when their perches were closer to the river or were closer to the ground (Steidl and Anthony, 1996).

Despite the many theories involving bubble formation (both as a direct cause of injury, see *Acoustically-Induced Bubble Formation Due to Sonars and Other Pressure-related Injury* section and an indirect cause of stranding), Southall *et al.* (2007) summarizes that there is either scientific disagreement or a lack of information regarding each of the following important points: (1) Received acoustical exposure conditions for animals involved in stranding events; (2) pathological interpretation of observed lesions in stranded marine mammals; (3) acoustic exposure conditions required to induce such physical trauma directly; (4) whether noise exposure may cause behavioral reactions (such as atypical diving behavior) that secondarily cause bubble formation and tissue damage; and (5) the extent the post mortem artifacts introduced by decomposition before sampling, handling, freezing, or necropsy procedures affect interpretation of observed lesions.

Strandings in the NWTT Study Area

Stranded marine mammals are reported along the entire western coast of the United States each year. Marine mammals strand due to natural or

anthropogenic causes; the majority of reported type of occurrences in marine mammal strandings in this region include fishery interactions, illness, predation, and vessel strikes (Carretta *et al.,* 2017b; Helker *et al.,* 2017; National Marine Fisheries Service, 2016). Stranding events that are associated with active UMEs on the Northwest Coast of the United States (inclusive of the NWTT Study Area) were previously discussed in the *Description of Marine Mammals and Their Habitat in the Area of the Specified Activities* section.

From 2007–2016, 43,125 marine mammal strandings were confirmed by the West Coast Marine Mammal Stranding Network including 33,569 in California (including areas outside the NWTT Study Area), 3,776 in Oregon, and 5,780 in Washington (10 year Data Summary Report, West Coast Marine Mammal Stranding Network 2017). The most common marine mammal to strand in the NWTT Study Area was pinnipeds, which comprise 94 percent of strandings in California, 90 percent of strandings in Oregon, and 89 percent of strandings in Washington. The next most common group was odontocetes, with harbor porpoises being the most common species. Gray whales were reported to be the most common large whale species to strand on the U.S. West Coast in all states. Where evidence of human interaction can be determined (9 percent as reported in the 10-year summary), the most common source of interaction on the U.S. West Coast was fishery interaction for pinnipeds, small cetaceans and large whales. The Behm Canal portion of the Study Area is a very small portion of the Southeast Regional Subarea of the Alaska Marine Mammal Stranding Network. A 10-year summary report is not available in this region however, in 2019 there were 40 confirmed strandings in the entire Southeast Regional Subarea, and 30 of these strandings were harbor seals or Steller sea lions.

One stranding event has been investigated for a possible link to Navy activities in the NWTT Study Area. Between May 2 and June 2, 2003, approximately 16 strandings involving 15 harbor porpoises and one Dall's porpoise in the Eastern Strait of Juan de Fuca and Haro Strait were reported to the Northwest Marine Mammal Stranding Network. Given that the USS SHOUP was known to have operated sonar in the Haro strait on May 5, 2003, and that behavioral reactions of killer whales were possibly linked to these sonar operations, NMFS undertook an analysis of whether sonar caused the strandings of the porpoises (National Marine Fisheries Service, 2005). NMFS determined that the 2003 strandings and similar harbor porpoise strandings over the following years were normal given a number of factors as described in Huggins *et al.* (2015). The 2015 NWTT FEIS/OEIS includes a comprehensive review of all strandings and the events involving the USS SHOUP on May 5, 2003. Additional information on this event is available in the Navy's Technical Report on Marine Mammal Strandings Associated with U.S. Navy Sonar Activities (U.S. Department of the Navy, 2017b). In the years since the SHOUP incident, annual numbers of stranded porpoises have been comparable (and sometimes higher) and have also shown similar causes of death (when determinable) to the causes of death noted in the SHOUP investigation (Huggins *et al.,* 2015).

Marine Mammal Habitat

The Navy's proposed training and testing activities could potentially affect marine mammal habitat through the introduction of impacts to the prey species of marine mammals, acoustic habitat (sound in the water column), water quality, and biologically important habitat for marine mammals. Each of these potential effects was considered in the 2019 NWTT DSEIS/OEIS and was determined by the Navy to have no effect on marine mammal habitat. Based on the information below and the supporting information included in the 2019 NWTT DSEIS/OEIS, NMFS has determined that the proposed training and training activities would not have adverse or long-term impacts on marine mammal habitat.

Effects to Prey

Sound may affect marine mammals through impacts on the abundance, behavior, or distribution of prey species (*e.g.,* crustaceans, cephalopods, fish, zooplankton). Marine mammal prey varies by species, season, and location and, for some species, is not well documented. Here, we describe studies regarding the effects of noise on known marine mammal prey.

Fish utilize the soundscape and components of sound in their environment to perform important functions such as foraging, predator avoidance, mating, and spawning (*e.g.,* Zelick *et al.,* 1999; Fay, 2009). The most likely effects on fishes exposed to loud, intermittent, low-frequency sounds are behavioral responses (*i.e.,* flight or avoidance). Short duration, sharp sounds (such as pile driving or air guns) can cause overt or subtle changes in fish behavior and local distribution. The reaction of fish to acoustic sources depends on the physiological state of the fish, past exposures, motivation (*e.g.,* feeding, spawning, migration), and other environmental factors. Key impacts to fishes may include behavioral responses, hearing damage, barotrauma (pressure-related injuries), and mortality.

Fishes, like other vertebrates, have a variety of different sensory systems to glean information from ocean around them (Astrup and Mohl, 1993; Astrup, 1999; Braun and Grande, 2008; Carroll *et al.,* 2017; Hawkins and Johnstone, 1978; Ladich and Popper, 2004; Ladich and Schulz-Mirbach, 2016; Mann, 2016; Nedwell *et al.,* 2004; Popper *et al.,* 2003; Popper *et al.,* 2005). Depending on their hearing anatomy and peripheral sensory structures, which vary among species, fishes hear sounds using pressure and particle motion sensitivity capabilities and detect the motion of surrounding water (Fay *et al.,* 2008) (terrestrial vertebrates generally only detect pressure). Most marine fishes primarily detect particle motion using the inner ear and lateral line system, while some fishes possess additional morphological adaptations or specializations that can enhance their sensitivity to sound pressure, such as a gas-filled swim bladder (Braun and Grande, 2008; Popper and Fay, 2011).

Hearing capabilities vary considerably between different fish species with data only available for just over 100 species out of the 34,000 marine and freshwater fish species (Eschmeyer and Fong, 2016). In order to better understand acoustic impacts on fishes, fish hearing groups are defined by species that possess a similar continuum of anatomical features which result in varying degrees of hearing sensitivity (Popper and Hastings, 2009a). There are four hearing groups defined for all fish species (modified from Popper *et al.,* 2014) within this analysis and they include: Fishes without a swim bladder (*e.g.,* flatfish, sharks, rays, *etc.*); fishes with a swim bladder not involved in hearing (*e.g.,* salmon, cod, pollock, *etc.*); fishes with a swim bladder involved in hearing (*e.g.,* sardines, anchovy, herring, *etc.*); and fishes with a swim bladder involved in hearing and high-frequency hearing (*e.g.,* shad and menhaden). Most marine mammal fish prey species would not be likely to perceive or hear Navy mid- or high-frequency sonars. While hearing studies have not been done on sardines and northern anchovies, it would not be unexpected for them to possess hearing similarities to Pacific herring (up to 2–5 kHz) (Mann *et al.,* 2005). Currently, less data are available to estimate the range of best sensitivity for fishes without a swim bladder.

In terms of physiology, multiple scientific studies have documented a lack of mortality or physiological effects to fish from exposure to low- and mid-frequency sonar and other sounds (Halvorsen *et al.,* 2012; Jørgensen *et al.,* 2005; Juanes *et al.,* 2017; Kane *et al.,* 2010; Kvadsheim and Sevaldsen, 2005; Popper *et al.,* 2007; Popper *et al.,* 2016; Watwood *et al.,* 2016). Techer *et al.* (2017) exposed carp in floating cages for up to 30 days to low-power 23 and 46 kHz sources without any significant physiological response. Other studies have documented either a lack of TTS in species whose hearing range cannot perceive Navy sonar, or for those species that could perceive sonar-like signals, any TTS experienced would be recoverable (Halvorsen *et al.,* 2012; Ladich and Fay, 2013; Popper and Hastings, 2009a, 2009b; Popper *et al.,* 2014; Smith, 2016). Only fishes that have specializations that enable them to hear sounds above about 2,500 Hz (2.5 kHz) such as herring (Halvorsen *et al.,* 2012; Mann *et al.,* 2005; Mann, 2016; Popper *et al.,* 2014) would have the potential to receive TTS or exhibit behavioral responses from exposure to mid-frequency sonar. In addition, any sonar induced TTS to fish whose hearing range could perceive sonar would only occur in the narrow spectrum of the source (*e.g.,* 3.5 kHz) compared to the fish's total hearing range (*e.g.,* 0.01 kHz to 5 kHz). Overall, Navy sonar sources are much narrower in terms of source frequency compared to a given fish species full hearing range (Halvorsen *et al.,* 2012; Jørgensen *et al.,* 2005; Juanes *et al.,* 2017; Kane *et al.,* 2010; Kvadsheim & Sevaldsen, 2005; Popper *et al.,* 2007; Popper and Hawkins, 2016; Watwood *et al.,* 2016).

In terms of behavioral responses, Juanes *et al.* (2017) discuss the potential for negative impacts from anthropogenic soundscapes on fish, but the author's focus was on broader based sounds such as ship and boat noise sources. Watwood *et al.* (2016) also documented no behavioral responses by reef fish after exposure to mid-frequency active sonar. Doksaeter *et al.* (2009; 2012) reported no behavioral responses to mid-frequency naval sonar by Atlantic herring; specifically, no escape reactions (vertically or horizontally) were observed in free swimming herring exposed to mid-frequency sonar transmissions. Based on these results (Doksaeter *et al.,* 2009; Doksaeter *et al.,* 2012; Sivle *et al.,* 2012), Sivle *et al.* (2014) created a model in order to report on the possible population-level effects on Atlantic herring from active naval sonar. The authors concluded that the use of naval sonar poses little risk to populations of herring regardless of season, even when the herring populations are aggregated and directly exposed to sonar. Finally, Bruintjes *et al.* (2016) commented that fish exposed to any short-term noise within their hearing range might initially startle, but would quickly return to normal behavior.

Occasional behavioral reactions to intermittent explosions and impulsive sound sources are unlikely to cause long-term consequences for individual fish or populations. Fish that experience hearing loss as a result of exposure to explosions and impulsive sound sources may have a reduced ability to detect relevant sounds such as predators, prey, or social vocalizations. However, PTS has not been known to occur in fishes and any hearing loss in fish may be as temporary as the timeframe required to repair or replace the sensory cells that were damaged or destroyed (Popper *et al.,* 2005; Popper *et al.,* 2014; Smith *et al.,* 2006). It is not known if damage to auditory nerve fibers could occur, and if so, whether fibers would recover during this process. It is also possible for fish to be injured or killed by an explosion in the immediate vicinity of the surface from dropped or fired ordnance, or near the bottom from shallow water bottom-placed underwater mine warfare detonations. Physical effects from pressure waves generated by underwater sounds (*e.g.,* underwater explosions) could potentially affect fish within proximity of training or testing activities. SPLs of sufficient strength have been known to cause injury to fish and fish mortality (summarized in Popper *et al.,* 2014). The shock wave from an underwater explosion is lethal to fish at close range, causing massive organ and tissue damage and internal bleeding (Keevin and Hempen, 1997). At greater distance from the detonation point, the extent of mortality or injury depends on a number of factors including fish size, body shape, orientation, and species (Keevin and Hempen, 1997; Wright, 1982). At the same distance from the source, larger fish are generally less susceptible to death or injury, elongated forms that are round in cross-section are less at risk than deep-bodied forms, and fish oriented sideways to the blast suffer the greatest impact (Edds-Walton and Finneran, 2006; O'Keeffe, 1984; O'Keeffe and Young, 1984; Wiley *et al.,* 1981; Yelverton *et al.,* 1975). Species with gas-filled organs are more susceptible to injury and mortality than those without them (Gaspin, 1975; Gaspin *et al.,* 1976; Goertner *et al.,* 1994). Barotrauma injuries have been documented during controlled exposure to impact pile driving (an impulsive noise source, as are explosives and air guns) (Halvorsen *et al.,* 2012b; Casper *et al.,* 2013).

Fish not killed or driven from a location by an explosion might change their behavior, feeding pattern, or distribution. Changes in behavior of fish have been observed as a result of sound produced by explosives, with effect intensified in areas of hard substrate (Wright, 1982). However, Navy explosive use avoids hard substrate to the best extent practical during underwater detonations, or deep-water surface detonations. Stunning from pressure waves could also temporarily immobilize fish, making them more susceptible to predation. The abundances of various fish (and invertebrates) near the detonation point for explosives could be altered for a few hours before animals from surrounding areas repopulate the area. However, these populations would likely be replenished as waters near the detonation point are mixed with adjacent waters. Repeated exposure of individual fish to sounds from underwater explosions is not likely and exposures are expected to be short-term and localized. Long-term consequences for fish populations would not be expected.

For fishes exposed to Navy sonar, there would be limited sonar use spread out in time and space across large offshore areas such that only small areas are actually ensonified (tens of miles) compared to the total life history distribution of fish prey species. There would be no probability for mortality or physical injury from sonar, and for most species, no or little potential for hearing or behavioral effects, except to a few select fishes with hearing specializations (*e.g.,* herring) that could perceive mid-frequency sonar. Training and testing exercises involving explosions are dispersed in space and time; therefore, repeated exposure of individual fishes are unlikely. Mortality and injury effects to fishes from explosives would be localized around the area of a given in-water explosion, but only if individual fish and the explosive (and immediate pressure field) were co-located at the same time. Fishes deeper in the water column or on the bottom would not be affected by water surface explosions. Repeated exposure of individual fish to sound and energy from underwater explosions is not likely given fish movement patterns, especially schooling prey species. Most acoustic effects, if any, are expected to be short-term and localized.

Long-term consequences for fish populations, including key prey species within the NWTT Study Area, would not be expected.

Vessels and in-water devices do not normally collide with adult fish, most of which can detect and avoid them. Exposure of fishes to vessel strike stressors is limited to those fish groups that are large, slow-moving, and may occur near the surface, such as ocean sunfish, whale sharks, basking sharks, and manta rays. These species are distributed widely in offshore portions of the NWTT Study Area. Any isolated cases of a Navy vessel striking an individual could injure that individual, impacting the fitness of an individual fish. Vessel strikes would not pose a risk to most of the other marine fish groups, because many fish can detect and avoid vessel movements, making strikes rare and allowing the fish to return to their normal behavior after the ship or device passes. As a vessel approaches a fish, they could have a detectable behavioral or physiological response (*e.g.,* swimming away and increased heart rate) as the passing vessel displaces them. However, such reactions are not expected to have lasting effects on the survival, growth, recruitment, or reproduction of these marine fish groups at the population level and therefore would not have an impact on marine mammal species as prey items.

In addition to fish, prey sources such as marine invertebrates could potentially be impacted by sound stressors as a result of the proposed activities. However, most marine invertebrates' ability to sense sounds is very limited. In most cases, marine invertebrates would not respond to impulsive and non-impulsive sounds, although they may detect and briefly respond to nearby low-frequency sounds. These short-term responses would likely be inconsequential to invertebrate populations.

Invertebrates appear to be able to detect sounds (Pumphrey, 1950; Frings and Frings, 1967) and are most sensitive to low-frequency sounds (Packard *et al.,* 1990; Budelmann and Williamson, 1994; Lovell *et al.,* 2005; Mooney *et al.,* 2010). Data on response of invertebrates such as squid, another marine mammal prey species, to anthropogenic sound is more limited (de Soto, 2016; Sole *et al.,* 2017b). Data suggest that cephalopods are capable of sensing the particle motion of sounds and detect low frequencies up to 1–1.5 kHz, depending on the species, and so are likely to detect air gun noise (Kaifu *et al.,* 2008; Hu *et al.,* 2009; Mooney *et al.,* 2010; Samson *et al.,* 2014). Sole *et al.* (2017b) reported physiological injuries to cuttlefish in cages placed at-sea when exposed during a controlled exposure experiment to low-frequency sources (315 Hz, 139 to 142 dB re: 1 μPa^2 and 400 Hz, 139 to 141 dB re: 1 μPa^2). Fewtrell and McCauley (2012) reported squids maintained in cages displayed startle responses and behavioral changes when exposed to seismic air gun sonar (136–162 re: 1 $\mu Pa^2 \cdot s$). However, the sources Sole *et al.* (2017a) and Fewtrell and McCauley (2012) used are not similar and were much lower than typical Navy sources within the NWTT Study Area. Nor do the studies address the issue of individual displacement outside of a zone of impact when exposed to sound. Cephalopods have a specialized sensory organ inside the head called a statocyst that may help an animal determine its position in space (orientation) and maintain balance (Budelmann, 1992). Packard *et al.* (1990) showed that cephalopods were sensitive to particle motion, not sound pressure, and Mooney *et al.* (2010) demonstrated that squid statocysts act as an accelerometer through which particle motion of the sound field can be detected. Auditory injuries (lesions occurring on the statocyst sensory hair cells) have been reported upon controlled exposure to low-frequency sounds, suggesting that cephalopods are particularly sensitive to low-frequency sound (Andre *et al.,* 2011; Sole *et al.,* 2013). Behavioral responses, such as inking and jetting, have also been reported upon exposure to low-frequency sound (McCauley *et al.,* 2000b; Samson *et al.,* 2014). Squids, like most fish species, are likely more sensitive to low frequency sounds, and may not perceive mid- and high-frequency sonars such as Navy sonars. Cumulatively for squid as a prey species, individual and population impacts from exposure to Navy sonar and explosives, like fish, are not likely to be significant, and explosive impacts would be short-term and localized.

Explosions could kill or injure nearby marine invertebrates. Vessels also have the potential to impact marine invertebrates by disturbing the water column or sediments, or directly striking organisms (Bishop, 2008). The propeller wash (water displaced by propellers used for propulsion) from vessel movement and water displaced from vessel hulls can potentially disturb marine invertebrates in the water column and is a likely cause of zooplankton mortality (Bickel *et al.,* 2011). The localized and short-term exposure to explosions or vessels could displace, injure, or kill zooplankton, invertebrate eggs or larvae, and macro-invertebrates. However, mortality or long-term consequences for a few animals is unlikely to have measurable effects on overall populations. Long-term consequences to marine invertebrate populations would not be expected as a result of exposure to sounds of vessels in the NWTT Study Area.

Impacts to benthic communities from impulsive sound generated by active acoustic sound sources are not well documented. (*e.g.,* Andriguetto-Filho *et al.,* 2005; Payne *et al.,* 2007; 2008; Boudreau *et al.,* 2009). There are no published data that indicate whether temporary or permanent threshold shifts, auditory masking, or behavioral effects occur in benthic invertebrates (Hawkins *et al.,* 2014) and some studies showed no short-term or long-term effects of air gun exposure (*e.g.,* Andriguetto-Filho *et al.,* 2005; Payne *et al.,* 2007; 2008; Boudreau *et al.,* 2009). Exposure to air gun signals was found to significantly increase mortality in scallops, in addition to causing significant changes in behavioral patterns during exposure (Day *et al.,* 2017). However, the authors state that the observed levels of mortality were not beyond naturally occurring rates. Explosions and pile driving could potentially kill or injure nearby marine invertebrates; however, mortality or long-term consequences for a few animals is unlikely to have measurable effects on overall populations.

There is little information concerning potential impacts of noise on zooplankton populations. However, one recent study (McCauley *et al.,* 2017) investigated zooplankton abundance, diversity, and mortality before and after exposure to air gun noise, finding that the mortality rate for zooplankton after airgun exposure was two to three times more compared with controls for all taxa. The majority of taxa present were copepods and cladocerans; for these taxa, the range within which effects on abundance were detected was up to approximately 1.2 km. In order to have significant impacts on *r*-selected species such as plankton, the spatial or temporal scale of impact must be large in comparison with the ecosystem concerned (McCauley *et al.,* 2017). Therefore, the large scale of effect observed here is of concern—particularly where repeated noise exposure is expected—and further study is warranted.

Military expended materials resulting from training and testing activities could potentially result in minor long-term changes to benthic habitat, however the impacts of small amount of expended materials are unlikely to have

measurable effects on overall populations. Military expended materials may be colonized over time by benthic organisms that prefer hard substrate and would provide structure that could attract some species of fish or invertebrates.

Overall, the combined impacts of sound exposure, explosions, vessel strikes, and military expended materials resulting from the proposed activities would not be expected to have measurable effects on populations of marine mammal prey species. Prey species exposed to sound might move away from the sound source, experience TTS, experience masking of biologically relevant sounds, or show no obvious direct effects. Mortality from decompression injuries is possible in close proximity to a sound, but only limited data on mortality in response to air gun noise exposure are available (Hawkins *et al.,* 2014). The most likely impacts for most prey species in a given area would be temporary avoidance of the area. Surveys using towed air gun arrays move through an area relatively quickly, limiting exposure to multiple impulsive sounds. In all cases, sound levels would return to ambient once a survey ends and the noise source is shut down and, when exposure to sound ends, behavioral and/or physiological responses are expected to end relatively quickly (McCauley *et al.,* 2000b). The duration of fish avoidance of a given area after survey effort stops is unknown, but a rapid return to normal recruitment, distribution, and behavior is anticipated. While the potential for disruption of spawning aggregations or schools of important prey species can be meaningful on a local scale, the mobile and temporary nature of most surveys and the likelihood of temporary avoidance behavior suggest that impacts would be minor. Long-term consequences to marine invertebrate populations would not be expected as a result of exposure to sounds or vessels in the NWTT Study Area.

Acoustic Habitat

Acoustic habitat is the soundscape which encompasses all of the sound present in a particular location and time, as a whole when considered from the perspective of the animals experiencing it. Animals produce sound for, or listen for sounds produced by, conspecifics (communication during feeding, mating, and other social activities), other animals (finding prey or avoiding predators), and the physical environment (finding suitable habitats, navigating). Together, sounds made by animals and the geophysical environment (*e.g.,* produced by earthquakes, lightning, wind, rain, waves) make up the natural contributions to the total acoustics of a place. These acoustic conditions, termed acoustic habitat, are one attribute of an animal's total habitat.

Soundscapes are also defined by, and acoustic habitat influenced by, the total contribution of anthropogenic sound. This may include incidental emissions from sources such as vessel traffic or may be intentionally introduced to the marine environment for data acquisition purposes (as in the use of air gun arrays) or for Navy training and testing purposes (as in the use of sonar and explosives and other acoustic sources). Anthropogenic noise varies widely in its frequency, content, duration, and loudness, and these characteristics greatly influence the potential habitat-mediated effects to marine mammals (please also see the previous discussion on ''Masking''), which may range from local effects for brief periods of time to chronic effects over large areas and for long durations. Depending on the extent of effects to habitat, animals may alter their communications signals (thereby potentially expending additional energy) or miss acoustic cues (either conspecific or adventitious). Problems arising from a failure to detect cues are more likely to occur when noise stimuli are chronic and overlap with biologically relevant cues used for communication, orientation, and predator/prey detection (Francis and Barber, 2013). For more detail on these concepts see, *e.g.,* Barber *et al.,* 2009; Pijanowski *et al.,* 2011; Francis and Barber, 2013; Lillis *et al.,* 2014.

The term ''listening area'' refers to the region of ocean over which sources of sound can be detected by an animal at the center of the space. Loss of communication space concerns the area over which a specific animal signal (used to communicate with conspecifics in biologically important contexts such as foraging or mating) can be heard, in noisier relative to quieter conditions (Clark *et al.,* 2009). Lost listening area concerns the more generalized contraction of the range over which animals would be able to detect a variety of signals of biological importance, including eavesdropping on predators and prey (Barber *et al.,* 2009). Such metrics do not, in and of themselves, document fitness consequences for the marine animals that live in chronically noisy environments. Long-term population-level consequences mediated through changes in the ultimate survival and reproductive success of individuals are difficult to study, and particularly so underwater. However, it is increasingly well documented that aquatic species rely on qualities of natural acoustic habitats, with researchers quantifying reduced detection of important ecological cues (*e.g.,* Francis and Barber, 2013; Slabbekoorn *et al.,* 2010) as well as survivorship consequences in several species (*e.g.,* Simpson *et al.,* 2014; Nedelec *et al.,* 2015).

The sounds produced during training and testing activities can be widely dispersed or concentrated in small areas for varying periods. Sound produced from training and testing activities in the NWTT Study Area is temporary and transitory. Any anthropogenic noise attributed to training and testing activities in the NWTT Study Area would be temporary and the affected area would be expected to immediately return to the original state when these activities cease.

Water Quality

Training and testing activities may introduce water quality constituents into the water column. Based on the analysis of the 2019 NWTT DSEIS/OEIS, military expended materials (*e.g.,* undetonated explosive materials) would be released in quantities and at rates that would not result in a violation of any water quality standard or criteria. NMFS has reviewed this analysis and concurs that it reflects the best available science. High-order explosions consume most of the explosive material, creating typical combustion products. For example, in the case of Royal Demolition Explosive, 98 percent of the products are common seawater constituents and the remainder is rapidly diluted below threshold effect level. Explosion by-products associated with high order detonations present no secondary stressors to marine mammals through sediment or water. However, low order detonations and unexploded ordnance present elevated likelihood of impacts on marine mammals.

Indirect effects of explosives and unexploded ordnance to marine mammals via sediment is possible in the immediate vicinity of the ordnance. Degradation products of Royal Demolition Explosive are not toxic to marine organisms at realistic exposure levels (Rosen and Lotufo, 2010). Relatively low solubility of most explosives and their degradation products means that concentrations of these contaminants in the marine environment are relatively low and readily diluted. Furthermore, while explosives and their degradation products were detectable in marine sediment approximately 6–12 in (0.15–0.3 m) away from degrading ordnance, the concentrations of these compounds

were not statistically distinguishable from background beyond 3–6 ft (1–2 m) from the degrading ordnance. Taken together, it is possible that marine mammals could be exposed to degrading explosives, but it would be within a very small radius of the explosive (1–6 ft (0.3–2 m)).

Equipment used by the Navy within the NWTT Study Area, including ships and other marine vessels, aircraft, and other equipment, are also potential sources of by-products. All equipment is properly maintained in accordance with applicable Navy and legal requirements. All such operating equipment meets Federal water quality standards, where applicable.

Estimated Take of Marine Mammals

This section indicates the number of takes that NMFS is proposing to authorize, which is based on the amount of take that NMFS anticipates could occur or the maximum amount that is reasonably 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 preliminarily agrees that the methods the Navy has put forth described herein to estimate take (including the model, thresholds, and density estimates), and the resulting numbers estimated for authorization, are appropriate and based on the best available science.

Takes would be predominantly in the form of harassment, but a small number of mortalities are also possible. For a military readiness activity, 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).

Proposed authorized takes would primarily be in the form of Level B harassment, as use of the acoustic and explosive sources (*i.e.,* sonar and explosives) is most 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. There is also the potential for Level A harassment, in the form of auditory injury to result from exposure to the sound sources utilized in training and testing activities. Lastly, no more than three serious injuries or mortalities total (over the seven-year period) of large whales could potentially occur through vessel collisions. Although we analyze the impacts of these potential serious injuries or mortalities that are proposed for authorization, the proposed mitigation and monitoring measures are expected to minimize the likelihood (*i.e.,* further lower the already low probability) that ship strike (and the associated serious injury or mortality) would occur.

Generally speaking, for acoustic impacts NMFS estimates 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) the number of days of activities or events.

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 take by 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 behavioral Level B harassment thresholds have been refined to better consider the best available science (*e.g.,* incorporating both received level and distance), they also still have some built-in conservative factors 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. We describe the application of this Level B 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. In summary, we believe these behavioral Level B harassment thresholds are the most appropriate method for predicting behavioral Level B harassment given the best available science and the associated uncertainty.

Hearing Impairment (TTS/PTS) and Tissue Damage and Mortality

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) and impulsive (explosives) sources.

These thresholds (Tables 10 and 11) 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 10—ACOUSTIC THRESHOLDS IDENTIFYING THE ONSET OF TTS AND PTS FOR NON-IMPULSIVE SOUND SOURCES BY FUNCTIONAL HEARING GROUPS

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
Otarid Pinnipeds (Underwater)	199	219

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 11 to predict the onset of TTS, PTS, tissue damage, and mortality for explosives (impulsive) and other impulsive sound sources.

TABLE 11—ONSET OF TTS, PTS, TISSUE DAMAGE, AND MORTALITY THRESHOLDS FOR MARINE MAMMALS FOR EXPLOSIVES

Functional hearing group	Species	Weighted onset TTS [1]	Weighted onset PTS	Mean onset slight GI tract injury	Mean onset slight lung injury	Mean onset mortality
Low-frequency cetaceans.	All mysticetes	168 dB SEL or 213 dB Peak SPL.	183 dB SEL or 219 dB Peak SPL.	237 dB Peak SPL	Equation 1	Equation 2.
Mid-frequency cetaceans.	Most delphinids, medium and large toothed whales.	170 dB SEL or 224 dB Peak SPL.	185 dB SEL or 230 dB Peak SPL.	237 dB Peak SPL.		
High-frequency cetaceans.	Porpoises and *Kogia spp.*	140 dB SEL or 196 dB Peak SPL.	155 dB SEL or 202 dB Peak SPL.	237 dB Peak SPL.		
Phocidae	Harbor seal, Hawaiian monk seal, Northern elephant seal.	170 dB SEL or 212 dB Peak SPL.	185 dB SEL or 218 dB Peak SPL.	237 dB Peak SPL.		
Otariidae	California sea lion, Guadalupe fur seal, Northern fur seal.	188 dB SEL or 226 dB Peak SPL.	203 dB SEL or 232 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.
[1] Peak thresholds are unweighted.

The criteria used to assess the onset of TTS and PTS due to exposure to sonars (non-impulsive, see Table 10 above) are discussed further in the Navy's rulemaking/LOA application (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). Refer to the ''Criteria and Thresholds for U.S. Navy Acoustic and Explosive Effects Analysis (Phase III)'' report (U.S. Department of the Navy, 2017c) 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 under the *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 (Ellison *et al.,* 2011; Southall *et al.,* 2007). 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.

Sonar

As noted above, the Navy coordinated with NMFS to develop Level B behavioral harassment thresholds specific to their military readiness activities utilizing active sonar. These behavioral response thresholds are used to estimate the number of animals that

may exhibit a behavioral response that rises to the level of a take when exposed to sonar and other transducers. The way the criteria were derived is discussed in detail in the ''Criteria and Thresholds for U.S. Navy Acoustic and Explosive Effects Analysis (Phase III)'' report (U.S. Department of the Navy, 2017c). Developing the 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 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 for calculating take and to support the determinations made in this proposed rule.

As discussed 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; and 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 used 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 behavioral Level B harassment. We consider application of this behavioral Level B 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 *Preliminary Analysis and Negligible Impact Determination* section and would be authorized.

In the Navy's acoustic impact analyses during Phase II (the previous phase of Navy testing and training, 2013–2018, see also Navy's ''Criteria and Thresholds for U.S. Navy Acoustic and Explosive Effects Analysis Technical Report'', 2012), the likelihood of behavioral Level B 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 beaked whales during Phase II analyses. Instead, a step function at an SPL of 140 dB re: 1 µPa was used for beaked whales as the threshold to predict Level B harassment by behavioral disturbance.

Developing the behavioral Level B harassment criteria for Phase III (the current phase of Navy training and testing activities) 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 (See also Navy's ''Criteria and Thresholds for U.S. Navy Acoustic and Explosive Effects Analysis (Phase III) Technical Report'', 2017). Six behavioral response field studies with observations of 14 different marine mammal species reactions to sonar or sonar-like signals and 6 captive animal behavioral studies with observations of 8 different species reactions to sonar or sonar-like signals were used to provide a robust data set for the derivation of the Navy's Phase III marine mammal behavioral response criteria. All behavioral response research that has been published since the derivation of the Navy's Phase III criteria (c.a. December 2016) has been examined and is consistent with the current behavioral response functions. 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 12 below). These distances were determined by examining all available published field observations of behavioral reactions to sonar or sonar-like signals that included the distance between the sound source and the marine mammal. The longest distance, rounded up to the nearest 5-km increment, was chosen as the cutoff distance for each behavioral criteria group (*i.e.* odontocetes, mysticetes, and beaked whales). For animals within the cutoff distance, behavioral response functions for each behavioral criteria group based on a received SPL as presented in Chapter 6, Section 6.4.2.1 (Methods for Analyzing Impacts from Sonars and other Transducers) of the Navy's rulemaking/LOA application were 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 at 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 (however, we note that helicopter dipping sonars were considered in the intense sound source group, despite lower source levels, because of data indicating that marine mammals are sometimes more responsive to the less predictable employment of this source). 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 farther ranges than shown in Table 12, versus less intense events.

TABLE 12—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 AT 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	10	20
Beaked Whales	25	50
Harbor Porpoise	20	40

Notes: dB re: 1 µPa at 1 m = decibels referenced to 1 micropascal at 1 meter, km = kilometer, SL = source level.

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 are shown in Tables 13 through 17. 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 (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. As noted previously, NMFS carefully reviewed, and contributed to, the Navy's proposed behavioral Level B harassment thresholds and cutoff distances for each behavioral criteria group, and agrees that these methods represent the best available science at this time for determining impacts to marine mammals from sonar and other transducers.

Table 13 illustrates the maximum likely percentage of exposed individuals taken at the indicated received level and associated range (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 low-frequency active sonar (LFAS).

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Table 13 -- Ranges to Estimated Behavioral Level B Harassment Takes for Sonar Bin LF4 Over a Representative Range of Environments Within the NWTT Study Area.

Received Level (dB re: 1 µPa)	Mean Range (meters) with Minimum and Maximum Values in Parentheses	Probability of Behavioral Response for Sonar Bin LF4				
		Odontocete	Mysticete	Pinniped	Beaked Whale	Harbor Porpoise
196	1 (0–1)	100%	100%	100%	100%	100%
190	3 (0–3)	100%	98%	99%	100%	100%
184	6 (0–8)	99%	88%	98%	100%	100%
178	13 (0–30)	97%	59%	92%	100%	100%
172	29 (0–230)	91%	30%	76%	99%	100%
166	64 (0–100)	78%	20%	48%	97%	100%
160	148 (0–310)	58%	18%	27%	93%	100%
154	366 (230–850)	40%	17%	18%	83%	100%
148	854 (300–2,025)	29%	16%	16%	66%	100%
142	1,774 (300–5,025)	25%	13%	15%	45%	100%
136	3,168 (300–8,525)	23%	9%	15%	28%	100%
130	5,167 (300–30,525)	20%	5%	15%	18%	100%
124	7,554 (300–93,775)	17%	2%	14%	14%	100%
118	10,033 (300–100,000*)	12%	1%	13%	12%	0%
112	12,700 (300–100,000*)	6%	0%	9%	11%	0%
106	15,697 (300–100,000*)	3%	0%	5%	11%	0%
100	17,846 (300–100,000*)	1%	0%	2%	8%	0%

* Indicates maximum range to which acoustic model was run, a distance of approximately 100 km 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 12 for behavioral cut-off distances). dB re: 1 µPa = decibels referenced to 1 micropascal, LF = low-frequency

Tables 14 through 16 identify the maximum likely percentage of exposed individuals taken at the indicated received level and associated range for mid-frequency active sonar (MFAS).

Table 14 -- Ranges to Estimated Behavioral Level B Harassment Takes for Sonar Bin MF1 Over a Representative Range of Environments Within the NWTT Study Area.

Received Level (dB re: 1 µPa)	Mean Range (meters) with Minimum and Maximum Values in Parentheses	Probability of Behavioral Response for Sonar Bin MF1				
		Odontocete	Mysticete	Pinniped	Beaked Whale	Harbor Porpoise
196	112 (80–170)	100%	100%	100%	100%	100%
190	262 (80–410)	100%	98%	99%	100%	100%
184	547 (80–1,025)	99%	88%	98%	100%	100%
178	1,210 (80–3,775)	97%	59%	92%	100%	100%
172	2,508 (80–7,525)	91%	30%	76%	99%	100%
166	4,164 (80–16,025)	78%	20%	48%	97%	100%
160	6,583 (80–28,775)	58%	18%	27%	93%	100%
154	10,410 (80–47,025)	40%	17%	18%	83%	100%
148	16,507 (80–63,525)	29%	16%	16%	66%	100%
142	21,111 (80–94,025)	25%	13%	15%	45%	100%
136	26,182 (80–100,000*)	23%	9%	15%	28%	100%
130	31,842 (80–100,000*)	20%	5%	15%	18%	100%
124	34,195 (80–100,000*)	17%	2%	14%	14%	100%
118	36,557 (80–100,000*)	12%	1%	13%	12%	0%
112	38,166 (80–100,000*)	6%	0%	9%	11%	0%
106	39,571 (80–100,000*)	3%	0%	5%	11%	0%
100	41,303 (80–100,000*)	1%	0%	2%	8%	0%

* Indicates maximum range to which acoustic model was run, a distance of approximately 100 km 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 12 for behavioral cut-off distances). dB re: 1 µPa = decibels referenced to 1 micropascal, MF = mid-frequency

Table 15 -- Ranges to Estimated Behavioral Level B Harassment Takes for Sonar Bin MF4 Over a Representative Range of Environments Within the NWTT Study Area.

Received Level (dB re: 1 µPa)	Mean Range (meters) with Minimum and Maximum Values in Parentheses	Probability of Behavioral Response for Sonar Bin MF4				
		Odontocete	Mysticete	Pinniped	Beaked Whale	Harbor Porpoise
196	8 (0–8)	100%	100%	100%	100%	100%
190	16 (0–20)	100%	98%	99%	100%	100%
184	34 (0–40)	99%	88%	98%	100%	100%
178	68 (0–85)	97%	59%	92%	100%	100%
172	155 (120–300)	91%	30%	76%	99%	100%
166	501 (290–975)	78%	20%	48%	97%	100%
160	1,061 (480–2,275)	58%	18%	27%	93%	100%
154	1,882 (525–4,025)	40%	17%	18%	83%	100%
148	2,885 (525–7,525)	29%	16%	16%	66%	100%
142	4,425 (525–14,275)	25%	13%	15%	45%	100%
136	9,902 (525–48,275)	23%	9%	15%	28%	100%
130	20,234 (525–56,025)	20%	5%	15%	18%	100%
124	23,684 (525–91,775)	17%	2%	14%	14%	100%
118	28,727 (525–100,000*)	12%	1%	13%	12%	0%
112	37,817 (525–100,000*)	6%	0%	9%	11%	0%
106	42,513 (525–100,000*)	3%	0%	5%	11%	0%
100	43,367 (525–100,000*)	1%	0%	2%	8%	0%

* Indicates maximum range to which acoustic model was run, a distance of approximately 100 km 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 12 for behavioral cut-off distances). dB re: 1 µPa = decibels referenced to 1 micropascal, MF = mid-frequency

Table 16 -- Ranges to Estimated Behavioral Level B Harassment Takes for Sonar Bin MF5 Over a Representative Range of Environments Within the NWTT Study Area.

Received Level (dB re: 1 µPa)	Mean Range (meters) with Minimum and Maximum Values in Parentheses	Probability of Behavioral Response for Sonar Bin MF5				
		Odontocete	Mysticete	Pinniped	Beaked Whale	Harbor Porpoise
196	0 (0–0)	100%	100%	100%	100%	100%
190	1 (0–3)	100%	98%	99%	100%	100%
184	5 (0–7)	99%	88%	98%	100%	100%
178	14 (0–18)	97%	59%	92%	100%	100%
172	29 (0–35)	91%	30%	76%	99%	100%
166	58 (0–70)	78%	20%	48%	97%	100%
160	127 (0–280)	58%	18%	27%	93%	100%
154	375 (0–1,000)	40%	17%	18%	83%	100%
148	799 (490–1,775)	29%	16%	16%	66%	100%
142	1,677 (600–3,525)	25%	13%	15%	45%	100%
136	2,877 (675–7,275)	23%	9%	15%	28%	100%
130	4,512 (700–12,775)	20%	5%	15%	18%	100%
124	6,133 (700–19,275)	17%	2%	14%	14%	100%
118	7,880 (700–26,275)	12%	1%	13%	12%	0%
112	9,673 (700–33,525)	6%	0%	9%	11%	0%
106	12,095 (700–45,275)	3%	0%	5%	11%	0%
100	18,664 (700–48,775)	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 12 for behavioral cut-off distances). dB re: 1 µPa = decibels referenced to 1 micropascal, MF = mid-frequency

Table 17 identifies the maximum likely percentage of exposed individuals taken at the indicated received level and associated range for high-frequency active sonar (HFAS).

Table 17 -- Ranges to Estimated Behavioral Level B Harassment Takes for Sonar Bin HF4 Over a Representative Range of Environments Within the NWTT Study Area.

Received Level (dB re: 1 µPa)	Mean Range (meters) with Minimum and Maximum Values in Parentheses	Probability of Behavioral Response for Sonar Bin HF4				
		Odontocete	Mysticete	Pinniped	Beaked Whale	Harbor Porpoise
196	4 (0–7)	100%	100%	100%	100%	100%
190	10 (0–16)	100%	98%	99%	100%	100%
184	20 (0–40)	99%	88%	98%	100%	100%
178	42 (0–85)	97%	59%	92%	100%	100%
172	87 (0–270)	91%	30%	76%	99%	100%
166	177 (0–650)	78%	20%	48%	97%	100%
160	338 (25–825)	58%	18%	27%	93%	100%
154	577 (55–1,275)	40%	17%	18%	83%	100%
148	846 (60–1,775)	29%	16%	16%	66%	100%
142	1,177 (60–2,275)	25%	13%	15%	45%	100%
136	1,508 (60–3,025)	23%	9%	15%	28%	100%
130	1,860 (60–3,525)	20%	5%	15%	18%	100%
124	2,202 (60–4,275)	17%	2%	14%	14%	100%
118	2,536 (60–4,775)	12%	1%	13%	12%	0%
112	2,850 (60–5,275)	6%	0%	9%	11%	0%
106	3,166 (60–6,025)	3%	0%	5%	11%	0%
100	3,470 (60–6,775)	1%	0%	2%	8%	0%

Notes: dB re: 1 µPa = decibels referenced to 1 micropascal, HF = high-frequency

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Explosives

Phase III explosive criteria for behavioral Level B harassment thresholds for marine mammals is the functional hearing groups' TTS onset threshold (in SEL) minus 5 dB (see Table 18 below and Table 11 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 Effects Analysis (Phase III)'' report (U.S. Department of the Navy, 2017c) for detailed information on how the criteria and thresholds were derived. NMFS continues to concur that this approach represents the best available science for determining impacts to marine mammals from explosives.

TABLE 18—BEHAVIORAL LEVEL B HARASSMENT THRESHOLDS FOR EXPLOSIVES FOR MARINE MAMMALS

Medium	Functional hearing group	SEL (weighted)
Underwater	Low-frequency cetaceans	163
Underwater	Mid-frequency cetaceans	165
Underwater	High-frequency cetaceans	135
Underwater	Phocids	165
Underwater	Otariids	183

Note: Weighted SEL thresholds in dB re: 1 μPa^2s underwater.

Navy's Acoustic Effects Model

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 NWTT 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 sound level received by 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 ''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, 2018).

Sonar and Other Transducers and Explosives

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 ranges to received sound levels in 6-dB steps from five 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 are shown in Tables 13 through 17 above. 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 PTS for five representative sonar systems for an exposure of 30 seconds is shown in Table 19 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 19—RANGE TO PERMANENT THRESHOLD SHIFT (METERS) FOR FIVE REPRESENTATIVE SONAR SYSTEMS

Hearing group	Approximate PTS (30 seconds) ranges (meters) [1]				
	Sonar bin HF4	Sonar bin LF4	Sonar bin MF1	Sonar bin MF4	Sonar bin MF5
High-frequency cetaceans	38 (22–85)	0 (0–0)	195 (80–330)	30 (30–40)	9 (8–11)
Low-frequency cetaceans	0 (0–0)	2 (1–3)	67 (60–110)	15 (15–17)	0 (0–0)
Mid-frequency cetaceans	1 (0–3)	0 (0–0)	16 (16–19)	3 (3–3)	0 (0–0)
Otariids	0 (0–0)	0 (0–0)	6 (6–6)	0 (0–0)	0 (0–0)
Phocids	0 (0–0)	0 (0–0)	46 (45–75)	11 (11–12)	0 (0–0)

[1] PTS ranges extend from the sonar or other transducer 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 parentheses.

Notes: HF = high-frequency, LF = low-frequency, MF = mid-frequency, PTS = permanent threshold shift.

The tables below illustrate the range to TTS for 1, 30, 60, and 120 seconds from five representative sonar systems (see Tables 20 through 24).

TABLE 20—RANGES TO TEMPORARY THRESHOLD SHIFT (METERS) FOR SONAR BIN LF4 OVER A REPRESENTATIVE RANGE OF ENVIRONMENTS WITHIN THE NWTT STUDY AREA

Hearing group	Approximate TTS ranges (meters) [1]			
	Sonar bin LF4			
	1 second	30 seconds	60 seconds	120 seconds
High-frequency cetaceans	0 (0–0)	0 (0–0)	0 (0–0)	1 (0–1)

TABLE 20—RANGES TO TEMPORARY THRESHOLD SHIFT (METERS) FOR SONAR BIN LF4 OVER A REPRESENTATIVE RANGE OF ENVIRONMENTS WITHIN THE NWTT STUDY AREA—Continued

Hearing group	Approximate TTS ranges (meters) [1]			
	Sonar bin LF4			
	1 second	30 seconds	60 seconds	120 seconds
Low-frequency cetaceans	22 (19–30)	32 (25–230)	41 (30–230)	61 (45–100)
Mid-frequency cetaceans	0 (0–0)	0 (0–0)	0 (0–0)	0 (0–0)
Otariids	0 (0–0)	0 (0–0)	0 (0–0)	0 (0–0)
Phocids	2 (1–3)	4 (3–4)	4 (4–5)	7 (6–9)

[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 extends 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 parentheses.
Notes: HF = high-frequency, TTS = temporary threshold shift.

TABLE 21—RANGES TO TEMPORARY THRESHOLD SHIFT (METERS) FOR SONAR BIN MF1 OVER A REPRESENTATIVE RANGE OF ENVIRONMENTS WITHIN THE NWTT STUDY AREA

Hearing group	Approximate TTS ranges (meters) [1]			
	Sonar bin MF1			
	1 second	30 seconds	60 seconds	120 seconds
High-frequency cetaceans	2,466 (80–6,275)	2,466 (80–6,275)	3,140 (80–10,275)	3,740 (80–13,525)
Low-frequency cetaceans	1,054 (80–2,775)	1,054 (80–2,775)	1,480 (80–4,525)	1,888 (80–5,275)
Mid-frequency cetaceans	225 (80–380)	225 (80–380)	331 (80–525)	411 (80–700)
Otariids	67 (60–110)	67 (60–110)	111 (80–170)	143 (80–250)
Phocids	768 (80–2,025)	768 (80–2,025)	1,145 (80–3,275)	1,388 (80–3,775)

[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 extends 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 parentheses. Ranges for 1 second and 30 second periods are identical for Bin MF1 because this system nominally pings every 50 seconds; therefore, these periods encompass only a single ping.
Notes: MF = mid-frequency, TTS = temporary threshold shift.

TABLE 22—RANGES TO TEMPORARY THRESHOLD SHIFT (METERS) FOR SONAR BIN MF4 OVER A REPRESENTATIVE RANGE OF ENVIRONMENTS WITHIN THE NWTT STUDY AREA

Hearing group	Approximate TTS ranges (meters) [1]			
	Sonar bin MF4			
	1 second	30 seconds	60 seconds	120 seconds
High-frequency cetaceans	279 (220–600)	647 (420–1,275)	878 (500–1,525)	1,205 (525–2,275)
Low-frequency cetaceans	87 (85–110)	176 (130–320)	265 (190–575)	477 (290–975)
Mid-frequency cetaceans	22 (22–25)	35 (35–45)	50 (45–55)	71 (70–85)
Otariids	8 (8–8)	15 (15–17)	19 (19–23)	25 (25–30)
Phocids	66 (65–80)	116 (110–200)	173 (150–300)	303 (240–675)

[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 extends 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 parentheses.
Notes: MF = mid-frequency, TTS = temporary threshold shift.

TABLE 23—RANGES TO TEMPORARY THRESHOLD SHIFT (METERS) FOR SONAR BIN MF5 OVER A REPRESENTATIVE RANGE OF ENVIRONMENTS WITHIN THE NWTT STUDY AREA

Hearing group	Approximate TTS ranges (meters) [1]			
	Sonar bin MF5			
	1 second	30 seconds	60 seconds	120 seconds
High-frequency cetaceans	115 (110–180)	115 (110–180)	174 (150–390)	292 (210–825)
Low-frequency cetaceans	11 (10–13)	11 (10–13)	17 (16–19)	24 (23–25)
Mid-frequency cetaceans	6 (0–9)	6 (0–9)	12 (11–14)	18 (17–22)
Otariids	0 (0–0)	0 (0–0)	0 (0–0)	0 (0–0)

TABLE 23—RANGES TO TEMPORARY THRESHOLD SHIFT (METERS) FOR SONAR BIN MF5 OVER A REPRESENTATIVE RANGE OF ENVIRONMENTS WITHIN THE NWTT STUDY AREA—Continued

Hearing group	Approximate TTS ranges (meters) [1]			
	Sonar bin MF5			
	1 second	30 seconds	60 seconds	120 seconds
Phocids	9 (8–11)	9 (8–11)	15 (14–17)	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 extends 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 parentheses.

Notes: MF = mid-frequency, TTS = temporary threshold shift.

TABLE 24—RANGES TO TEMPORARY THRESHOLD SHIFT (METERS) FOR SONAR BIN HF4 OVER A REPRESENTATIVE RANGE OF ENVIRONMENTS WITHIN THE NWTT STUDY AREA

Hearing group	Approximate TTS Ranges (meters) [1]			
	Sonar bin HF4			
	1 second	30 seconds	60 seconds	120 seconds
High-frequency cetaceans	236 (60–675)	387 (60–875)	503 (60–1,025)	637 (60–1,275)
Low-frequency cetaceans	2 (0–3)	3 (1–6)	5 (3–8)	8 (5–12)
Mid-frequency cetaceans	12 (7–20)	21 (12–40)	29 (17–60)	43 (24–90)
Otariids	0 (0–0)	0 (0–0)	0 (0–0)	1 (0–1)
Phocids	3 (0–5)	6 (4–10)	9 (5–15)	14 (8–25)

[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 extends 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 parentheses.

Notes: HF = high-frequency, 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 (Impacts from Explosives) of the Navy's rulemaking/LOA application and the ''Criteria and Thresholds for U.S. Navy Acoustic and Explosive Effects Analysis (Phase III)'' report (U.S. Department of the Navy, 2017c)) and the explosive propagation calculations from the Navy Acoustic Effects Model (see Chapter 6, Section 6.5.2.2 (Impact Ranges for Explosives) 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 E11 (greater than 500 lb to 650 lb net explosive weight) (Tables 25 through 31). 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. NMFS has reviewed the range distance to effect data provided by the Navy and concurs with the analysis. 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, 2018).

Tables 25 through 29 show 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. Ranges are provided for a representative source depth and cluster size (the number of rounds fired, or buoys dropped, within a very short duration) 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 30 and 31, respectively.

Table 25 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 25—SEL-BASED RANGES TO ONSET PTS, ONSET TTS, AND BEHAVIORAL REACTION (IN METERS) FOR HIGH-FREQUENCY CETACEANS

Range to effects for explosives: High-frequency cetaceans [1]					
Bin	Source depth (m)	Cluster size	Range to PTS (m)	Range to TTS (m)	Range to behavioral (m)
E1	0.1	1	361 (350–370)	1,108 (1,000–1,275)	1,515 (1,025–2,025)
		18	1,002 (925–1,025)	2,404 (1,275–4,025)	3,053 (1,275–5,025)
E2	0.1	1	439 (420–450)	1,280 (1,025–1,775)	1,729 (1,025–2,525)

TABLE 25—SEL-BASED RANGES TO ONSET PTS, ONSET TTS, AND BEHAVIORAL REACTION (IN METERS) FOR HIGH-FREQUENCY CETACEANS—Continued

Range to effects for explosives: High-frequency cetaceans [1]					
Bin	Source depth (m)	Cluster size	Range to PTS (m)	Range to TTS (m)	Range to behavioral (m)
		5	826 (775–875)	1,953 (1,275–3,025)	2,560 (1,275–4,275)
E3	10	1	1,647 (160–3,525)	2,942 (160–10,275)	3,232 (160–12,275)
		12	3,140 (160–9,525)	3,804 (160–17,525)	3,944 (160–21,775)
	18.25	1	684 (550–1,000)	2,583 (1,025–5,025)	4,217 (1,525–7,525)
		12	1,774 (1,025–3,775)	5,643 (1,775–10,025)	7,220 (2,025–13,275)
E4	10	2	1,390 (950–3,025)	5,250 (2,275–8,275)	7,004 (2,775–11,275)
	30	2	1,437 (925–2,775)	4,481 (1,525–7,775)	5,872 (2,775–10,525)
	70	2	1,304 (925–2,275)	3,845 (2,525–7,775)	5,272 (3,525–9,525)
	90	2	1,534 (900–2,525)	5,115 (2,525–7,525)	6,840 (3,275–10,275)
E5	0.1	1	940 (850–1,025)	2,159 (1,275–3,275)	2,762 (1,275–4,275)
		20	1,930 (1,275–2,775)	4,281 (1,775–6,525)	5,176 (2,025–7,775)
E7	10	1	2,536 (1,275–3,775)	6,817 (2,775–11,025)	8,963 (3,525–14,275)
	30	1	1,916 (1,025–4,275)	5,784 (2,775–10,525)	7,346 (2,775–12,025)
E8	45.75	1	1,938 (1,275–4,025)	4,919 (1,775–11,275)	5,965 (2,025–15,525)
E10	0.1	1	1,829 (1,025–2,775)	4,166 (1,775–6,025)	5,023 (2,025–7,525)
E11	91.4	1	3,245 (2,025–6,775)	6,459 (2,525–15,275)	7,632 (2,775–19,025)
	200	1	3,745 (3,025–5,025)	7,116 (4,275–11,275)	8,727 (5,025–15,025)

[1] Average distance (meters) to PTS, TTS, and behavioral thresholds are depicted above the minimum and maximum distances (due to varying propagation environments), which are in parentheses.
Notes: PTS = permanent threshold shift, SEL = sound exposure level, TTS = temporary threshold shift.

Table 26 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 low-frequency cetaceans based on the developed thresholds.

TABLE 26—SEL-BASED RANGES TO ONSET PTS, ONSET TTS, AND BEHAVIORAL REACTION (IN METERS) FOR LOW-FREQUENCY CETACEANS

Range to effects for explosives: Low-frequency cetaceans [1]					
Bin	Source depth (meters)	Cluster size	Range to PTS (meters)	Range to TTS (meters)	Range to behavioral (meters)
E1	0.1	1	52 (50–55)	221 (120–250)	354 (160–420)
		18	177 (110–200)	656 (230–875)	836 (280–1,025)
E2	0.1	1	66 (55–70)	276 (140–320)	432 (180–525)
		5	128 (90–140)	512 (200–650)	735 (250–975)
E3	10	1	330 (160–550)	1,583 (160–4,025)	2,085 (160–7,525)
		12	1,177 (160–2,775)	2,546 (160–11,775)	2,954 (160–17,025)
	18.25	1	198 (180–220)	1,019 (490–2,275)	1,715 (625–4,025)
		12	646 (390–1,025)	3,723 (800–9,025)	6,399 (1,025–46,525)
E4	10	2	462 (400–600)	3,743 (2,025–7,025)	6,292 (2,525–13,275)
	30	2	527 (330–950)	3,253 (1,775–4,775)	5,540 (2,275–8,275)
	70	2	490 (380–775)	3,026 (1,525–4,775)	5,274 (2,275–7,775)
	90	2	401 (360–500)	3,041 (1,275–4,525)	5,399 (1,775–9,275)
E5	0.1	1	174 (100–260)	633 (220–850)	865 (270–1,275)
		20	550 (200–700)	1,352 (420–2,275)	2,036 (700–4,275)
E7	10	1	1,375 (875–2,525)	7,724 (3,025–15,025)	11,787 (4,525–25,275)
	30	1	1,334 (675–2,025)	7,258 (2,775–11,025)	11,644 (4,525–24,275)
E8	45.75	1	1,227 (575–2,525)	3,921 (1,025–17,275)	7,961 (1,275–48,525)
E10	0.1	1	546 (200–700)	1,522 (440–5,275)	3,234 (850–30,525)
E11	91.4	1	2,537 (950–5,525)	11,249 (1,775–50,775)	37,926 (6,025–94,775)
	200	1	2,541 (1,525–4,775)	7,407 (2,275–43,275)	42,916 (6,275–51,275)

[1] Average distance (meters) is shown with the minimum and maximum distances due to varying propagation environments in parentheses. Values depict the range produced by SEL hearing threshold criteria levels.
Notes: PTS = permanent threshold shift, SEL = sound exposure level, TTS = temporary threshold shift.

Table 27 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 mid-frequency cetaceans based on the developed thresholds.

TABLE 27—SEL-BASED RANGES TO ONSET PTS, ONSET TTS, AND BEHAVIORAL REACTION (IN METERS) FOR MID-FREQUENCY CETACEANS

Range to effects for explosives: Mid-frequency cetaceans [1]					
Bin	Source depth (meters)	Cluster size	Range to PTS (meters)	Range to TTS (meters)	Range to behavioral (meters)
E1	0.1	1	25 (25–25)	118 (110–120)	203 (190–210)
		18	96 (90–100)	430 (410–440)	676 (600–700)
E2	0.1	1	30 (30–30)	146 (140–150)	246 (230–250)
		5	64 (60–65)	298 (290–300)	493 (470–500)
E3	10	1	61 (50–100)	512 (160–750)	928 (160–2,025)
		12	300 (160–625)	1,604 (160–3,525)	2,085 (160–5,525)
	18.25	1	40 (35–40)	199 (180–280)	368 (310–800)
		12	127 (120–130)	709 (575–1,000)	1,122 (875–2,525)
E4	10	2	73 (70–75)	445 (400–575)	765 (600–1,275)
	30	2	71 (65–90)	554 (320–1,025)	850 (525–1,775)
	70	2	63 (60–85)	382 (320–675)	815 (525–1,275)
	90	2	59 (55–85)	411 (310–900)	870 (525–1,275)
E5	0.1	1	79 (75–80)	360 (350–370)	575 (525–600)
		20	295 (280–300)	979 (800–1,275)	1,442 (925–1,775)
E7	10	1	121 (110–130)	742 (575–1,275)	1,272 (875–2,275)
	30	1	111 (100–130)	826 (500–1,775)	1,327 (925–2,275)
E8	45.75	1	133 (120–170)	817 (575–1,525)	1,298 (925–2,525)
E10	0.1	1	273 (260–280)	956 (775–1,025)	1,370 (900–1,775)
E11	91.4	1	242 (220–310)	1,547 (1,025–3,025)	2,387 (1,275–4,025)
	200	1	209 (200–300)	1,424 (1,025–2,025)	2,354 (1,525–3,775)

[1] Average distance (meters) is shown with the minimum and maximum distances due to varying propagation environments in parentheses.
Note: PTS = permanent threshold shift, SEL = sound exposure level, TTS = temporary threshold shift.

Table 28 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 otariid pinnipeds based on the developed thresholds.

TABLE 28—SEL-BASED RANGES TO ONSET PTS, ONSET TTS, AND BEHAVIORAL REACTION (IN METERS) FOR OTARIIDS

Range to effects for explosives: Otariids [1]					
Bin	Source depth (meters)	Cluster size	Range to PTS (meters)	Range to TTS (meters)	Range to behavioral (meters)
E1	0.1	1	7 (7–8)	34 (30–35)	58 (55–60)
		18	25 (25–25)	124 (120–130)	208 (200–210)
E2	0.1	1	9 (9–10)	43 (40–45)	72 (70–75)
		5	19 (19–20)	88 (85–90)	145 (140–150)
E3	10	1	21 (18–25)	135 (120–210)	250 (160–370)
		12	82 (75–100)	551 (160–875)	954 (160–2,025)
	18.25	1	15 (15–15)	91 (85–95)	155 (150–160)
		12	53 (50–55)	293 (260–430)	528 (420–825)
E4	10	2	30 (30–30)	175 (170–180)	312 (300–350)
	30	2	25 (25–25)	176 (160–250)	400 (290–750)
	70	2	26 (25–35)	148 (140–200)	291 (250–400)
	90	2	26 (25–35)	139 (130–190)	271 (250–360)
E5	0.1	1	25 (24–25)	111 (110–120)	188 (180–190)
		20	93 (90–95)	421 (390–440)	629 (550–725)
E7	10	1	60 (60–60)	318 (300–360)	575 (500–775)
	30	1	53 (50–65)	376 (290–700)	742 (500–1,025)
E8	45.75	1	55 (55–55)	387 (310–750)	763 (525–1,275)
E10	0.1	1	87 (85–90)	397 (370–410)	599 (525–675)
E11	91.4	1	100 (100–100)	775 (550–1,275)	1,531 (900–3,025)
	200	1	94 (90–100)	554 (525–700)	1,146 (900–1,525)

[1] Average distance (meters) is shown with the minimum and maximum distances due to varying propagation environments in parentheses.
Notes: PTS = permanent threshold shift, SEL = sound exposure level, TTS = temporary threshold shift.

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 phocid pinnipeds based on the developed thresholds.

TABLE 29—SEL-BASED RANGES TO ONSET PTS, ONSET TTS, AND BEHAVIORAL REACTION (IN METERS) FOR PHOCIDS

Range to effects for explosives: Phocids [1]					
Bin	Source depth (meters)	Cluster size	Range to PTS (meters)	Range to TTS (meters)	Range to behavioral (meters)
E1	0.1	1	47 (45–50)	219 (210–230)	366 (350–370)
		18	171 (160–180)	764 (725–800)	1,088 (1,025–1,275)
E2	0.1	1	59 (55–60)	273 (260–280)	454 (440–460)
		5	118 (110–120)	547 (525–550)	881 (825–925)
E3	10	1	185 (160–260)	1,144 (160–2,775)	1,655 (160–4,525)
		12	760 (160–1,525)	2,262 (160–8,025)	2,708 (160–12,025)
	18.25	1	112 (110–120)	628 (500–950)	1,138 (875–2,525)
		12	389 (330–625)	2,248 (1,275–4,275)	4,630 (1,275–8,525)
E4	10	2	226 (220–240)	1,622 (950–3,275)	3,087 (1,775–5,775)
	30	2	276 (200–600)	1,451 (1,025–2,275)	2,611 (1,775–4,275)
	70	2	201 (180–280)	1,331 (1,025–1,775)	2,403 (1,525–3,525)
	90	2	188 (170–270)	1,389 (975–2,025)	2,617 (1,775–3,775)
E5	0.1	1	151 (140–160)	685 (650–700)	1,002 (950–1,025)
		20	563 (550–575)	1,838 (1,275–2,275)	2,588 (1,525–3,525)
E7	10	1	405 (370–490)	3,185 (1,775–6,025)	5,314 (2,275–11,025)
	30	1	517 (370–875)	2,740 (1,775–4,275)	4,685 (3,025–7,275)
E8	45.75	1	523 (390–1,025)	2,502 (1,525–6,025)	3,879 (2,025–10,275)
E10	0.1	1	522 (500–525)	1,800 (1,275–2,275)	2,470 (1,525–3,275)
E11	91.4	1	1,063 (675–2,275)	5,043 (2,775–10,525)	7,371 (3,275–18,025)
	200	1	734 (675–850)	5,266 (3,525–9,025)	7,344 (5,025–12,775)

[1] Average distance (meters) is shown with the minimum and maximum distances due to varying propagation environments in parentheses.
Notes: PTS = permanent threshold shift, SEL = sound exposure level, TTS = temporary threshold shift.

Table 30 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 30—RANGES [1] TO NON-AUDITORY INJURY (IN METERS) FOR ALL MARINE MAMMAL HEARING GROUPS

Bin	Range to non-auditory injury (meters) [1]
E1	12 (11–13)
E2	16 (15–16)
E3	25 (25–45)
E4	31 (23–50)
E5	40 (40–40)
E7	104 (80–190)
E8	149 (130–210)
E10	153 (100–400)
E11	419 (350–725)

[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 shown in Table 31 below.

TABLE 31—RANGES [1] TO MORTALITY (IN METERS) FOR ALL MARINE MAMMAL HEARING GROUPS AS A FUNCTION OF ANIMAL MASS

Bin	Range to mortality (meters) for various animal mass intervals (kg) [1]					
	10 kg	250 kg	1,000 kg	5,000 kg	25,000 kg	72,000 kg
E1	3 (2–3)	1 (0–3)	0 (0–0)	0 (0–0)	0 (0–0)	0 (0–0)
E2	4 (3–5)	2 (1–3)	1 (0–1)	0 (0–0)	0 (0–0)	0 (0–0)
E3	10 (9–20)	5 (3–20)	2 (1–5)	0 (0–3)	0 (0–1)	0 (0–1)
E4	13 (11–19)	7 (4–13)	3 (2–4)	2 (1–3)	1 (1–1)	1 (0–1)
E5	13 (11–15)	7 (4–11)	3 (3–4)	2 (1–3)	1 (1–1)	1 (0–1)
E7	49 (40–80)	27 (15–60)	13 (10–20)	9 (5–12)	4 (4–6)	3 (2–4)
E8	65 (60–75)	34 (22–55)	17 (14–20)	11 (9–13)	6 (5–6)	5 (4–5)
E10	43 (40–50)	25 (16–40)	13 (11–16)	9 (7–11)	5 (4–6)	4 (3–4)
E11	185 (90–230)	90 (30–170)	40 (30–50)	28 (23–30)	15 (13–16)	11 (9–13)

[1] Average distance to mortality (meters) is depicted above the minimum and maximum distances, which are in parentheses for each animal mass interval.
Notes: kg = kilogram.

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 NMFS' Stock Assessment Reports (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, spatial habitat modeling developed by NMFS' Southwest Fisheries Science Center 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.

Ideally, density data would be available for all species throughout the study area year-round, in order to best estimate the impacts of Navy activities on marine species. However, in many places, ship availability, lack of funding, inclement weather conditions, and high sea states prevent the completion of comprehensive year-round surveys. Even with surveys that are completed, poor conditions may result in lower sighting rates for species that would typically be sighted with greater frequency under favorable conditions. Lower sighting rates preclude having an acceptably low uncertainty in the density estimates. A high level of uncertainty, indicating a low level of confidence in the density estimate, is typical for species that are rare or difficult to sight. In areas where survey data are limited or non-existent, known or inferred associations between marine habitat features and the likely presence of specific species are sometimes used to predict densities in the absence of actual animal sightings. Consequently, there is no single source of density data for every area, species, and season because of the fiscal costs, resources, and effort involved in providing enough survey coverage to sufficiently estimate density.

To characterize marine species density for large oceanic regions, the Navy reviews, critically assesses, and prioritizes existing density estimates from multiple sources, requiring the development of a systematic method for selecting the most appropriate density estimate for each combination of species/stock, area, and season. The selection and compilation of the best available marine species density data resulted in the Navy Marine Species Density Database (NMSDD), which includes seasonal density values for every marine mammal species and stock present within the NWTT Study Area. This database is described in the technical report titled ''U.S. Navy Marine Species Density Database Phase III for the Northwest Training and Testing Study Area'' (U.S. Department of the Navy, 2019), hereafter referred to as the Density Technical Report. NMFS vetted all cetacean densities by the Navy prior to use in the Navy's acoustic analysis for the current NWTT rulemaking process.

A variety of density data and density models are needed in order to develop a density database that encompasses the entirety of the NWTT Study Area. Because this data is collected using different methods with varying amounts of accuracy and uncertainty, the Navy has developed a 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 models in order of preference.

1. Spatial density models 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 as a function of 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.

2. Stratified design-based density estimates use line-transect survey data with the sampling area divided (stratified) into sub-regions, and a density is predicted for each sub-region (see Barlow, 2016; Becker *et al.,* 2016; Bradford *et al.,* 2017; Campbell *et al.,* 2014; Jefferson *et al.,* 2014). While geographically stratified density estimates provide a better indication of a species' distribution within the study area, the uncertainty is typically high because each sub-region estimate is based on a smaller stratified segment of the overall survey effort.

3. Design-based density estimations use line-transect survey data from land and aerial surveys designed to cover a specific geographic area (see Carretta *et al.,* 2015). These estimates use the same survey data as stratified design-based estimates, but are not segmented into sub-regions and instead provide one estimate for a large surveyed area. Although relative environmental suitability (RES) models provide estimates for areas of the oceans that have not been surveyed using information on species occurrence and inferred habitat associations and have been used in past density databases, these models were not used in the current quantitative analysis.

The Navy describes some of the challenges of interpreting the results of the quantitative analysis summarized above and described in the Density Technical Report: ''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 mammal 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 (U.S. Department of the Navy, 2017a).''

The Navy's estimate of abundance (based on density estimates used in the NWTT Study Area) utilizes NMFS' SARs, except for species with high site fidelity/smaller home ranges within the NWTT Study Area, relative to their geographic distribution (*e.g.,* harbor seals). For harbor seals in the inland waters, more up-to-date, site specific population estimates were available. For some species, the stock assessment for a given species may exceed the Navy's density prediction because those species' home range extends beyond the Study Area boundaries. For other species, the stock assessment abundance may be much less than the number of animals in the Navy's modeling given that the NWTT Study Area extends beyond the U.S waters covered by the SAR abundance estimate. The primary source of density estimates are geographically specific survey data and either peer-reviewed line-transect estimates or habitat-based density models that have been extensively validated to provide the most accurate estimates possible.

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 *Preliminary 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 Request

The 2019 NWTT DSEIS/OEIS considered all training and testing activities proposed to occur in the NWTT 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 by harassment of marine mammals from the Navy's planned activities.

- Acoustics (sonar and other transducers);
- Explosives (explosive shock wave and sound, assumed to encompass the risk due to fragmentation); and
- Vessel strike

Acoustic and explosive sources have the potential to result in incidental takes of marine mammals by harassment and injury. Vessel strikes have the potential to result in incidental take from injury, serious injury, and/or mortality.

The quantitative analysis process used for the 2019 NWTT DSEIS/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 *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, 2018). 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 the risk for model-estimated PTS for exposures to sonars and for model-estimated mortality for exposures to explosives, based on species sightability, observation area, visibility, and the ability to exercise positive control over the sound source. Where the analysis indicates mitigation would effectively reduce risk, the model-estimated PTS are considered reduced to TTS and the model-estimated mortalities are considered reduced to injury. For a complete explanation of the process for assessing the effects of mitigation, see the Navy's rulemaking/LOA application and 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, 2018). The extent to which the mitigation areas reduce impacts on the affected species is addressed separately in the *Preliminary 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 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 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:

$$\textit{Mitigation Effectiveness} = \textit{Species Sightability} \times \textit{Visibility} \times \textit{Observation Area} \times \textit{Positive Control}$$

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 the standard ''detection probability'' referred to as g(0) is most appropriate. Also, Visibility = 1 − sum of individual visibility reduction factors; Observation Area = portion of impact range that can be continuously observed during an event; and 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 (U.S. Department of the Navy, 2018).

To quantify the number of marine mammals predicted to be sighted by Lookouts in the injury zone during implementation of procedural mitigation 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 in the injury zone during implementation of mitigation, as calculated by the equation above, would avoid being exposed to these higher level impacts. To quantify the number of marine mammals predicted to be sighted by Lookouts in the mortality zone during implementation of procedural mitigation 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 in the mortality zone by Lookouts during implementation of procedural mitigation, 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 NAEMO (animal movement) model overestimates the number of marine mammals that would be exposed to sound sources that could cause PTS because the model does not consider horizontal movement of animats, including avoidance of high intensity sound exposures. Therefore, the potential for animal avoidance is considered separately. At close ranges and high sound levels, avoidance of the area immediately around the sound source is one of the assumed behavioral responses for marine mammals. Animal avoidance refers to the movement out of the immediate injury zone for subsequent exposures, not wide-scale area avoidance. Various researchers have demonstrated that cetaceans can perceive the location and movement of a sound source (*e.g.,* vessel, seismic source, *etc.*) relative to their own location and react with responsive movement away from the source, often at distances of 1 km or more (Au & Perryman,1982; Jansen *et al.,* 2010; Richardson *et al.,* 1995; Tyack *et al.,* 2011; Watkins, 1986; Würsig *et al.,* 1998) A marine mammal's ability to avoid a sound source and reduce its cumulative sound energy exposure would reduce risk of both PTS and TTS. However, the quantitative analysis conservatively only considers the potential to reduce some instances of PTS by accounting for marine mammals swimming away to avoid repeated high-level sound exposures. All reductions in PTS impacts from likely avoidance behaviors are instead considered TTS impacts.

NMFS coordinated with the Navy 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 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, 2018) and Chapter 6 (*Take Estimates for Marine Mammals*) and Chapter 11 (*Mitigation Measures*) of the Navy's rulemaking/LOA application.

As a general matter, NMFS does not prescribe the methods for estimating take for any applicant, but we review and ensure that applicants use the best available science, and methodologies that are logical and technically sound. Applicants may use different methods of calculating take (especially when using models) and still get to a result that is representative of the best available science and that allows for a rigorous and accurate evaluation of the effects on the affected populations. There are multiple pieces of the Navy take estimation methods—propagation models, animat movement models, and behavioral thresholds, for example. NMFS evaluates the acceptability of these pieces as they evolve and are used in different rules and impact analyses. Some of the pieces of the Navy's take estimation process have been used in Navy incidental take rules since 2009 and undergone multiple public comment processes; all of them have undergone extensive internal Navy review, and all of them have undergone comprehensive review by NMFS, which has sometimes resulted in modifications to methods or models.

The Navy uses rigorous review processes (verification, validation, and accreditation processes; peer and public review) to ensure the data and methodology it uses represent the best available science. For instance, the NAEMO model is the result of a NMFS-led Center for Independent Experts (CIE) review of the components used in earlier models. The acoustic propagation component of the NAEMO model (CASS/GRAB) is accredited by the Oceanographic and Atmospheric Master Library (OAML), and many of the environmental variables used in the NAEMO model come from approved OAML databases and are based on in-situ data collection. The animal density components of the NAEMO model are base products of the NMSDD, which includes animal density components that have been validated and reviewed by a variety of scientists from NMFS Science Centers and academic institutions. Several components of the model, for example the Duke University habitat-based density models, have been published in peer reviewed literature. Others like the Atlantic Marine Assessment Program for Protected Species, which was conducted by NMFS Science Centers, have undergone quality assurance and quality control (QA/QC) processes. Finally, the NAEMO model simulation components underwent QA/QC review and validation for model parts such as the scenario builder, acoustic builder, scenario simulator, *etc.,* conducted by qualified statisticians and modelers to ensure accuracy. Other models and methodologies have gone through similar review processes.

In summary, we believe the Navy's methods, including the method for incorporating mitigation and avoidance, are the most appropriate methods for predicting PTS, tissue damage, TTS, and behavioral disruption. 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 be taken through PTS, tissue damage, TTS, or behavioral disruption.

Summary of Requested Take From Training and Testing Activities

Based on the methods discussed in the previous sections and the Navy's model and quantitative assessment of mitigation, the Navy provided its take estimate and request for authorization of takes incidental to the use of acoustic and explosive sources for training and testing activities both annually (based on the maximum number of activities that could occur per 12-month period) and over the seven-year period covered by the Navy's rulemaking/LOA application. The following species/stocks present in the NWTT Study Area were modeled by the Navy and estimated to have 0 takes of any type from any activity source: Eastern North Pacific Northern Resident stock of killer whales, Western North Pacific stock of gray whales, and California stock of harbor seals. NMFS has reviewed the Navy's data, methodology, and analysis and determined that it is complete and accurate. NMFS agrees that the estimates for incidental takes by harassment from all sources requested for authorization are the maximum number of instances in which marine mammals are reasonably expected to be taken.

Estimated Harassment Take From Training and Testing Activities

For training and testing activities, Tables 32 and 33 summarize the Navy's take estimate and request and the annual and maximum amount and type of Level A harassment and Level B harassment for the seven-year period that NMFS concurs is reasonably expected to occur by species and stock. Note that take by Level B harassment includes both behavioral disruption and TTS. Tables 6–14–41 (sonar and other transducers) and 6–56–71 (explosives) in Section 6 of the Navy's rulemaking/LOA application provide the comparative amounts of TTS and behavioral disruption for each species and stock annually, noting that if a modeled marine mammal was ''taken'' through exposure to both TTS and behavioral disruption in the model, it was recorded as a TTS.

TABLE 32—ANNUAL AND SEVEN-YEAR TOTAL SPECIES-SPECIFIC TAKE ESTIMATES PROPOSED FOR AUTHORIZATION FROM ACOUSTIC AND EXPLOSIVE SOUND SOURCE EFFECTS FOR ALL TRAINING ACTIVITIES IN THE NWTT STUDY AREA

Species	Stock	Annual		7-Year total	
		Level B	Level A	Level B	Level A
Order Cetacea					
Suborder Mysticeti (baleen whales)					
Family Balaenopteridae (rorquals):					
Blue whale *	Eastern North Pacific	2	0	11	0
Fin whale *	Northeast Pacific	0	0	0	0
	California/Oregon/Washington	54	0	377	0
Sei whale *	Eastern North Pacific	30	0	206	0
Minke whale	Alaska	0	0	0	0
	California/Oregon/Washington	110	0	767	0
Humpback whale *	Central North Pacific	5	0	31	0
	California/Oregon/Washington	4	0	32	0
Family Eschrichtiidae (gray whale):					
Gray whale	Eastern North Pacific	2	0	10	0
Suborder Odontoceti (toothed whales)					
Family Delphinidae (dolphins):					
Bottlenose dolphin	California/Oregon/Washington Offshore.	5	0	33	0
Killer whale	Alaska Resident	0	0	0	0
	Eastern North Pacific Offshore	68	0	478	0
	West Coast Transient	78	0	538	0
	Southern Resident †	3	0	15	0
Northern right whale dolphin	California/Oregon/Washington	7,941	0	55,493	0
Pacific white-sided dolphin	North Pacific	0	0	0	0
	California/Oregon/Washington	5,284	0	36,788	0
Risso's dolphin	California/Oregon/Washington	2,286	0	15,972	0
Short-beaked common dolphin	California/Oregon/Washington	1,165	0	8,124	0
Short-finned pilot whale	California/Oregon/Washington	57	0	398	0
Striped dolphin	California/Oregon/Washington	439	0	3,059	0
Family Kogiidae (Kogia species):					
Kogia species Pygmy	California/Oregon/Washington	381	0	2,664	0
Family Phocoenidae (porpoises):					
Dall's porpoise	Alaska	0	0	0	0
	California/Oregon/Washington	13,299	8	92,793	48
Harbor porpoise	Southeast Alaska	0	0	0	0
	Northern Oregon/Washington Coast	299	0	2,092	0
	Northern California/Southern Oregon.	21	0	145	0
	Washington Inland Waters	12,315	43	79,934	291
Family Physeteridae (sperm whale):					
Sperm whale *	California/Oregon/Washington	512	0	3,574	0
Family Ziphiidae (beaked whales):					
Baird's beaked whale	California/Oregon/Washington	556	0	3,875	0
Cuvier's beaked whale	California/Oregon/Washington	1,462	0	10,209	0

TABLE 32—ANNUAL AND SEVEN-YEAR TOTAL SPECIES-SPECIFIC TAKE ESTIMATES PROPOSED FOR AUTHORIZATION FROM ACOUSTIC AND EXPLOSIVE SOUND SOURCE EFFECTS FOR ALL TRAINING ACTIVITIES IN THE NWTT STUDY AREA—Continued

Species	Stock	Annual		7-Year total	
		Level B	Level A	Level B	Level A
Mesoplodon species	California/Oregon/Washington	652	0	4,549	0
Suborder Pinnipedia					
Family Otariidae (sea lions and fur seals):					
California sea lion	U.S. Stock	3,624	0	25,243	0
Steller sea lion	Eastern U.S.	108	0	743	0
Guadalupe fur seal *	Mexico	608	0	4,247	0
Northern fur seal	Eastern Pacific	2,134	0	14,911	0
	California	43	0	300	0
Family Phocidae (true seals):					
Harbor seal	Southeast Alaska—Clarence Strait	0	0	0	0
	Oregon/Washington Coastal	0	0	0	0
	Washington Northern Inland Waters	669	5	3,938	35
	Hood Canal	2,686	1	18,662	5
	Southern Puget Sound	1,090	1	6,657	6
Northern elephant seal	California	1,909	1	13,324	1

* ESA-listed species (all stocks) within the NWTT Study Area.
† Only designated stocks are ESA-listed.

TABLE 33—ANNUAL AND SEVEN-YEAR TOTAL SPECIES-SPECIFIC TAKE ESTIMATES PROPOSED FOR AUTHORIZATION FROM ACOUSTIC AND EXPLOSIVE SOUND SOURCE EFFECTS FOR ALL TRAINING ACTIVITIES IN THE NWTT STUDY AREA

Species	Stock	Annual		7-Year total	
		Level B	Level A	Level B	Level A
Order Cetacea					
Suborder Mysticeti (baleen whales)					
Family Balaenopteridae (rorquals):					
Blue whale *	Eastern North Pacific	8	0	38	0
Fin whale *	Northeast Pacific	2	0	10	0
	California/Oregon/Washington	81	0	392	0
Sei whale *	Eastern North Pacific	53	0	258	0
Minke whale	Alaska	2	0	9	0
	California/Oregon/Washington	192	0	916	0
Humpback whale *	Central North Pacific	110	0	578	0
	California/Oregon/Washington	89	0	460	0
Family Eschrichtiidae (gray whale):					
Gray whale	Eastern North Pacific	41	0	189	0
Suborder Odontoceti (toothed whales)					
Family Delphinidae (dolphins):					
Bottlenose dolphin	California/Oregon/Washington Offshore.	3	0	14	0
Killer whale	Alaska Resident	34	0	202	0
	Eastern North Pacific Offshore	89	0	412	0
	West Coast Transient	154	0	831	0
	Southern Resident †	48	0	228	0
Northern right whale dolphin	California/Oregon/Washington	13,759	1	66,457	7
Pacific white-sided dolphin	North Pacific	101	0	603	0
	California/Oregon/Washington	15,681	1	76,980	8
Risso's dolphin	California/Oregon/Washington	4,069	0	19,637	0
Short-beaked common dolphin	California/Oregon/Washington	984	0	3,442	0
Short-finned pilot whale	California/Oregon/Washington	31	0	126	0
Striped dolphin	California/Oregon/Washington	344	0	1,294	0
Family Kogiidae (Kogia species):					
Kogia species	California/Oregon/Washington	501	1	2,376	9
Family Phocoenidae (porpoises):					
Dall's porpoise	Alaska	638	0	3,711	0
	California/Oregon/Washington	20,398	90	98,470	523
Harbor porpoise	Southeast Alaska	130	0	794	0
	Northern Oregon/Washington Coast	52,113	103	265,493	525

TABLE 33—ANNUAL AND SEVEN-YEAR TOTAL SPECIES-SPECIFIC TAKE ESTIMATES PROPOSED FOR AUTHORIZATION FROM ACOUSTIC AND EXPLOSIVE SOUND SOURCE EFFECTS FOR ALL TRAINING ACTIVITIES IN THE NWTT STUDY AREA—Continued

Species	Stock	Annual		7-Year total	
		Level B	Level A	Level B	Level A
	Northern California/Southern Oregon.	2,018	86	12,131	432
	Washington Inland Waters	17,228	137	115,770	930
Family Physeteridae (sperm whale):					
Sperm whale *	California/Oregon/Washington	327	0	1,443	0
Family Ziphiidae (beaked whales):					
Baird's beaked whale	California/Oregon/Washington	420	0	1,738	0
Cuvier's beaked whale	California/Oregon/Washington	1,077	0	4,979	0
Mesoplodon species	California/Oregon/Washington	470	0	2,172	0
Suborder Pinnipedia					
Family Otariidae (sea lions and fur seals):					
California sea lion	U.S. Stock	20,474	1	93,906	5
Steller sea lion	Eastern U.S.	2,130	0	10,745	0
Guadalupe fur seal *	Mexico	887	0	4,022	0
Northern fur seal	Eastern Pacific	9,458	0	45,813	0
	California	189	0	920	0
Family Phocidae (true seals):					
Harbor seal	Southeast Alaska—Clarence Strait	2,352	0	13,384	0
	Oregon/Washington Coastal	1,180	2	6,222	11
	Washington Northern Inland Waters	578	0	3,227	0
	Hood Canal	58,784	0	396,883	0
	Southern Puget Sound	5,748	3	39,511	24
Northern elephant seal	California	2,935	3	14,120	18

* ESA-listed species (all stocks) within the NWTT Study Area.
† Only designated stocks are ESA-listed.

Estimated Take From Vessel Strikes by Serious Injury or Mortality

Vessel strikes from commercial, recreational, and military vessels are known to affect large whales and have resulted in serious injury and occasional fatalities to cetaceans (Berman-Kowalewski *et al.,* 2010; Calambokidis, 2012; Douglas *et al.,* 2008; Laggner 2009; Lammers *et al.,* 2003). Records of collisions date back to the early 17th century, and the worldwide number of collisions appears to have increased steadily during recent decades (Laist *et al.,* 2001; Ritter 2012).

Numerous studies of interactions between surface vessels and marine mammals have demonstrated that free-ranging marine mammals often, but not always (*e.g.,* McKenna *et al.,* 2015), engage in avoidance behavior when surface vessels move toward them. It is not clear whether these responses are caused by the physical presence of a surface vessel, the underwater noise generated by the vessel, or an interaction between the two (Amaral and Carlson, 2005; Au and Green, 2000; Bain *et al.,* 2006; Bauer 1986; Bejder *et al.,* 1999; Bejder and Lusseau, 2008; Bejder *et al.,* 2009; Bryant *et al.,* 1984; Corkeron, 1995; Erbe, 2002; Félix, 2001; Goodwin and Cotton, 2004; Lemon *et al.,* 2006; Lusseau, 2003; Lusseau, 2006; Magalhaes *et al.,* 2002; Nowacek *et al.,* 2001; Richter *et al.,* 2003; Scheidat *et al.,* 2004; Simmonds, 2005; Watkins, 1986; Williams *et al.,* 2002; Wursig *et al.,* 1998). Several authors suggest that the noise generated during motion is probably an important factor (Blane and Jaakson, 1994; Evans *et al.,* 1992; Evans *et al.,* 1994). Water disturbance may also be a factor. These studies suggest that the behavioral responses of marine mammals to surface vessels are similar to their behavioral responses to predators. Avoidance behavior is expected to be even stronger in the subset of instances during which the Navy is conducting training or testing activities using active sonar or explosives.

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.,* sperm whales). In addition, some baleen whales seem generally unresponsive to vessel sound, making them more susceptible to vessel collisions (Nowacek *et al.,* 2004). These species are primarily large, slow 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 ability and number of personnel observing, 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), under certain circumstances (vessel speed and location of the whale relative to the ship's centerline), 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 Navy 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; and
- 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 NWTT Study Area or while in transit.

Data from the ports of Vancouver, British Columbia; Seattle, Washington; and Tacoma, Washington indicate there were more than 7,000 commercial vessel transits in 2017 associated with visits to just those ports (The Northwest Seaport Alliance, 2018; Vancouver Fraser Port Authority). This number of vessel transits does not account for other vessel traffic in the Strait of Juan de Fuca or Puget Sound including commercial ferries, tourist vessels, or recreational vessels. Additional commercial traffic in the NWTT Study Area also includes vessels transiting offshore along the Pacific coast, bypassing ports in Canada and Washington; traffic associated with ports to the south along the coast of Washington and in Oregon; and vessel traffic in Southeast Alaska (Nuka Research & Planning Group, 2012). Navy vessel traffic accounts for only a small portion of vessel activities in the NWTT Study Area. The Navy has, in total, the following homeported operational vessels: 2 Aircraft carriers, 6 destroyers, 14 submarines, and 22 smaller security vessels with a combined annual total of 241 Navy vessel transits (see Appendix A (Navy Activities Descriptions) of the 2019 DSEIS/OEIS for descriptions of the number of vessels used during the various types of Navy's proposed activities). Activities involving military vessel movement would be widely dispersed throughout the NWTT Study Area.

Navy vessel strike records have been kept since 1995, and since 1995 there have been two recorded strikes of whales by Navy vessels (or vessels being operated on behalf of the Navy) in the NWTT Study Area. Neither strike was associated with training or testing activities. The first strike occurred in 2012 by a Navy destroyer off the southern coast of Oregon while in transit to San Diego. The whale was suspected to be a minke whale due to the appearance and size (25 ft, dark with white belly), however the Navy could not rule out the possibility that it was a juvenile fin whale. The whale was observed swimming after the strike and no blood or injury was sighted. The second strike occurred in 2016 by a U.S. Coast Guard cutter operating on behalf of the Navy as part of a Maritime Security Operation escort vessel in the Strait of Juan de Fuca. The whale was positively identified as a humpback whale. It was observed for 10 minutes post-collision and appeared normal at the surface. There was no blood observed in the water and the whale subsequently swam away.

In order to account for the potential risk from vessel movement within the NWTT Study Area within the seven-year period in particular, the Navy requested incidental takes based on probabilities derived from a Poisson distribution using ship strike data between 2009–2018 in the NWTT Study Area (the time period from when current mitigation measures to reduce the likelihood of vessel strikes were instituted until the Navy conducted the analysis for the Navy's application), as well as historical at-sea days in the NWTT Study Area from 2009–2018 and estimated potential at-sea days for the period from 2020 to 2027 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 2020 to 2027. The analysis for the period of 2020 to 2027 is described in detail in Chapter 6.6 (Vessel Strike Analysis) of the Navy's rulemaking/LOA application.

For the same reasons listed above, describing why a Navy vessel strike is comparatively unlikely, it is highly unlikely that a Navy vessel would strike a whale, dolphin, porpoise, or pinniped without detecting it and, accordingly, NMFS is confident that the Navy's reported strikes are accurate and appropriate for use in the analysis. Specifically, Navy ships have multiple Lookouts, including on the forward part of the ship that can visually detect a hit animal, in the unlikely event ship personnel do not feel the strike. Unlike the situation for non-Navy ships engaged in commercial activities, NMFS and the Navy have no evidence that the Navy has struck a whale and not detected it. Navy's strict internal procedures and mitigation requirements include reporting of any vessel strikes of marine mammals, and the Navy's discipline, extensive training (not only for detecting marine mammals, but for detecting and reporting any potential navigational obstruction), and strict chain of command give NMFS a high level of confidence that all strikes actually get reported.

The Navy used those two whale strikes in their calculations to determine the number of strikes likely to result from their activities and evaluated data beginning in 2009. The Navy's Marine Species Awareness Training was first used in 2006 and was fully integrated across the Navy in 2009, which is why the Navy uses 2009 as the date to begin the analysis. The adoption of additional mitigation measures to address ship strike also began in 2009, and will remain in place along with additional mitigation measures during the seven years of this rule. The probability analysis concluded that there was a 26 percent chance that zero whales would be struck by Navy vessels over the seven-year period, and a 35, 24, 11, and 4 percent chance that one, two, three, or four whales, respectively, would be struck over the seven-year period (with a 74 percent chance total that at least one whale would be struck over the seven-year period). Therefore, the Navy estimates, and NMFS agrees, that there is some probability that the Navy could strike, and take by serious injury or

mortality, up to three large whales incidental to training and testing activities within the NWTT Study Area over the course of the seven years.

Small whales, delphinids, porpoises, and pinnipeds are not expected to be struck by Navy vessels. In addition to the reasons listed above that make it unlikely that the Navy will hit a large whale (more maneuverable ships, larger crew, *etc.*), the following are the additional reasons that vessel strike of dolphins, small whales, porpoises, and pinnipeds is considered very unlikely. Dating back more than 20 years and for as long as it has kept records, the Navy has no records of individuals of these groups being struck by a vessel as a result of Navy activities and, further, their smaller size and maneuverability make a strike unlikely. Also, NMFS has never received any reports from other authorized activities indicating that these species have been struck by vessels. Worldwide ship strike records show little evidence of strikes of these groups from the shipping sector and larger vessels and the majority of the Navy's activities involving faster-moving vessels (that could be considered more likely to hit a marine mammal) are located in offshore areas where smaller delphinid, porpoise, and pinniped densities are lower. Based on this information, NMFS concurs with the Navy's assessment and recognizes the potential for incidental take by vessel strike of large whales only (*i.e.,* no dolphins, small whales, porpoises, or pinnipeds) over the course of the seven-year regulations from training and testing activities.

Taking into account the available information regarding how many of any given stock could be struck and therefore should be authorized for take, NMFS considered three factors in addition to those considered in the Navy's request: (1) The relative likelihood of hitting one stock versus another based on available strike data from all vessel types as denoted in the SARs, (2) whether the Navy has ever definitively struck an individual from a particular species or stock in the NWTT Study Area, and if so, how many times, and (3) whether there are records that an individual from a particular species or stock has been struck by any vessel in the NWTT Study Area, and if so, how many times (based on ship strike records provided by the NMFS West Coast Region in February 2020). To address number (1) above, NMFS compiled information from NMFS' SARs on detected annual rates of large whale serious injury or mortality (M/SI) from vessel collisions (Table 34). The annual rates of large whale serious injury or mortality from vessel collisions from the SARs help inform the relative susceptibility of large whale species to vessel strike in NWTT Study Area as recorded systematically over the last five years (the period used for the SARs). However, we note that the SARs present strike data from the stock's entire range, which is much larger than the NWTT Study Area, and available ship strike records show that the majority of strikes that occur off the United States West Coast occur in southern California. We summed the annual rates of serious injury or mortality from vessel collisions as reported in the SARs, then divided each species' annual rate by this sum to get the proportion of strikes for each species/stock. To inform the likelihood of striking a particular species of large whale, we multiplied the proportion of striking each species by the probability of striking at least one whale (*i.e.,* 74 percent, as described by the Navy's probability analysis above). We note that these probabilities vary from year to year as the average annual mortality for a given five-year window in the SAR changes; however, over the years and through changing SARs, stocks tend to consistently maintain a relatively higher or relatively lower likelihood of being struck (and we include the annual averages from 2017 SARs in Table 34 to illustrate).

The probabilities calculated as described above are then considered in combination with the information indicating the species that the Navy has definitively hit in the NWTT Study Area since 1995 (since they started tracking consistently) and the species that are known to have been struck by any vessel (through regional stranding data) in the NWTT Study Area. We also note that Rockwood *et al.* (2017) modeled the likely vessel strike of blue whales, fin whales, and humpback whales on the U.S. West Coast (discussed in more detail in the *Serious Injury or Mortality* subsection of the *Preliminary Analysis and Negligible Impact Determination* section), and those numbers help inform the relative likelihood that the Navy will hit those stocks.

For each indicated stock, Table 34 includes the percent likelihood of hitting an individual whale once based on SAR data, total strikes from Navy vessels (from 1995), total strikes from any vessel (from 2000 from regional stranding data), and modeled vessel strikes from Rockwood *et al.* (2017). The last column indicates the annual serious injury or mortality proposed for authorization.

TABLE 34—SUMMARY OF FACTORS CONSIDERED IN DETERMINING THE NUMBER OF INDIVIDUALS IN EACH STOCK POTENTIALLY STRUCK BY A VESSEL

ESA status	Species	Stock	Annual rate of M/SI from vessel collision (observed from 2017 SARs)	Annual rate of M/SI from vessel collision (observed from 2019 Draft SARs)	Percent likelihood of hitting individual from species/ stock once (from 2019 Draft SARs)	Total known strikes in OR, WA, northern CA (from 2000 to present) [1]	Total known navy strikes in NWTT study area	Rockwood *et al.* (2017) modeled vessel strikes [5]	MMPA proposed authorized takes (from the 3 total)	Annual proposed authorized take
Listed	Blue whale	Eastern North Pacific	0	0.4	3.7			18	0	0
	Fin whale	Northeast Pacific	0.2	0.4	3.7	[2] 10			2	0.29
		CA/OR/WA	1.8	1.6	14.8	[2] 10		43	2	0.29
	Sei whale	Eastern North Pacific	0	0.2	1.85				0	0
	Humpback whale	CA/OR/WA (Mexico and Central America DPS).	1.1	2.1	19.425	[3] 4	[4] 1	22	2	0.29
	Sperm whale	CA/OR/WA	0.2	0	0	3			1	0.14
Not Listed	Minke whale	Alaska	0	0	0				0	0
		CA/OR/WA	0	0	0	1	1		1	0.14
	Gray whale	Eastern North Pacific	2	0.8	7.4	9			1	0.14
	Humpback whale	Central North Pacific (Hawaii DPS)	2.6	2.5	23.125	[3] 4	[4] 1		2	0.29

[1] Only one ship strike was reported in California in the NWTT Study Area (which is limited to Humbolt and Del Norte Counties). This strike occurred in 2004 in Humbolt County and was not identified to species.

[2] A total of 10 fin whale strikes are reported in the regional stranding database, however no information on stock is provided. As these two stocks of fin whales are known to overlap spatially and temporally in the NWTT Study Area, the 10 reported strikes could come from either stock or a combination of both stocks.

[3] A total of 4 humpback whales strikes are reported in the regional stranding database, however no information on stock is provided. As these two stocks of humpback whales are known to overlap spatially and temporally in the NWTT Study Area, the 4 reported strikes could come from either stock or a combination of both stocks.

[4] One humpback whale was reported as struck by a U.S. Coast Guard cutter operating on behalf of the Navy, however it was not possible for the Navy to determine which stock this whale came from. As these two stocks of humpback whales are known to overlap spatially and temporally in the NWTT Study Area, this whale could have come from either stock.

[5] Rockwood *et al.* modeled likely annual vessel strikes off the West Coast for these three species only.

Accordingly, stocks that have no record of having been struck by any vessel are considered unlikely to be struck by the Navy in the seven-year period of the rule. Stocks that have never been struck by the Navy, have rarely been struck by other vessels, and have a low likelihood of being struck based on the SAR calculation and a low relative abundance (Eastern North Pacific stock of blue whales, Eastern North Pacific stock of sei whales, and Alaska stock of minke whales) are also considered unlikely to be struck by the Navy during the seven-year rule. This rules out all but seven stocks.

The two stocks of humpback whales (CA/OR/WA and Central North Pacific) and two stocks of fin whales (CA/OR/WA and Northeast Pacific) are known to overlap spatially and temporally in the NWTT Study Area, and it is not possible to distinguish the difference between individuals of these stocks based on visual sightings in the field. The Navy has previously struck a humpback whale in the NWTT Study Area and it is the second most common species struck by any vessel in the Study Area based on stranding data. Based on the SAR data, the two stocks of humpback whales also have the highest likelihood of being struck. Though the Navy has not definitively struck a fin whale in the NWTT Study Area (noting that the Navy could not rule out that the minke whale strike could have been a juvenile fin whale), fin whales are the most common species struck by any vessel in the Study Area based on stranding data. Based on the SAR data, the CA/OR/WA stock has the third highest likelihood of being struck. Based on all of these factors, it is considered reasonably likely that humpback whales (from either the CA/OR/WA or Central North Pacific stocks) could be struck twice and fin whales (from either the CA/OR/WA or Northeast Pacific stocks) could be struck twice during the seven-year rule.

Based on the SAR data, the CA/OR/WA stock of sperm whales and CA/OR/WA stock of minke whales have a very low likelihood of being struck. However, 3 sperm whales have been struck by non-Navy vessels in the NWTT Study Area (in 2002, 2007, and 2012) and the Navy has previously struck a minke whale in the NWTT Study Area. Therefore, we consider it reasonable to predict that an individual from each of these stocks could be struck by the Navy once during the seven-year rule. Finally, based on stranding data, gray whales are the second most commonly struck whale in the NWTT Study Area and the SAR data indicates that on average, 0.8 whales from this stock are struck throughout the stock's range each year. Based on these data, we consider it reasonable to predict that an individual from the Eastern North Pacific stock of gray whales could be struck by the Navy once during the seven-year rule.

In conclusion, although it is generally unlikely that any whales will be struck in a year, based on the information and analysis above, NMFS anticipates that no more than three whales have the potential to be taken by serious injury or mortality over the seven-year period of the rule. Of those three whales over the seven years, no more than two may come from any of the following species/stocks: Fin whale (which may come from either the Northeast Pacific or CA/OR/WA stock) and humpback whale (which may come from either the Central North Pacific or CA/OR/WA stock). Additionally, of those three whales over the seven years no more than one may come from any of the following species/stocks: Sperm whale (CA/OR/WA stock), minke whale (CA/OR/WA stock), and gray whale (Eastern North Pacific stock). Accordingly, NMFS has evaluated under the negligible impact standard the M/SI of 0.14 or 0.29 whales annually from each of these species or stocks (*i.e.,* 1 or 2 takes, respectively, divided by seven years to get the annual number), along with the expected incidental takes by harassment. We do not anticipate, nor propose to authorize, ship strike takes to blue whales (Eastern North Pacific stock), minke whales (Alaska stock), or sei whales (Eastern North Pacific stock).

Proposed Mitigation Measures

Under section 101(a)(5)(A) of the MMPA, NMFS must set forth the permissible methods of taking pursuant to the activity, and other means of effecting the least practicable adverse impact on the species or stocks and their habitat, paying particular attention to rookeries, mating grounds, and areas of similar significance, and on the availability of the species or stocks for subsistence uses (''least practicable adverse impact''). NMFS does not have a regulatory definition for least practicable adverse impact. The 2004 NDAA 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 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 previous rules we have published, such as the Navy's Hawaii-Southern California Training and Testing (HSTT) rule (83 FR 66846; December 27, 2018), Atlantic Fleet Training and Testing (AFTT) rule (84 FR 70712; December 23, 2019), and Mariana Islands Training and Testing (MITT) proposed rule (85 FR 5782; January 31, 2020).

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 [3] and, therefore are considered in evaluating population level impacts.

As stated in the preamble to the proposed rule for the MMPA 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. The 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.[4]

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). Section 3(11) of 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. 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 under MMPA section 3(11), the term ''stock'' in the MMPA is interchangeable with the statutory term ''population stock.'' 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' statutory findings for enacting the MMPA, nearly all of which are most applicable at the species or stock (*i.e.,* population) level. *See* MMPA section 2 (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, 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.[5] 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.'' *Pritzker* 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 language above might be construed as 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

[3] A growth rate can be positive, negative, or flat.

[4] 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 rule.

[5] 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).

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 *Preliminary 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.

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—and the best available science has been used here. 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 could become available in the future and necessitate 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 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 its 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. We discuss consideration of these factors in greater detail below.

1. *Reduction of adverse impacts to marine mammal species or stocks and their habitat.*[6] 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) 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

[6] 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.

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 potential biological removal (PBR) level (as defined in MMPA section 3(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, will include personnel safety, practicality of implementation, and impact on the effectiveness of the military readiness activity (see MMPA section 101(a)(5)(A)(ii)).

Assessment of Mitigation Measures for NWTT Study Area

NMFS has fully reviewed the specified activities and the mitigation measures included in the Navy's rulemaking/LOA application and the 2019 NWTT DSEIS/OEIS to determine if the mitigation measures would result in the least practicable adverse impact on marine mammals and their habitat. 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 Navy's evaluation process used to develop, assess, and select mitigation measures, which was informed by input from NMFS, can be found in Chapter 5 (*Mitigation*) and Appendix K (*Geographic Mitigation Assessment*) of the 2019 NWTT DSEIS/OEIS. The process described in Chapter 5 (*Mitigation*) and Appendix K (*Geographic Mitigation Assessment*) of the 2019 NWTT DSEIS/OEIS robustly supported NMFS' independent evaluation of whether the mitigation measures would meet the least practicable adverse impact standard. The Navy would be required to implement the mitigation measures identified in this rule for the full seven years to avoid or reduce potential impacts from acoustic, explosive, and physical disturbance and strike stressors.

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 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 still necessary for NMFS to consider whether there are additional practicable measures that would meaningfully reduce the probability or severity of impacts that could affect reproductive success or survivorship.

Overall the Navy has agreed to procedural mitigation measures that would 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 would use a combination of delayed starts, powerdowns, and shutdowns to avoid mortality or serious injury, 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 would also implement multiple time/area restrictions that would reduce take of marine mammals in areas or at times where they are known to engage in important behaviors, such as 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.

The Navy assessed the practicability of the proposed measures 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 are supportable. As described in more detail below, NMFS has independently evaluated the measures the Navy proposed in the manner described earlier in this section (*i.e.,* in consideration of their ability to reduce adverse impacts on marine mammal species and their habitat and their practicability for implementation). We have determined that the measures will significantly and adequately reduce impacts on the affected marine mammal species and stocks and their habitat and, further, be practicable for Navy implementation. Therefore, the mitigation measures assure that the Navy's activities will have the least practicable adverse impact on the species or stocks and their habitat.

The Navy also evaluated numerous measures in the 2019 NWTT DSEIS/OEIS that were not included in the Navy's rulemaking/LOA application, and NMFS independently reviewed and preliminarily concurs with the 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 2019 NWTT DSEIS/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 or the public, through scoping or public comment on environmental compliance documents. Appendix K (*Geographic Mitigation Assessment*) of the 2019 NWTT DSEIS/OEIS includes an in-depth analysis of

time/area restrictions that have been recommended over time or previously implemented as a result of litigation (outside of the NWTT Study Area). As described in Chapter 5 (*Mitigation*) of the 2019 NWTT DSEIS/OEIS, commenters sometimes recommend that the Navy reduce its overall amount of training, reduce explosive use, modify its sound sources, completely replace live training with computer simulation, or include time of day restrictions. Many 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 described in Chapter 5 (*Mitigation*) of the 2019 NWTT DSEIS/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 Navy's judgment on the impacts of potential mitigation measures to personnel safety, practicality of implementation, and the effectiveness of training and testing within the NWTT Study Area 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 2019 NWTT DSEIS/OEIS, the Navy evaluated additional potential procedural mitigation measures, including increased mitigation zones, ramp-up measures, 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 2019 NWTT DSEIS/OEIS). NMFS independently reviewed the Navy's evaluation and concurs with this assessment, which supports NMFS' preliminary 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 warranted.

Last, Appendix K (*Geographic Mitigation Assessment*) of the 2019 NWTT DSEIS/OEIS describes a comprehensive method for analyzing potential geographic mitigation that includes consideration of both a biological assessment of how the potential time/area limitation would benefit the species and its habitat (*e.g.,* is a key area of biological importance or would result in avoidance or reduction of impacts) in the context of the stressors of concern in the specific area and an operational assessment of the practicability of implementation (*e.g.,* including an assessment of the specific importance of that area for training, considering proximity to training ranges and emergency landing fields and other issues). For most of the areas that were considered in the 2019 NWTT DSEIS/OEIS but not included in this rule, the Navy found that the mitigation was not warranted because the anticipated reduction of adverse impacts on marine mammal species and their habitat was not sufficient to offset the impracticability of implementation. In some cases potential benefits to marine mammals were non-existent, while in others the consequences on mission effectiveness were too great.

NMFS has reviewed the Navy's analysis in Chapter 5 *Mitigation* and Appendix K *Geographic Mitigation Assessment* of the 2019 NWTT DSEIS/OEIS, which considers the same factors that NMFS considers to satisfy the least practicable adverse impact standard, and concurs with the analysis and conclusions. Therefore, NMFS is not proposing to include any of the measures that the Navy ruled out in the 2019 NWTT DSEIS/OEIS. Below are the mitigation measures that NMFS determined will ensure the least practicable adverse impact on all affected species and their habitat, including the specific considerations for military readiness activities. The following sections describe the mitigation measures that would be implemented in association with the training and testing activities analyzed in this document. The mitigation measures are organized into two categories: Procedural mitigation and mitigation areas.

Procedural Mitigation

Procedural mitigation is mitigation that the Navy would implement whenever and wherever an applicable training or testing activity takes place within the NWTT 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 35) is designed to aid Lookouts and other applicable Navy personnel with their observation, environmental compliance, and reporting responsibilities. The remainder of the procedural mitigation measures (Tables 36 through 49) are organized by stressor type and activity category and include acoustic stressors (*i.e.,* active sonar, weapons firing noise), explosive stressors (*i.e.,* sonobuoys, torpedoes, medium-caliber and large-caliber projectiles, missiles, bombs, mine counter-measure and neutralization activities, mine neutralization involving Navy divers), 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, non-explosive bombs and mine shapes).

TABLE 35—PROCEDURAL MITIGATION FOR ENVIRONMENTAL AWARENESS AND EDUCATION

Procedural mitigation description
Stressor or Activity: • All training and testing activities, as applicable. Mitigation Requirements: • 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:

TABLE 35—PROCEDURAL MITIGATION FOR ENVIRONMENTAL AWARENESS AND EDUCATION—Continued

Procedural mitigation description
—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 36 and 37.

Procedural Mitigation for Active Sonar

Procedural mitigation for active sonar is described in Table 36 below.

TABLE 36—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 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 aerial systems 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). • Sources that are not hull-mounted: —1 Lookout on the ship or aircraft conducting the activity. Mitigation Requirements: • Mitigation zones: —1,000 yd power down, 500 yd power down, and 200 yd or 100 yd shut down for low-frequency active sonar ≥200 decibels (dB) and hull-mounted mid-frequency active sonar. —200 yd or 100 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 a marine mammal is observed within 1,000 yd of the sonar source; power down an additional 4 dB (10 dB total) if a marine mammal is observed within 500 yd; cease transmission if a cetacean in the NWTT Offshore Area, NWTT Inland Area, or Western Behm Canal is observed within 200 yd; cease transmission if a pinniped in the NWTT Offshore Area or Western Behm Canal is observed within 200 yd and cease transmission if a pinniped in NWTT Inland Waters is observed within 100 yd (except if hauled out on, or in the water near, man-made structures and vessels). —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 transmission if a cetacean or pinniped in the NWTT Offshore Area or Western Behm Canal is observed within 200 yd of the sonar source; cease transmission if a pinniped in NWTT Inland Waters is observed within 100 yd (except if hauled out on, or in the water near, man-made structures and vessels). • Commencement/recommencement conditions after a marine mammal sighting before or during the activity:

TABLE 36—PROCEDURAL MITIGATION FOR ACTIVE SONAR—Continued

Procedural mitigation description
—The Navy will 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 minutes for aircraft-deployed sonar sources or 30 minutes 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 Lookout 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 Weapons Firing Noise

Procedural mitigation for weapons firing noise is described in Table 37 below.

TABLE 37—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 in Table 40 for Explosive Medium-Caliber and Large-Caliber Projectiles or Table 47 for Small-, Medium-, and Large-Caliber Non-Explosive Practice Munitions. Mitigation Requirements: • 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 will 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 minutes; 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 38 through 44.

Procedural Mitigation for Explosive Sonobuoys

Procedural mitigation for explosive sonobuoys is described in Table 38 below.

TABLE 38—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 a 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 marine mammals 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 minutes): —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.

TABLE 38—PROCEDURAL MITIGATION FOR EXPLOSIVE SONOBUOYS—Continued

Procedural mitigation description
• 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 will 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 minutes when the activity involves aircraft that have fuel constraints, or 30 minutes 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 will 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 39 below.

TABLE 39—PROCEDURAL MITIGATION FOR EXPLOSIVE TORPEDOES

Procedural Mitigation Description
Stressor or Activity: • Explosive torpedoes. 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) will support observing the mitigation zone for marine mammals 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; 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 will 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 minutes when the activity involves aircraft that have fuel constraints, or 30 minutes 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 will assist in the visual observation of the area where detonations occurred.

Procedural Mitigation for Explosive Medium-Caliber and Large-Caliber Projectiles

Procedural mitigation for Explosive Medium-Caliber and Large-Caliber Projectiles is described in Table 40 below.

TABLE 40—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 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 Table 37 for Weapons Firing Noise. • 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 marine mammals while performing their regular duties. Mitigation Requirements: • Mitigation zones: —600 yd around the intended impact location for explosive medium-caliber projectiles. —1,000 yd around the intended impact location for 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 will 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 30 minutes 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 will assist in the visual observation of the area where detonations occurred.

Procedural Mitigation for Explosive Missiles

Procedural mitigation for explosive missiles is described in Table 41 below.

TABLE 41—PROCEDURAL MITIGATION FOR EXPLOSIVE MISSILES

Procedural mitigation description
Stressor or Activity: • Aircraft-deployed explosive missiles: —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) will support observing the mitigation zone for marine mammals while performing their regular duties. Mitigation Requirements: • Mitigation zone: —2,000 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 before or during the activity: —The Navy will 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 minutes when the activity involves aircraft that have fuel constraints, or 30 minutes 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.

TABLE 41—PROCEDURAL MITIGATION FOR EXPLOSIVE MISSILES—Continued

Procedural mitigation description
—If additional platforms are supporting this activity (*e.g.,* providing range clearance), these assets will 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 42 below.

TABLE 42—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) will support observing the mitigation zone for marine mammals 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 will 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 minutes; 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 will 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 43 below.

TABLE 43—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) will support observing the mitigation zone for marine mammals while performing their regular duties. Mitigation Requirements: • Mitigation zones: —600 yd around the detonation site for activities using ≤5 lb net explosive weight. —2,100 yd around the detonation site for activities using >5–60 lb net explosive weight. • Prior to the initial start of the activity (*e.g.,* when maneuvering on station; typically, 10 minutes when the activity involves aircraft that have fuel constraints, or 30 minutes 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:

TABLE 43—PROCEDURAL MITIGATION FOR EXPLOSIVE MINE COUNTERMEASURE AND NEUTRALIZATION ACTIVITIES—Continued

Procedural mitigation description
—Observe for marine mammals; if observed, cease detonations. • Commencement/recommencement conditions after a marine mammal sighting before or during the activity: —The Navy will 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 minutes when the activity involves aircraft that have fuel constraints, or 30 minutes when the activity involves aircraft that are not typically fuel constrained. • After completion of the activity (typically 10 minutes when the activity involves aircraft that have fuel constraints, or 30 minutes 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 will assist in the visual observation of the area where detonations occurred.

Procedural Mitigation for Explosive Mine Neutralization Activities lnvolving Navy Divers

Procedural mitigation for explosive mine neutralization activities involving Navy divers is described in Table 44 below.

TABLE 44—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 on two small boats with one Lookout each, one of which will be a Navy biologist. • All divers placing the charges on mines will support the Lookouts while performing their regular duties and will report applicable sightings to the lead Lookout, the supporting small boat, or the Range Safety Officer. • 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 marine mammals while performing their regular duties. Mitigation Requirements: • Mitigation zone: —500 yd around the detonation site during activities using >0.5–2.5 lb net explosive weight. • Prior to the initial start of the activity (starting 30 minutes before the first planned detonation): —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. —The Navy will ensure the area is clear of marine mammals for 30 minutes prior to commencing a detonation. —A Navy biologist will serve as the lead Lookout and will make the final determination that the mitigation zone is clear of any biological resource sightings prior to the commencement of a detonation. The Navy biologist will maintain radio communication with the unit conducting the event and the other Lookout. • During the activity: —Observe the mitigation zone for marine mammals; if observed, cease detonations. —To the maximum extent practicable depending on mission requirements, safety, and environmental conditions, boats will position themselves near the midpoint of the mitigation zone radius (but outside of the detonation plume and human safety zone), will position themselves on opposite sides of the detonation location, and will 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. —The Navy will use only positively controlled charges (*i.e.,* no time-delay fuses). —The Navy will use the smallest practicable charge size for each activity. —Activities will be conducted in Beaufort sea state number 2 conditions or better and will not be conducted in low visibility conditions. • Commencement/recommencement conditions after a marine mammal sighting before or during the activity: —The Navy will 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 30 minutes. • After each detonation and the completion of an activity (for 30 minutes): —Observe for marine mammals in the vicinity of where detonations occurred and immediately downstream of the detonation location; 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 will assist in the visual observation of the area where detonations occurred. • Additional requirements: —At the Hood Canal Explosive Ordnance Disposal Range and Crescent Harbor Explosive Ordnance Disposal Range, naval units will obtain permission from the appropriate designated Command authority prior to conducting explosive mine neutralization activities involving the use of Navy divers.

TABLE 44—PROCEDURAL MITIGATION FOR EXPLOSIVE MINE NEUTRALIZATION ACTIVITIES INVOLVING NAVY DIVERS—Continued

Procedural mitigation description
—At the Hood Canal Explosive Ordnance Disposal Range, during February, March, and April (the juvenile migration period for Hood Canal Summer Run Chum), the Navy will not use explosives in bin E3 (>0.5–2.5 lb net explosive weight), and will instead use explosives in bin E0 (<0.1 lb net explosive weight). —At the Hood Canal Explosive Ordnance Disposal Range, during August, September, and October (the adult migration period for Hood Canal summer-run chum and Puget Sound Chinook), the Navy will avoid the use of explosives in bin E3 (>0.5–2.5 lb net explosive weight), and will instead use explosive bin E0 (<0.1 lb net explosive weight) to the maximum extent practicable unless necessitated by mission requirements. —At the Crescent Harbor Explosive Ordnance Disposal Range, the Navy will conduct explosive activities at least 1,000 m from the closest point of land to avoid or reduce impacts on fish (*e.g.,* bull trout) in nearshore habitat areas.

Procedural Mitigation for Physical Disturbance and Strike Stressors

Mitigation measures for physical disturbance and strike stressors are provided in Tables 45 through 49.

Procedural Mitigation for Vessel Movement

Procedural mitigation for vessel movement is described in Table 45 below.

TABLE 45—PROCEDURAL MITIGATION FOR VESSEL MOVEMENT

Procedural mitigation description
Stressor or Activity: • Vessel movement: —The mitigation will 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, during Transit Protection Program exercises or other events involving escort vessels), (3) the vessel is operated autonomously, or (4) when impractical based on mission requirements (*e.g.,* during test body retrieval by range craft). Number of Lookouts and Observation Platform: • 1 Lookout on the vessel that is underway. Mitigation Requirements: • Mitigation zones: —500 yd (for surface ships other than small boats) around whales. —200 yd (for surface ships other than small boats) around all marine mammals other than whales (except bow-riding dolphins and pinnipeds hauled out on man-made navigational structures, port structures, and vessels). —100 yd (for small boats, such as range craft) around 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: —Prior to Small Boat Attack exercises at Naval Station Everett, Naval Base Kitsap Bangor, or Naval Base Kitsap Bremerton, Navy event planners will coordinate with Navy biologists during the event planning process. Navy biologists will work with NMFS to determine the likelihood of marine mammal presence in the planned training location. Navy biologists will notify event planners of the likelihood of species presence as they plan specific details of the event (*e.g.,* timing, location, duration). The Navy will provide additional environmental awareness training to event participants. The training will alert participating ship and aircraft crews to the possible presence of marine mammals in the training location. Lookouts will use the information to assist their visual observation of applicable mitigation zones and to aid in the implementation of procedural mitigation. —If a marine mammal vessel strike occurs, the Navy will follow the established incident reporting procedures.

Procedural Mitigation for Towed In-Water Devices

TABLE 46—PROCEDURAL MITIGATION FOR TOWED IN-WATER DEVICES

Procedural mitigation description
Stressor or Activity: • Towed in-water devices: —Mitigation applies to devices towed from a manned surface platform or manned aircraft, or when a manned support craft is already participating in an activity involving in-water devices being towed by unmanned platforms. —The mitigation will 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 towing platform or support craft. Mitigation Requirements: • Mitigation zones: —250 yd (for in-water devices towed by aircraft or surface ships other than small boats) around marine mammals (except bow-riding dolphins and pinnipeds hauled out on man-made navigational structures, port structures, and vessels).

TABLE 46—PROCEDURAL MITIGATION FOR TOWED IN-WATER DEVICES—Continued

Procedural mitigation description
—100 yd (for in-water devices towed by small boats, such as range craft) around marine mammals (except bow-riding dolphins and pinnipeds hauled out on man-made navigational structures, port structures, and vessels). • 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

TABLE 47—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 in Table 37 for Weapons Firing Noise. Mitigation Requirements: • 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 will 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 minutes for aircraft-based firing or 30 minutes 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

TABLE 48—PROCEDURAL MITIGATION FOR NON-EXPLOSIVE MISSILES

Procedural mitigation description
Stressor or Activity: • Aircraft-deployed non-explosive missiles: —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 will 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 minutes when the activity involves aircraft that have fuel constraints, or 30 minutes when the activity involves aircraft that are not typically fuel constrained.

Procedural Mitigation for Non-Explosive Bombs and Mine Shapes

TABLE 49—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: • Mitigation zone: —1,000 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 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 will 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 minutes; 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 would implement mitigation measures within mitigation areas to avoid or minimize potential impacts on marine mammals. A full technical analysis (for which the methods were summarized above) of the mitigation areas that the Navy considered for marine mammals is provided in Appendix K (*Geographic Mitigation Assessment*) of the 2019 NWTT DSEIS/OEIS. The Navy took into account public comments received on the 2019 NWTT DSEIS/OEIS, the best available science, and the practicability of implementing additional mitigation measures and has enhanced its mitigation areas and mitigation measures beyond those that were included in the 2015–2020 regulations to further reduce impacts to marine mammals.

Information on the mitigation measures that the Navy will implement within mitigation areas is provided in Table 50 (see below). The mitigation applies year-round unless specified otherwise in the table.

NMFS conducted an independent analysis of the mitigation areas that the Navy proposed, which are described below. NMFS preliminarily concurs with the Navy's analysis, which 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 or their habitat in the manner described in the Navy's analysis and this rule. NMFS is heavily reliant on the Navy's description of operational practicability, since the Navy is best equipped to describe the degree to which a given mitigation measure affects personnel safety or mission effectiveness, and is practical to implement. The Navy considers the measures in this proposed rule to be practicable, and NMFS concurs. We further discuss the manner in which the Geographic Mitigation Areas in the proposed rule will reduce the likelihood or severity of adverse impacts to marine mammal species or their habitat in the *Preliminary Analysis and Negligible Impact Determination* section.

TABLE 50—GEOGRAPHIC MITIGATION AREAS FOR MARINE MAMMALS IN THE NWTT STUDY AREA

Mitigation area description
Stressor or Activity: • Sonar. • Explosives. • Physical disturbance and strikes. Mitigation Requirements: • Marine Species Coastal Mitigation Area (year-round): —Within 50 nmi from shore in the Marine Species Coastal Mitigation Area, the Navy will not conduct: (1) Explosive training activities, (2) explosive testing activities (with the exception of explosive Mine Countermeasure and Neutralization Testing activities), and (3) non-explosive missile training activities. Should national security present a requirement to conduct these activities in the mitigation area, naval units will obtain permission from the appropriate designated Command authority prior to commencement of the activity. The Navy will provide NMFS with advance notification and include information about the event in its annual activity reports to NMFS. —Within 20 nmi from shore in the Marine Species Coastal Mitigation Area, the Navy will not conduct non-explosive large-caliber gunnery training activities and non-explosive bombing training activities. Should national security present a requirement to conduct these activities in the mitigation area, naval units will obtain permission from the appropriate designated Command authority prior to commencement of the activity. The Navy will provide NMFS with advance notification and include information about the event in its annual activity reports to NMFS.

TABLE 50—GEOGRAPHIC MITIGATION AREAS FOR MARINE MAMMALS IN THE NWTT STUDY AREA—Continued

Mitigation area description
—Within 12 nmi from shore in the Marine Species Coastal Mitigation Area, the Navy will not conduct: (1) Non-explosive small- and medium-caliber gunnery training activities, (2) non-explosive torpedo training activities, and (3) Anti-Submarine Warfare Tracking Exercise—Helicopter, Maritime Patrol Aircraft, Ship, or Submarine training activities. Should national security present a requirement to conduct these activities in the mitigation area, naval units will obtain permission from the appropriate designated Command authority prior to commencement of the activity. The Navy will provide NMFS with advance notification and include information about the event in its annual activity reports to NMFS.
• Olympic Coast National Marine Sanctuary Mitigation Area (year-round):
—Within the Olympic Coast National Marine Sanctuary Mitigation Area, the Navy will not conduct more than 32 hours of MF1 mid-frequency active sonar during training annually and will not conduct non-explosive bombing training activities. Should national security present a requirement to conduct more than 32 hours of MF1 mid-frequency active sonar during training annually or conduct non-explosive bombing training activities in the mitigation area, naval units will obtain permission from the appropriate designated Command authority prior to commencement of the activity. The Navy will provide NMFS with advance notification and include information about the event in its annual activity reports to NMFS.
—Within the Olympic Coast National Marine Sanctuary Mitigation Area, the Navy will not conduct more than 33 hours of MF1 mid-frequency active sonar during testing annually (except within the portion of the mitigation area that overlaps the Quinault Range Site) and will not conduct explosive Mine Countermeasure and Neutralization Testing activities. Should national security present a requirement for the Navy to conduct more than 33 hours of MF1 mid-frequency active sonar during testing annually (except within the portion of the mitigation area that overlaps the Quinault Range Site) or conduct explosive Mine Countermeasure and Neutralization Testing activities in the mitigation area, naval units will obtain permission from the appropriate designated Command authority prior to commencement of the activity. The Navy will provide NMFS with advance notification and include information about the event in its annual activity reports to NMFS.
• Stonewall and Heceta Bank Humpback Whale Mitigation Area (May 1–November 30):
—Within the Stonewall and Heceta Bank Humpback Whale Mitigation Area, the Navy will not use MF1 mid-frequency active sonar or explosives during training and testing from May 1 to November 30. Should national security present a requirement to use MF1 mid-frequency active sonar or explosives during training and testing from May 1 to November 30, naval units will obtain permission from the appropriate designated Command authority prior to commencement of the activity. The Navy will provide NMFS with advance notification and include information about the event in its annual activity reports to NMFS.
• Point St. George Humpback Whale Mitigation Area (July 1–November 30):
—Within the Point St. George Humpback Whale Mitigation Area, the Navy will not use MF1 mid-frequency active sonar or explosives during training and testing from July 1 to November 30. Should national security present a requirement to use MF1 mid-frequency active sonar or explosives during training and testing from July 1 to November 30, naval units will obtain permission from the appropriate designated Command authority prior to commencement of the activity. The Navy will provide NMFS with advance notification and include information about the event in its annual activity reports to NMFS.
• Puget Sound and Strait of Juan de Fuca Mitigation Area (year-round):
—Within the Puget Sound and Strait of Juan de Fuca Mitigation Area, the Navy will require units to obtain approval from the appropriate designated Command authority prior to: (1) The use of hull-mounted mid-frequency active sonar during training while underway, and (2) conducting ship and submarine active sonar pierside maintenance or testing.
—Within the Puget Sound and Strait of Juan de Fuca Mitigation Area for Civilian Port Defense—Homeland Security Anti-Terrorism/Force Protection Exercises, Navy event planners will coordinate with Navy biologists during the event planning process. Navy biologists will work with NMFS to determine the likelihood of gray whale and Southern Resident Killer Whale presence in the planned training location. Navy biologists will notify event planners of the likelihood of species presence as they plan specific details of the event (*e.g.,* timing, location, duration). The Navy will ensure environmental awareness of event participants. Environmental awareness will help alert participating ship and aircraft crews to the possible presence of marine mammals in the training location, such as gray whales and Southern Resident Killer Whales.
• Northern Puget Sound Gray Whale Mitigation Area (March 1–May 31):
—Within the Northern Puget Sound Gray Whale Mitigation Area, the Navy will not conduct Civilian Port Defense—Homeland Security Anti-Terrorism/Force Protection Exercises from March 1 to May 31. Should national security present a requirement to conduct Civilian Port Defense—Homeland Security Anti-Terrorism/Force Protection Exercises from March 1 to May 31, naval units will obtain permission from the appropriate designated Command authority prior to commencement of the activity. The Navy will provide NMFS with advance notification and include information about the event in its annual activity reports to NMFS.

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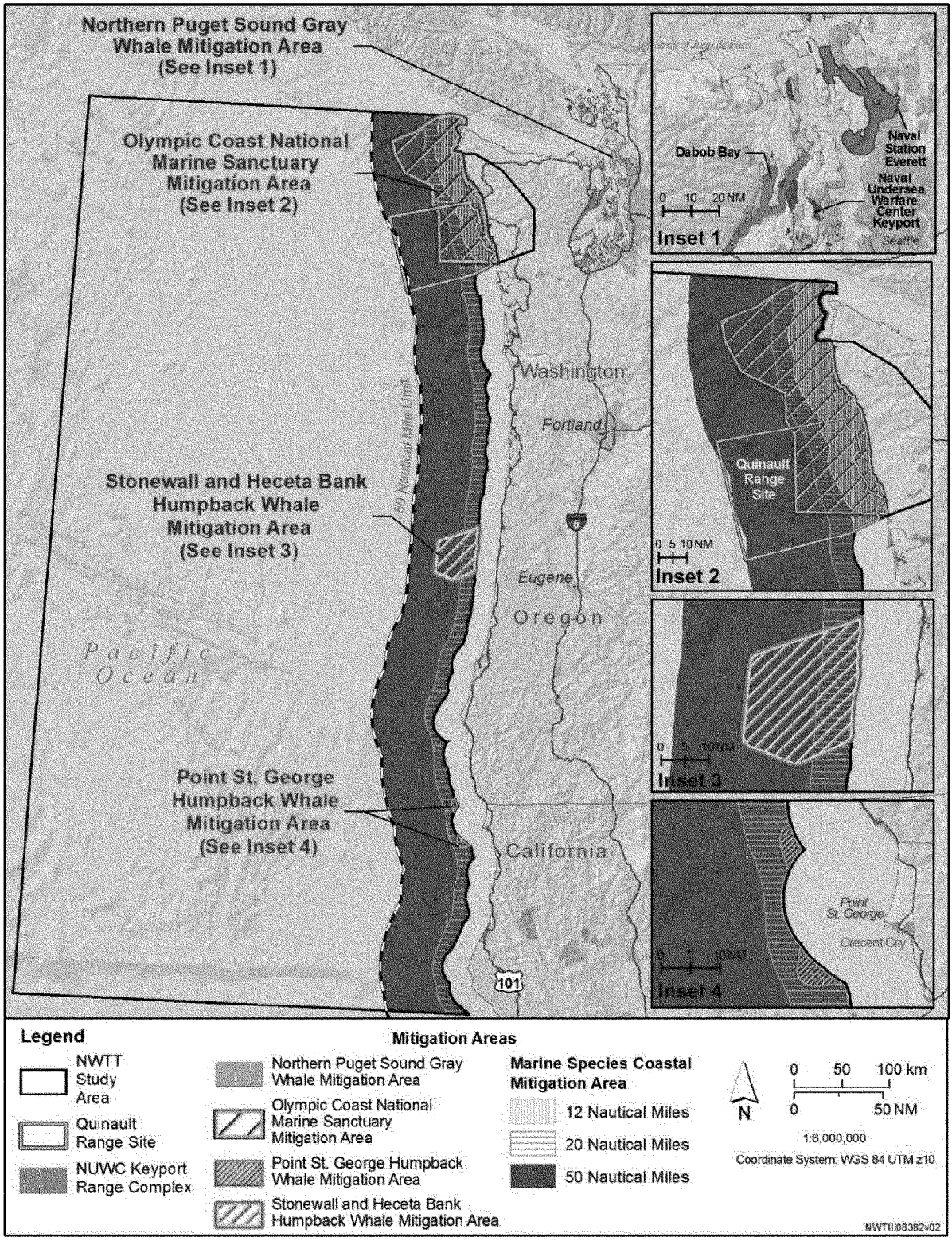

Figure 2 -- Geographic Mitigation Areas for Marine Mammals in the NWTT Study Area. (a color version of this map is presented as Figure 11-1 in the Navy's Application at *https://www.fisheries.noaa.gov/action/incidental-take-authorization-us-navy-northwest-training-and-testing-nwtt-2020*).

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Mitigation Conclusions

NMFS has carefully evaluated the Navy's proposed mitigation measures—many of which were developed with NMFS' input during the previous phases of Navy training and testing authorizations but several of which are new since implementation of the current 2015 to 2020 regulations—and considered a broad range of other measures (*i.e.,* the measures considered but eliminated in the 2019 NWTT DSEIS/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 their habitat. Our evaluation of potential 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 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 proposed measures, as well as other measures considered by the Navy and NMFS, NMFS has preliminarily determined that these proposed mitigation measures are appropriate means of effecting the least practicable adverse impact on marine mammal species and their habitat, paying particular attention to rookeries, mating grounds, and areas of similar significance, and considering specifically personnel safety, practicality of implementation, and impact on the effectiveness of the military readiness activity. Additionally, an adaptive management component helps further ensure that mitigation is regularly assessed and provides a mechanism to improve the mitigation, based on the factors above, through modification as appropriate.

The proposed rule comment period provides the public an opportunity to submit recommendations, views, and/or concerns regarding the Navy's activities and the proposed mitigation measures. While NMFS has preliminarily determined that the Navy's proposed mitigation measures would effect the least practicable adverse impact on the affected species and their habitat, NMFS will consider all public comments to help inform our final determination. Consequently, the proposed mitigation measures may be refined, modified, removed, or added to prior to the issuance of the final rule based on public comments received and, as appropriate, analysis of additional potential mitigation measures.

Proposed 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.

Although the Navy has been conducting research and monitoring in the NWTT Study Area for over 20 years, it developed a formal marine species monitoring program in support of the MMPA and ESA authorizations in 2009. This robust program has resulted in hundreds of technical reports and publications on marine mammals that have informed Navy and NMFS analyses in environmental planning documents, rules, and Biological Opinions. The reports are made available to the public on the Navy's marine species monitoring website (*www.navymarinespeciesmonitoring.us*) and the data on the Ocean Biogeographic Information System Spatial Ecological Analysis of Megavertebrate Populations (OBIS–SEAMAP) (*http://seamap.env.duke.edu/*).

The Navy will continue collecting monitoring data to inform our understanding of the occurrence of marine mammals in the NWTT Study Area; the likely exposure of marine mammals to stressors of concern in the NWTT Study Area; the response of marine mammals to exposures to stressors; the consequences of a particular marine mammal response to their individual fitness and, ultimately, populations; and the effectiveness of implemented mitigation measures. Taken together, mitigation and monitoring comprise the Navy's integrated approach for reducing environmental impacts from the specified activities. The Navy's overall monitoring approach seeks to leverage and build on existing research efforts whenever possible.

As agreed upon between the Navy and NMFS, the monitoring measures presented here, as well as the mitigation measures described above, focus on the protection and management of potentially affected marine mammals. A well-designed monitoring program can provide important feedback for validating assumptions made in analyses and allow for adaptive management of marine resources. Monitoring is required under the MMPA, and details of the monitoring program for the specified activities have been developed through coordination between NMFS and the Navy through the regulatory process for previous Navy at-sea training and testing activities.

Integrated Comprehensive Monitoring Program

The Navy's Integrated Comprehensive Monitoring Program (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 and NMFS 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 or accomplish one or more of the following top-level goals:

- An increase in the understanding of the likely occurrence of marine mammals and ESA-listed marine species in the vicinity of the action (*i.e.,* presence, abundance, distribution, and density of species);
- An increase in the understanding of the nature, scope, or context of the

likely exposure of marine mammals and ESA-listed species to any of the potential stressors associated with the action (*e.g.,* sound, explosive detonation, or expended materials), through better understanding of one or more of the following: (1) The nature of the action and its surrounding environment (*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 ESA-listed marine species with the action (in whole or part), and (4) the likely biological or behavioral context of exposure to the stressor for the marine mammal and ESA-listed marine species (*e.g.,* age class of exposed animals or known pupping, calving, or feeding areas);

- An increase in the 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 the 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 impacts on annual rates of recruitment or survival);
- An increase in the understanding of the effectiveness of mitigation and monitoring measures;
- A better understanding and record of the manner in which the Navy 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 serves to guide the investment of resources to most efficiently address ICMP objectives and intermediate scientific objectives developed through this process. The Strategic Planning Process 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; 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. More information on the Strategic Planning Process for Marine Species Monitoring including results, reports, and publications, is also available online (*http://www.navymarinespeciesmonitoring.us/*).

Past and Current Monitoring in the NWTT Study Area

The monitoring program has undergone significant changes since the first rule was issued for the NWTT Study Area in 2010, which highlights the monitoring program's evolution through the process of adaptive management. The monitoring program developed for the first cycle of environmental compliance documents (*e.g.,* U.S. Department of the Navy, 2008a, 2008b) utilized effort-based compliance metrics that were somewhat limiting. Through adaptive management discussions, the Navy designed and conducted monitoring studies according to scientific objectives and eliminated specific effort requirements.

Progress has also been made on the conceptual framework categories from the Scientific Advisory Group for Navy Marine Species Monitoring (U.S. Department of the Navy, 2011), ranging from occurrence of animals, to their exposure, response, and population consequences. The Navy continues to manage the Atlantic and Pacific program as a whole, with monitoring in each range complex taking a slightly different but complementary approach. The Navy has continued to use the approach of layering multiple simultaneous components in many of the range complexes to leverage an increase in return of the progress toward answering scientific monitoring questions. This includes in the NWTT Study Area, for example, (a) satellite tagging of blue whales, fin whales, humpback whales, and Southern Resident killer whales; (b) analysis of existing passive acoustic monitoring datasets; and (c) line-transect aerial surveys for marine mammals in Puget Sound, Washington.

Numerous publications, dissertations, and conference presentations have resulted from research conducted under the marine species monitoring program (*https://www.navymarinespeciesmonitoring.us/reading-room/publications/*), leading to a significant contribution to the body of marine mammal science. Publications on occurrence, distribution, and density have fed the modeling input, and publications on exposure and response have informed Navy and NMFS analysis of behavioral response and consideration of mitigation measures.

Furthermore, collaboration between the monitoring program and the Navy's research and development (*e.g.,* the Office of Naval Research) and demonstration-validation (*e.g.,* Living Marine Resources) programs has been strengthened, leading to research tools and products that have already transitioned to the monitoring program. These include Marine Mammal Monitoring on Ranges, controlled exposure experiment behavioral response studies, acoustic sea glider surveys, and global positioning system-enabled satellite tags. Recent progress has been made with better integration with monitoring across all Navy at-sea study areas, including the Atlantic Fleet Training and Testing Study Area in the Atlantic Ocean, and various other ranges. Publications from the Living Marine Resources and Office of Naval Research programs have also resulted in significant contributions to hearing, acoustic criteria used in effects modeling, exposure, and response, as well as in developing tools to assess biological significance (*e.g.,* consequences).

NMFS and the Navy also consider data collected during procedural mitigations as monitoring. Data are collected by shipboard personnel on hours spent training, hours of observation, hours of sonar, and marine mammals observed within the mitigation zones when mitigations are implemented. These data are provided to NMFS in both classified and unclassified annual exercise reports, which would continue under this proposed rule.

NMFS has received multiple years' worth of annual exercise and monitoring reports addressing active

sonar use and explosive detonations within the NWTT 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 proposed training and testing activities within the NWTT 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 *https://www.navymarinespeciesmonitoring.us/reporting/.*

The Navy's marine species monitoring program typically supports several monitoring projects in the NWTT Study Area at any given time. Additional details on the scientific objectives for each project can be found at *https://www.navymarinespeciesmonitoring.us/regions/pacific/current-projects/.* Projects can be either major multi-year efforts, or one to two-year special studies. The emphasis on monitoring in the Pacific Northwest is directed towards collecting and analyzing tagging data related to the occurrence of blue whales, fin whales, humpback whales, and Southern Resident killer whales. In 2017, researchers deployed 28 tags on blue whales and one tag on a fin whale off southern and central California (Mate *et al.,* 2017). Detailed analyses for the 2017 tagging effort are ongoing and will be available later in a final report and posted at *https://www.navymarinespeciesmonitoring.us/.* Humpback whales have been tagged with satellite tags, and biopsy samples have been collected (Mate *et al.,* 2017). Location information on Southern Resident killer whales was provided via satellite tag data and acoustic detections (Hanson *et al.,* 2018). Also, distribution of Chinook salmon (a key prey species of Southern Resident killer whales) in coastal waters from Alaska to Northern California was studied (Shelton *et al.,* in review). Future monitoring efforts in the NWTT Study Area are anticipated to continue along the same objectives: Determining the species and populations of marine mammals present and potentially exposed to Navy training and testing activities in the NWTT Study Area, through tagging, passive acoustic monitoring, refined modeling, photo identification, biopsies, and visual monitoring.

Adaptive Management

The proposed regulations governing the take of marine mammals incidental to Navy training and testing activities in the NWTT 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 seven-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. 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 more effectively accomplishing the goals of the mitigation and monitoring and if the measures are practicable. If the modifications to the mitigation, monitoring, or reporting measures are substantial, NMFS would publish a notice of the planned LOAs in the **Federal Register** and solicit public comment.

The following are some of the possible sources of applicable data to be considered through the adaptive management process: (1) Results from monitoring and exercise reports, as required by MMPA authorizations; (2) compiled results of Navy funded research and development 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.*

Proposed 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.*

There are several different reporting requirements pursuant to the current regulations. All of these reporting requirements would be continued under this proposed rule for the seven-year period.

Notification of Injured, Live Stranded or Dead Marine Mammals

The Navy would 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 NWTT Monitoring Report

The Navy would submit an annual report to NMFS of the NWTT monitoring describing the implementation and results from the previous calendar year. Data collection methods would be standardized across Pacific Range Complexes including the MITT, HSTT, NWTT, and Gulf of Alaska (GOA) Study Areas to allow for comparison in different geographic locations. The draft of the annual monitoring report would be submitted either three months after the end of the calendar year or three months after the conclusion of the monitoring year, to be determined by the Adaptive Management process. NMFS will submit comments or questions on the report, if any, within one month of receipt. The report will be considered final after the Navy has addressed NMFS' comments, or one month after submittal of the draft if NMFS does not provide comments on the draft report. Such a report would describe progress of knowledge made with respect to intermediate scientific objectives within the NWTT Study Area associated with the ICMP. Similar study questions would be treated together so that summaries can be provided for each topic area. The report need not include analyses and content that do not provide direct assessment of cumulative progress on the monitoring plan study questions. NMFS would submit comments on the draft monitoring report, if any, within three months of receipt. The report would be considered final after the Navy has addressed NMFS' comments, or three months after the submittal of the draft if NMFS does not have comments.

As an alternative, the Navy may submit a Pacific-Range Complex annual

Monitoring Plan report to fulfill this requirement. Such a report describes progress of knowledge made with respect to monitoring study questions across multiple Navy ranges associated with the ICMP. Similar study questions would be treated together so that progress on each topic is summarized across multiple Navy ranges. The report need not include analyses and content that does not provide direct assessment of cumulative progress on the monitoring study question. This would continue to allow the Navy to provide a cohesive monitoring report covering multiple ranges (as per ICMP goals), rather than entirely separate reports for the NWTT, GOA, MITT, and HSTT Study Areas.

Annual NWTT Training Exercise Report and Testing Activity Reports

Each year, the Navy would submit one preliminary report (Quick Look Report) to NMFS detailing the status of applicable sound sources within 21 days after the anniversary of the date of issuance of the LOA. Each year, the Navy would also submit a detailed report (NWTT Annual Training Exercise Report and Testing Activity Report) to NMFS within three months after the one-year anniversary of the date of issuance of the LOA. NMFS will submit comments or questions on the report, if any, within one month of receipt. The report will be considered final after the Navy has addressed NMFS' comments, or one month after submittal of the draft if NMFS does not provide comments on the draft report. The annual report would contain a summary of all sound sources used (total hours or quantity (per the LOA) of each bin of sonar or other non-impulsive source; total annual number of each type of explosive exercises; and total annual expended/detonated rounds (missiles, bombs, sonobuoys, *etc.*) for each explosive bin). The annual report will also contain cumulative sonar and explosive use quantity from previous years' reports through the current year. Additionally, if there were any changes to the sound source allowance in the reporting year, or cumulatively, the report would include a discussion of why the change was made and include analysis to support how the change did or did not affect the analysis in the NWTT EIS/OEIS and MMPA final rule. The annual report would also include the details regarding specific requirements associated with specific mitigation areas. The analysis in the detailed report would be based on the accumulation of data from the current year's report and data collected from previous annual reports. The final annual/close-out report at the conclusion of the authorization period (year seven) would also serve as the comprehensive close-out report and include both the final year annual use compared to annual authorization as well as a cumulative seven-year annual use compared to seven-year authorization. Information included in the annual reports may be used to inform future adaptive management of activities within the NWTT Study Area.

The Annual NWTT Training Exercise Report and Testing Activity Navy report (classified or unclassified versions) could be consolidated with other exercise reports from other range complexes in the Pacific Ocean for a single Pacific Exercise Report, if desired.

Other Reporting and Coordination

The Navy would continue to report and coordinate with NMFS for the following:

- Annual marine species monitoring technical review meetings that also include researchers and the Marine Mammal Commission (currently, every two years a joint Pacific-Atlantic meeting is held); and
- Annual Adaptive Management meetings that also include the Marine Mammal Commission (recently modified to occur in conjunction with the annual monitoring technical review meeting).

Preliminary Analysis and Negligible Impact Determination

General 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. For Level A harassment or Level B harassment (as presented in Tables 32 and 33), in addition to considering estimates of the number of marine mammals that might be taken NMFS considers other factors, such as the likely nature of any responses (*e.g.,* intensity, duration) and 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, and ambient noise levels).

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 both annually and over the seven-year period covered by this proposed rule, and then identified the maximum number of takes we believe could occur (mortality) or are reasonably expected to occur (harassment) 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.*). For this proposed rule we evaluated the likely impacts of the enumerated maximum number of harassment takes that are proposed for authorization and reasonably expected to occur, in the context of the specific circumstances surrounding these predicted takes. We also include a specific assessment of serious injury or mortality (hereafter referred to as M/SI) takes that could occur, as well as consideration of the traits and statuses of the affected species and stocks. Last, we collectively evaluated this information, as well as other more taxa-specific information and mitigation measure effectiveness, in group-specific assessments that support our negligible impact conclusions for each stock or species. Because all of the Navy's specified activities would occur within the ranges of the marine mammal stocks identified in the rule, all negligible impact analyses and determinations are at the stock level (*i.e.,* additional species-level determinations are not needed).

Harassment

The Specified Activities reflect representative levels of training and testing activities. The *Description of the Specified Activity* section describes annual activities. 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 maximum annual totals and seven-year totals indicated in Tables 32 and 33. We base our analysis and negligible impact determination on the maximum number of takes that would be reasonably expected to occur annually and are proposed to be 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 32 and 33, 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 stocks), 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 reviewed and concurs appropriately predicts the maximum amount of harassment that is reasonably likely to occur. 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 (as described in the *Estimated Take of Marine Mammals* section), 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 Section 6 of the Navy's rulemaking/LOA application, 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 harassment 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 harassment and Level B harassment threshold) that are anticipated to occur over the seven-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, which means that the number of individuals taken is smaller than the total estimated takes. 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 a larger portion of a species is being taken by Navy activities, 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 or more likely sequential. Where the number of instances of take is less than 100 percent of the abundance and there is no information to specifically suggest that a small subset of animals is being repeatedly taken over a high number of sequential days, the overall magnitude is generally considered low, as it could on one extreme mean that every take represents a separate individual in the population being taken on one day (a very minimal impact) or, more likely, that some smaller number of individuals are taken on one day annually and some are taken on a few not likely sequential days annually, and of course some are not taken at all.

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, for some individuals of some species 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, for some species 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 activities and the movement patterns of marine mammals, it is unlikely that individuals from most stocks would be taken over more than a few sequential days. This means that even where repeated takes of individuals are likely to occur, they are more likely to result from non-sequential exposures from different activities, and, even if sequential, individual animals are not predicted to be taken for more than several 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.

Physiological Stress Response

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 that could affect reproduction or survival.

Behavioral Response

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 individual animals from sonar and other active sound sources during training and testing activities would be primarily from ASW events. Unlike other Navy training and testing Study Areas, no major training exercises (MTEs) are proposed in the NWTT Study Area. In the range of potential behavioral effects that might expect to be part of a response that qualifies as an instance of 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. A less severe exposure of this nature 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 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.

To help assess this, for sonar (LFAS/MFAS/HFAS) used in the NWTT 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 also important. 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 of sound or at closer proximity to the source. Because 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. As noted previously in this proposed rule, behavioral response is likely highly variable between species, individuals within a species, and context of the exposure. Specifically, given a range of behavioral responses that may be classified as Level B harassment, to the degree that higher received levels of sound 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/proposed 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). Ellison *et al.* (2012) and Moore and Barlow (2013), among others emphasize 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

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 activity 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 (*Navy Activity Descriptions*) of the 2019 NWTT DSEIS/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, line array, 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 NWTT Study Area generally last for only a few hours (see Table 3). Some ASW testing activities range from several hours, to days, to up to 3 weeks for Pierside-Sonar Testing and Submarine Sonar Testing/Maintenance (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 Mine Countermeasure and Neutralization Testing would last 1–10 days (see Tables 3 and 4). The explosive component of these activities only lasts for minutes. 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. All of these factors make it unlikely that individuals would be exposed to the exercise for extended periods or on consecutive days.

Assessing the Number of Individuals Taken and the Likelihood of Repeated Takes

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 and the number of times those individuals are taken from this larger number of instances. One method that NMFS uses to help better understand the overall scope of the impacts is to compare these total instances of take against the abundance of that species (or stock if applicable). For example, if there are 100 harassment 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 and a few were not exposed at all. 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 species 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. It also provides a relative picture of the scale of impacts to each species.

In the ocean, unlike a modeling simulation with static animals, 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 with more resident species. In short, we expect that the total anticipated takes represent exposures of a smaller number of individuals of which some could 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 species-specific conclusions).

When calculating the proportion of a population affected by takes (*e.g.,* the number of takes divided by population abundance), which can also be helpful in estimating the number of days over which some individuals may be taken, it is important to choose an appropriate population estimate against which to make the comparison. The SARs, where available, 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). When the stock is known to range well outside of U.S. Exclusive Economic Zone (EEZ) boundaries, population estimates based on surveys conducted only within the U.S. EEZ are known to be underestimates. The information used to estimate take includes the best available survey abundance data to model density layers. Accordingly, in calculating the percentage of takes versus abundance for each species in order to assist in understanding both the percentage of the species affected, as well as how many days across a year individuals could be taken, we use the data most appropriate for the situation. For all species and stocks except for a few stocks of harbor seals for which SAR data are unavailable and Navy abundance surveys of the inland areas of the NWTT Study Area are used, the most recent NMFS SARs are used to calculate the proportion of a population affected by takes.

The estimates found in NMFS' SARs remain the official estimates of stock abundance where they are current. These estimates are typically generated from the most recent shipboard and/or aerial surveys conducted. In some cases, NMFS' abundance estimates show substantial year-to-year variability. However, for highly migratory species (*e.g.,* large whales) or those whose geographic distribution extends well

beyond the boundaries of the NWTT Study Area (*e.g.,* populations with distribution along the entire eastern Pacific Ocean rather than just the NWTT Study Area), comparisons to the SAR are appropriate. Many of the stocks present in the NWTT Study Area have ranges significantly larger than the NWTT Study Area and that abundance is captured by the SAR. A good descriptive example is migrating large whales, which traverse the NWTT Study Area for several days to weeks on their migrations. Therefore, at any one time there may be a stable number of animals, but over the course of the entire year the entire population may pass through the NWTT Study Area. Therefore, comparing the estimated takes to an abundance, in this case the SAR abundance, which represents the total population, may be more appropriate than modeled abundances for only the NWTT Study Area.

Temporary Threshold Shift

NMFS and the Navy have estimated that all 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 52–57 indicate the number of takes by TTS that may be incurred by different species from exposure to active sonar and explosives. 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, but below the range of the echolocation signals used for foraging. 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). 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. TTS from explosives would be broadband.

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 *Potential Effects of Specified Activities on Marine Mammals and their Habitat* section, 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. Since any hull-mounted sonar, such as the SQS–53, engaged in anti-submarine warfare training would be moving at between 10 and 15 knots and nominally pinging every 50 seconds, the vessel will have traveled a minimum distance of approximately 257 m during the time between those pings. A scenario could occur where an animal does not leave the vicinity of a ship or travels a course parallel to the ship, however, the close distances required make TTS exposure unlikely. For a Navy vessel moving at a nominal 10 knots, it is unlikely a marine mammal could maintain speed parallel to the ship and receive adequate energy over successive pings to suffer TTS.

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 6 dB differences in hearing sensitivity across time (Finneran *et al.,* 2000, 2002; Schlundt *et al.,* 2000).

3. Duration of TTS (recovery time)—In the TTS laboratory studies (as discussed in the *Potential Effects of Specified Activities on Marine Mammals and their Habitat* section), 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 NWTT 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 *Preliminary 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 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 52–57 indicate the number of incidental takes by TTS for each species 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 LFAS or HFAS 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 animal's hearing range) TTS. This means that for one to several times per year, for several minutes to maybe a few hours at most each, a taken individual will have slightly diminished hearing sensitivity (slightly more than natural variation, but nowhere near total deafness). More often than not, such an exposure would occur 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, 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 the Navy activities would result in behavioral changes or other impacts that would impact any individual's (of any hearing sensitivity) reproduction or survival.

Auditory 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, 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. Masking is also more of a concern from continuous sources (versus intermittent sonar signals) 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 are much more of a concern for masking, whereas comparatively short-term exposure to the predominantly intermittent pulses of often narrow frequency range 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 pings every 50 seconds. 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 other 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. While data are lacking on behavioral responses of marine mammals to continuously active sonars, mysticete species are known to be able to habituate to novel and continuous sounds (Nowacek *et al.,* 2004), suggesting that they are likely to have similar responses to high-duty cycle sonars. Furthermore, most of these systems are hull-mounted on surface ships with the ships moving at least 10 kn, and it is unlikely that the ship and the marine mammal would continue to move in the same direction and the marine mammal subjected to the same exposure due to that movement. 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 (but few mysticete 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 single marine mammal species' vocalizations.

Other sources used in Navy training and testing that are not explicitly addressed above, 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.

In conclusion, masking is more likely to occur in the presence of broadband, relatively continuous noise sources such as 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.

PTS from Sonar Acoustic Sources and Explosives and Tissue Damage from Explosives

Tables 52 through 57 indicate the number of individuals of each species for which Level A harassment in the form of PTS resulting from exposure to active sonar and/or explosives is estimated to occur. The number of individuals to potentially incur PTS annually (from sonar and explosives) for each species/stock ranges from 0 to 180 (the 180 is for the Inland Washington stock of harbor porpoise), but is more typically 0 or 1. No species/stocks have the potential to incur tissue damage from sonar or explosives.

Data suggest 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 has determined 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 represent the maximum number of instances in which marine mammals would be reasonably expected to incur PTS, and we have analyzed them accordingly.

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 discussed previously 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 range (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, 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.

The Navy implements mitigation measures (described in the *Proposed Mitigation Measures* section) during explosive activities, including delaying detonations when a marine mammal is observed in the mitigation zone. Nearly all explosive events would occur during daylight hours to improve the sightability of marine mammals and thereby improve mitigation effectiveness. Observing for marine mammals during the explosive activities would include visual 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 600 yds (656 m) to 2,500 yds (2,286 m) depending on the source (*e.g.,* explosive sonobuoy, explosive torpedo, explosive bombs; see Tables 38–44). For all of these reasons, the proposed mitigation measures associated with explosives are expected to be effective in preventing tissue damage to any potentially affected species, and no species are anticipated to incur tissue damage during the period of the proposed rule.

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. We note here that the takes from potential ship strikes 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 NWTT 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. In *Conservation Council for Hawaii* v. *National Marine Fisheries Service,* 97 F. Supp. 3d 1210 (D. Haw. 2015), which concerned a challenge to NMFS' regulations and LOAs to the Navy for activities assessed in the 2013–2018 HSTT MMPA rulemaking, the Court ruled that NMFS' failure to consider PBR when evaluating lethal takes in the negligible impact analysis under section 101(a)(5)(A) violated the requirement to use the best available science.

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 optimum sustainable population'' (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 reasonable assurance that the stock size is equal to or greater than the estimate (Barlow *et al.,* 1995), typically by using the 20th percentile of a log-normal distribution of the population estimate. 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), NMFS' long-standing regulatory definition of ''negligible impact,'' and the use of PBR under section 118. The standard for authorizing incidental take for activities other than commercial fisheries under section 101(a)(5) continues to be, among other things that are not related to PBR, whether the total taking will have a negligible impact on the species or stock. Nowhere does section 101(a)(5)(A) reference use of PBR to make the negligible impact finding or authorize incidental take through multi-year regulations, nor does its companion provision at 101(a)(5)(D) for authorizing non-lethal incidental take under the same negligible-impact standard. NMFS' MMPA implementing regulations state that take has a negligible impact when it does not ''adversely affect the species or stock through effects on annual rates of recruitment or survival''—likewise without reference to PBR. 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 standard of the negligible impact finding under section 101(a)(5)(A) (and section 101(a)(5)(D)), 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 in 1994, NMFS had used the concept almost entirely within the context of implementing sections 117 and 118 and other commercial fisheries management-related provisions of the MMPA. Prior to the Court's ruling in *Conservation Council for Hawaii* v. *National Marine Fisheries Service* and consideration of PBR in a series of section 101(a)(5) rulemakings, there were a few examples where PBR had informed agency deliberations under other MMPA sections and programs, such as playing a role in the issuance of a few scientific research permits and subsistence takings. But as the Court found when reviewing examples of past PBR consideration in *Georgia Aquarium* v. *Pritzker,* 135 F. Supp. 3d 1280 (N.D. Ga. 2015), where NMFS had considered PBR outside the commercial fisheries context, ''it has treated PBR as only one 'quantitative tool' and [has not used it]

as the sole basis for its impact analyses.'' Further, the agency's thoughts regarding the appropriate role of PBR in relation to MMPA programs outside the commercial fishing context have evolved since the agency's early application of PBR to section 101(a)(5) decisions. Specifically, NMFS' denial of a request for incidental take authorization for the U.S. Coast Guard in 1996 seemingly was based on the potential for lethal take in relation to PBR and did not appear to consider other factors that might also have informed the potential for ship strike in relation to negligible impact (61 FR 54157; October 17, 1996).

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 U.S. Fish and Wildlife Service 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 from all sources into the PBR value (*i.e.,* PBR minus the total annual anthropogenic mortality/serious injury estimate in the SAR), which is called ''residual PBR.'' (Wood *et al.,* 2012). We first focus our analysis on residual PBR because it incorporates anthropogenic mortality occurring from other sources. If the ongoing human-caused mortality from other sources does not exceed PBR, then residual PBR is a positive number, and we consider how the anticipated or potential incidental M/SI from the activities being evaluated compares to residual PBR using the framework in the following paragraph. If the ongoing anthropogenic mortality from other sources already exceeds PBR, then residual PBR is a negative number and we consider the M/SI from the activities being evaluated as described further below.

When ongoing total anthropogenic mortality from the applicant's specified activities does not exceed PBR and residual PBR is a positive number, as a simplifying analytical tool we first consider whether the specified activities could cause incidental M/SI that is less than 10 percent of residual PBR (the ''insignificance threshold,'' see below). If so, 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 other considerations such as information that illustrates uncertainty involved in the calculation of PBR for some stocks. In a few prior incidental take rulemakings, 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. The accuracy and certainty around the data that feed any PBR calculation, such as the abundance estimates, must be carefully considered to evaluate whether the calculated PBR accurately reflects the circumstances of the particular stock. 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,* which involved the challenge to NMFS' issuance of LOAs to the Navy in 2013 for activities in 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 that stock to reach or maintain its [OSP].'' OSP is defined as a population that 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, and thus is an aspirational management goal of the overall statute with no specific timeframe by which it should be met. PBR is designed to ensure minimal deviation from this overarching goal, with the formula for PBR typically ensuring that growth towards OSP is not reduced by more than 10 percent (or equilibrates to OSP 95 percent of the time). As PBR is applied by NMFS, it provides that growth toward OSP is not reduced by more than 10 percent, which certainly allows a stock to ''reach or maintain its [OSP]'' in a conservative and precautionary manner—and we can therefore clearly conclude that if PBR were not exceeded, there would not be adverse effects on the affected species or stocks. Nonetheless, it is equally clear that in some cases the time to reach this aspirational OSP level 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 through effects on its rates of recruitment or survival. Thus even in situations where the inputs to calculate PBR are thought to accurately represent factors such as the species' or stock's abundance or productivity rate, it is still possible for incidental take to have a negligible impact on the species or stock even where M/SI exceeds residual PBR or PBR.

As noted above, in some cases the ongoing human-caused mortality from activities other than those being evaluated already exceeds PBR and, therefore, residual PBR is negative. In these cases (such as is specifically discussed for the CA/OR/WA stock of humpback whales below), any additional mortality, no matter how small, and no matter how small relative to the mortality caused by other human activities, would result in greater exceedance of PBR. PBR is helpful in informing the analysis of the effects of mortality on a species or stock because it is important from a biological perspective to be able to consider how the total mortality in a given year may affect the population. However, section 101(a)(5)(A) of the MMPA indicates that NMFS shall authorize the requested incidental take from a specified activity if we find that ''the total of such taking [*i.e.,* from the specified activity] will have a negligible impact on such species or stock.'' In other words, the task under the statute is to evaluate the applicant's anticipated take in relation to their take's impact on the species or stock, not other entities' impacts on the species or stock. Neither the MMPA nor NMFS' implementing regulations call for consideration of other unrelated activities and their impacts on the species or stock. In fact, in response to public comments on the implementing regulations NMFS explained that such effects are not considered in making negligible impact findings under section 101(a)(5), although the extent to which a species or stock is being impacted by other anthropogenic activities is not ignored. Such effects are reflected in the baseline of existing impacts as reflected in the species' or stock's abundance, distribution, reproductive rate, and other biological indicators.

NMFS guidance for commercial fisheries provides insight when evaluating the effects of an applicant's incidental take as compared to the incidental take caused by other entities. Parallel to section 101(a)(5)(A), section 101(a)(5)(E) of the MMPA provides that NMFS shall allow the incidental take of ESA-listed endangered or threatened marine mammals by commercial fisheries if, among other things, the incidental M/SI from the commercial fisheries will have a negligible impact on the species or stock. As discussed earlier, the authorization of incidental take resulting from commercial fisheries and authorization for activities other than commercial fisheries are under two separate regulatory frameworks. However, when it amended the statute in 1994 to provide a separate incidental take authorization process for commercial fisheries, Congress kept the requirement of a negligible impact determination for this one category of species, thereby applying the standard to both programs. Therefore, while the structure and other standards of the two programs differ such that evaluation of negligible impact under one program may not be fully applicable to the other program (*e.g.,* the regulatory definition of ''negligible impact'' at 50 CFR 216.103 applies only to activities other than commercial fishing), guidance on determining negligible impact for commercial fishing take authorizations can be informative when considering incidental take outside the commercial fishing context. In 1999, NMFS published criteria for making a negligible impact determination pursuant to section 101(a)(5)(E) of the MMPA in a notice of proposed permits for certain fisheries (64 FR 28800; May 27, 1999). Criterion 2 stated if total human-related serious injuries and mortalities are greater than PBR, and fisheries-related mortality is less than 0.1 PBR, individual fisheries may be permitted if management measures are being taken to address non-fisheries-related serious injuries and mortalities. When fisheries-related serious injury and mortality is less than 10 percent of the total, the appropriate management action is to address components that account for the major portion of the total. This criterion addresses when total human-caused mortality is exceeding PBR, but the activity being assessed is responsible for only a small portion of the mortality. The analytical framework we use here appropriately incorporates elements of the one developed for use under section 101(a)(5)(E) and because the negligible impact determination under section 101(a)(5)(A) focuses on the activity being evaluated, it is appropriate to utilize the parallel concept from the framework for section 101(a)(5)(E).

Accordingly, we are using a similar criterion in our negligible impact analysis under section 101(a)(5)(A) to evaluate the relative role of an applicant's incidental take when other sources of take are causing PBR to be exceeded, but the take of the specified activity is comparatively small. Where this occurs, we may find that the impacts of the taking from the specified activity may (those impacts alone, before we have considered the combined effects from any harassment take) be negligible even when total human-caused mortality from all activities exceeds PBR if (in the context of a particular species or stock): The authorized mortality or serious injury would be less than or equal to 10 percent of PBR and management measures are being taken to address serious injuries and mortalities from the other activities (*i.e.,* other than the specified activities covered by the incidental take authorization under consideration). We must also determine, though, that impacts on the species or stock from other types of take (*i.e.,* harassment) caused by the applicant do not combine with the impacts from mortality or serious injury to result in adverse effects on the species or stock through effects on annual rates of recruitment or survival.

As discussed above, however, while PBR is useful in informing the evaluation of 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 is not determinative, including because, as explained above, the accuracy and certainty of the data used to calculate PBR for the species or stock must be

considered. And we reiterate the considerations discussed above for why it is not appropriate to consider PBR an absolute cap in the application of this guidance. Accordingly, we use PBR as a trigger for concern while also considering other relevant factors to provide a reasonable and appropriate means of evaluating the effects of potential mortality on rates of recruitment and survival, while acknowledging that it is possible to exceed PBR (or exceed 10 percent of PBR in the case where other human-caused mortality is exceeding PBR but the specified activity being evaluated is an incremental contributor, as described in the last paragraph) 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 or serious injury could occur follows. No M/SI are anticipated from the Navy's sonar activities or use of explosives. We first consider maximum potential incidental M/SI from the Navy's ship strike analysis for the affected mysticetes and sperm whales (see Table 51) 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 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 may occur over the course of the seven-year rule. Of the three total M/SI takes, the rule would authorize no more than two from any of the following species/stocks over the seven-year period: Fin whale (which may come from either the Northeast Pacific or CA/OR/WA stock) and humpback whale (which may come from either the Central North Pacific or CA/OR/WA stock). Of the three total M/SI takes, the rule also would authorize no more than one mortality from any of the following species/stocks over the seven-year period: Sperm whale (CA/OR/WA stock), minke whale (CA/OR/WA stock), and gray whale (Eastern North Pacific stock). We do not anticipate, nor authorize, ship strike takes to blue whale (Eastern North Pacific stock), minke whale (Alaska stock), or sei whale (Eastern North Pacific stock). This means an annual average of 0.14 whales from each species or stock where one mortality may occur and an annual average of 0.29 whales from each species or stock where two mortalities may occur, as described in Table 51, is proposed for authorization (*i.e.,* 1 or 2 takes over 7 years divided by 7 to get the annual number).

TABLE 51—SUMMARY INFORMATION RELATED TO MORTALITIES REQUESTED FOR SHIP STRIKE, 2020–2027

Species (stock)	Stock abundance (Nbest) *	Annual proposed NWTT authorized 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 *	Annual Navy HSTT authorized take (2018–2023) [5]	PBR *	Residual PBR-PBR minus annual M/SI and HSTT authorized take [3]	Stock trend *[4]	Recent UME (Y/N); number and year (since 2007)
Fin whale (Northeast Pacific).	3,168	0.29	0.4	N; 0	Y; 0.4	0	5.1	4.7	↑	N
Fin whale (CA/OR/WA)	9,029	0.29	≥43.5	Y; ≥0.5	Y; 43	0.4	81	37.1	↑	N
Humpback whale (Central North Pacific).	10,103	0.29	25	Y; 9.5	[6] Y; 3.9	0.4	83	57.6	↑	N
Humpback whale (CA/OR/WA).	2,900	0.29	≥42.1	Y; ≥17.3	Y; 22	0.2	33.4	−8.9	Stable (↑ (historically)	N
Sperm whale (CA/OR/WA).	1,997	0.14	0.4	Y; 0.4	N; 0	0	2.5	2.1	Unknown	N
Minke whale (CA/OR/WA).	636	0.14	≥1.3	Y; ≥1.3	N; 0	0	3.5	2.2	Unknown	N
Gray whale (Eastern North Pacific).	26,960	0.14	139	Y; 9.6	Y; 0.8	0.4	801	661.6	↑	Y, 264, 2019

* Presented in the 2019 draft SARs or most recent SAR.

[1] This column represents the annual take by serious injury or mortality by vessel collision and was calculated by the number of mortalities proposed for authorization divided by seven 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 NMFS Science Center research activities or Navy strikes authorized for training and testing activities. No NMFS Science Center or Navy M/SI takes for these stocks are recorded in the SARs and no NMFS Science Center M/SI incidental takes have been authorized.

[3] This value represents the calculated PBR minus the average annual estimate of ongoing anthropogenic mortalities (*i.e.,* total annual human-caused M/SI column and the annual authorized take from the HSTT column). This value represents the total PBR for the stock in the stock's entire range.

[4] See relevant SARs for more information regarding stock status and trends.

[5] This column represents annual M/SI take authorized through NMFS' current 5-year HSTT regulations/LOAs (83 FR 66846). Note that NMFS has proposed to replace the current HSTT regulations with 7-year regulations (84 FR 48388) which propose to authorize the same number of M/SI for the same species/stocks, but over a 7-year period rather than a 5-year period (resulting in slightly lower annual authorized take for each species/stock).

[6] This value represents average annual observed M/SI from ship strikes in Alaska (2.5) and Hawaii (1.4). For the purposes of analysis of potential ship strike (see the *Estimated Takes* section) we incorporated only Alaska ship strikes as only these ship strikes have the potential to overlap with the NWTT Study Area.

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 clearly not adversely affect annual rates of recruitment and survival. In this case, as shown in Table 51, the following species or stocks have potential M/SI from ship strike proposed for authorization below their insignificance threshold: Fin whale (both the Northeast Pacific and CA/OR/WA stocks), humpback whale (Central North Pacific stock), sperm whale (CA/OR/WA stock), minke whale (CA/OR/WA stock), and gray whale (Eastern North Pacific stock). While the M/SI proposed for authorization of gray whales (Eastern North Pacific stock) is below the insignificance threshold, because of the recent UME, we further address how the authorized M/SI and the UME inform the negligible impact determination immediately below. For the other five stocks with M/SI proposed for authorization 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 one stock (CA/OR/WA stock of humpback whales) with potential M/SI above the insignificance threshold, how that M/SI compares to residual PBR, as well as additional factors, are discussed below as well.

Gray Whales (Eastern North Pacific Stock)

For this stock, PBR is currently set at 801. The total annual M/SI from other sources of anthropogenic mortality is estimated to be 139. In addition, 0.4 annual mortalities have been authorized for this same stock in the current incidental take regulations for Navy testing and training activities in the HSTT Study Area. This yields a residual PBR of 661.6. The additional 0.29 annual mortalities that are proposed for authorization in this rule are well below the insignificance threshold (10 percent of residual PBR, in this case 66.16). Nonetheless, since January 2019, gray whale strandings along the west coast of North America have been significantly higher than the previous 18-year average. Preliminary findings from necropsies have shown evidence of poor to thin body condition. The seasonal pattern of elevated strandings in the spring and summer months is similar to that of the previous gray whale UME in 1999–2000. Current total monthly strandings are slightly higher than 1999 and lower than 2000. If strandings continue to follow a similar pattern, we would anticipate a decrease in strandings in late summer and fall. However, combined with other annual human-caused mortalities, and viewed through the PBR lens (for human-caused mortalities), total human-caused mortality (inclusive of the potential for additional UME deaths) would still fall well below residual PBR and the insignificance threshold. Because of the abundance, population trend (increasing, despite the UME in 1999–2000), and residual PBR (661.6) of this stock, this UME is not expected to have impacts on the population rate that, in combination with the effects of mortality proposed to be authorized, would affect annual rates of recruitment or survival.

Stocks With M/SI Above the Insignificance Threshold

Humpback Whale (CA/OR/WA Stock)

For this stock, PBR is currently set at 16.7 for U.S. waters and 33.4 for the stock's entire range. The total annual M/SI is estimated at greater than or equal to 42.1. Combined with 0.2 annual mortalities that have been authorized for this same stock in the current incidental take regulations for Navy testing and training activities in the HSTT Study Area, this yields a residual PBR of −8.9. NMFS proposes to authorize up to 2 M/SI takes over the seven-year duration of this rule, which would be 0.29 M/SI takes annually for the purposes of comparing to PBR and considering other possible effects on annual rates of recruitment and survival. This means that with the additional 0.29 M/SI annual takes proposed in this rule, residual PBR would be exceeded by 9.19.

In the commercial fisheries setting for ESA-listed marine mammals (which is similar to the non-fisheries incidental take setting, in that a negligible impact determination is required that is based on the assessment of take caused by the activity being analyzed) NMFS may find the impact of the authorized take from a specified activity to be negligible even if total human-caused mortality exceeds PBR, if the authorized mortality is less than 10 percent of PBR and management measures are being taken to address serious injuries and mortalities from the other activities causing mortality (*i.e.,* other than the specified activities covered by the incidental take authorization under consideration). When those considerations are applied in the section 101(a)(5)(A) context here, the proposed authorized lethal take (0.29 annually) of humpback whales from the CA/OR/WA stock is significantly less than 10 percent of PBR (in fact less than 1 percent of 33.4) and there are management measures in place to address M/SI from activities other than those the Navy is conducting (as discussed below).

Based on identical simulations as those conducted to identify Recovery Factors for PBR in Wade *et al.* (1998), but where values less than 0.1 were investigated (P. Wade, pers. comm.), we predict that where the mortality from a specified activity does not exceed Nmin * ½ Rmax * 0.013, the contemplated mortality for the specific activity will not delay the time to recovery by more than 1 percent. For this stock of humpback whales, Nmin * ½ Rmax * 0.013 = 1.45 and the annual mortality proposed for authorization is 0.29 (*i.e.,* less than 1.45), which means that the mortality proposed to be authorized in this rule for NWTT activities would not delay the time to recovery by more than 1 percent.

NMFS must also ensure that impacts by the applicant on the species or stock from other types of take (*i.e.,* harassment) do not combine with the impacts from M/SI to adversely affect the species or stock via impacts on annual rates of recruitment or survival, which is discussed further below in the species- and stock-specific section.

In November 2019, NMFS published 2019 draft SARs in which PBR is reported as 33.4 with the predicted average annual mortality greater than or equal to 42.1 (including 22 estimated from vessel collisions and greater than 17.3 observed fisheries interactions). While the observed M/SI from vessel strikes remains low at 2.2 per year, the 2018 final and 2019 draft SARs rely on a new method to estimate annual deaths by ship strike utilizing an encounter theory model that combined species distribution models of whale density, vessel traffic characteristics, and whale movement patterns obtained from satellite-tagged animals in the region to estimate encounters that would result in mortality (Rockwood *et al.,* 2017). The model predicts 22 annual mortalities of humpback whales from this stock from vessel strikes. The authors (Rockwood *et al.,* 2017) do not suggest that ship strikes suddenly increased to 22. In fact, the model is not specific to a year, but rather offers a generalized prediction of ship strikes off the U.S. West Coast. Therefore, if the Rockwood *et al.* (2017) model is an accurate representation of vessel strike, then similar levels of ship strike have been occurring in past years as well. Put another way, if the model is correct, for some number of years total human-caused mortality has been significantly underestimated, and PBR has been similarly exceeded by a notable amount, and yet the CA/OR/WA stock of humpback whales is considered stable (or increasing based on population trends since 1990) nevertheless.

The CA/OR/WA stock of humpback whales experienced a steady increase from the 1990s through approximately 2008, and more recent estimates through 2014 indicate a leveling off of the population size. This stock is comprised of the feeding groups of three DPSs. Two DPSs associated with this stock are listed under the ESA as either endangered (Central America DPS) or threatened (Mexico DPS), while the third (Hawaii DPS) is not listed. Humpback whales from the Hawaii DPS are anticipated to be rare in the Study Area with a probability of the DPS foraging in the waters of the Study Area of 1.6 percent (including summer areas of Oregon/California and Southern British Columbia/Washington from Wade, 2017). Humpback whales from the Mexico DPS and Central America DPS are anticipated to be more prevalent in the Study Area with probabilities of the DPSs foraging in the waters of the Study Area of 31.7 and 100 percent, respectively (including summer

areas of Oregon/California and Southern British Columbia/Washington from Wade, 2017).

As discussed earlier, we also take into consideration management measures in place to address M/SI caused by other activities. The California swordfish and thresher shark drift gillnet fishery is one of the primary causes of M/SI take from fisheries interactions for humpback whales on the West Coast. NMFS established the Pacific Offshore Cetacean Take Reduction Team in 1996 and prepared an associated Plan (POCTRP) to reduce the risk of M/SI via fisheries interactions. In 1997, NMFS published final regulations formalizing the requirements of the PCTRP, including the use of pingers following several specific provisions and the employment of Skipper education workshops.

Commercial fisheries such as crab pot, gillnet, and prawn fisheries are also a significant source of mortality and serious injury for humpback whales and other large whales and, unfortunately, have increased mortalities and serious injuries over recent years (Carretta *et al.,* 2019). However, the 2019 draft SAR notes that a recent increase in disentanglement efforts has resulted in an increase in the fraction of cases that are reported as non-serious injuries as a result of successful disentanglement. More importantly, since 2015, NMFS has engaged in a multi-stakeholder process in California (including California State resource managers, fishermen, non-governmental organizations (NGOs), and scientists) to identify and develop solutions and make recommendations to regulators and the fishing industry for reducing whale entanglements (see *http://www.opc.ca.gov/whale-entanglement-working-group/*), referred to as the Whale Entanglement Working Group. The Whale Entanglement Working Group has made significant progress since 2015 and is tackling the problem from multiple angles, including:

- Development of Fact Sheets and Best Practices for specific Fisheries issues (*e.g.,* California Dungeness Crab Fishing BMPs and the 2018–2019 Best Fishing Practices Guide);
- 2018–2019 Risk Assessment and Mitigation Program (RAMP) to support the state of California in working collaboratively with experts (fishermen, researchers, NGOs, *etc.*) to identify and assess elevated levels of entanglement risk and determine the need for management options to reduce risk of entanglement; and
- Support of pilot studies to test new fisheries technologies to reduce take (*e.g.,* Exploring Ropeless Fishing Technologies for the California Dungeness Crab Fishery).

The Working Group meets regularly, posts reports and annual recommendations, and makes all of their products and guidance documents readily accessible for the public. The March 2019 Working Group Report reported on the status of the fishery closure, progress and continued development of the RAMP (though there is a separate RAMP report), discussed the role of the Working Group (development of a new Charter), and indicated next steps.

Importantly, in early 2019, as a result of a litigation settlement agreement, the California Department of Fish and Wildlife (CDFW) closed the Dungeness crab fishery three months early for the year, which is expected to reduce the number of likely entanglements. The agreement also limits the fishery duration over the next couple of years and has different triggers to reduce or close it further. Further, pursuant to the settlement, CDFW is required to apply for a Section 10 Incidental Take Permit under the ESA to address protected species interactions with fishing gear and crab fishing gear (pots), and they have agreed to prepare a Conservation Plan by May 2020. Any request for such a permit must include a Conservation Plan that specifies, among other things, what steps the applicant will take to minimize and mitigate the impacts, and the funding that will be available to implement such steps.

Regarding measures in place to reduce mortality from other sources, the Channel Islands NMS staff coordinates, collects, and monitors whale sightings in and around a Whale Advisory Zone and the Channel Islands NMS region, which is within the area of highest vessel strike mortality (90th percentile) for humpback whales on the U.S. West Coast (Rockwood *et al.,* 2017). The seasonally established Whale Advisory Zone spans from Point Arguello to Dana Point, including the Traffic Separation Schemes in the Santa Barbara Channel and San Pedro Channel. Vessels transiting the area from June through November are recommended to exercise caution and voluntarily reduce speed to 10 kn or less for blue, humpback, and fin whales. Channel Island NMS observers collect information from aerial surveys conducted by NOAA, the U.S. Coast Guard, California Department of Fish and Game, and Navy chartered aircraft. Information on seasonal presence, movement, and general distribution patterns of large whales is shared with mariners, NMFS' Office of Protected Resources, the U.S. Coast Guard, the California Department of Fish and Game, the Santa Barbara Museum of Natural History, the Marine Exchange of Southern California, and whale scientists. Real time and historical whale observation data collected from multiple sources can be viewed on the Point Blue Whale Database.

More recently, similar efforts to reduce entanglement risk and severity have also been initiated in Oregon and Washington. Both Oregon and Washington are developing applications for ESA Incidental Take Permits for their commercial crab fisheries. They advocate similar best practices for their fishermen as California, and they are taking regulatory steps related to gear marking and pot limits.

In this case, 0.29 M/SI annually means the potential for two mortalities in one or two of the seven years and zero mortalities in five or six of those seven years. Therefore, the Navy would not be contributing to the total human-caused mortality at all in at least five of the seven, or 71.4 percent, of the years covered by this rule. That means that even if a humpback whale from the CA/OR/WA stock were to be struck, in at least five of the seven years there could be no effect on annual rates of recruitment or survival from Navy-caused M/SI. Additionally, the loss of a male would have far less, if any, of an effect on population rates than the loss of a reproductive female (as males are known to mate with multiple females), and absent any information suggesting that one sex is more likely to be struck than another, we can reasonably assume that there is a 50 percent chance that the strikes proposed to be authorized by this rule would be males, thereby further decreasing the likelihood of impacts on the population rate. In situations like this where potential M/SI is fractional, consideration must be given to the lessened impacts anticipated due to the absence of any M/SI in five or six of the years and due to the fact that strikes could be males. Lastly, we reiterate that PBR is a conservative metric and also not sufficiently precise to serve as an absolute predictor of population effects upon which mortality caps would appropriately be based. Wade *et al.* (1998), authors of the paper from which the current PBR equation is derived, note that ''Estimating incidental mortality in one year to be greater than the PBR calculated from a single abundance survey does not prove the mortality will lead to depletion; it identifies a population worthy of careful future monitoring and possibly indicates that mortality-mitigation efforts should be initiated.''

The information included here illustrates that this humpback whale stock is stable, the potential (and proposed authorized) mortality is well below 10 percent (0.87 percent) of PBR, and management actions are in place to minimize both fisheries interactions and ship strike from other vessel activity in one of the highest-risk areas for strikes. More specifically, although the total human-mortality exceeds PBR, the authorized mortality proposed for the Navy's specified activities would incrementally contribute less than 1 percent of that and, further, given the fact that it would occur in only one or two of the seven years with a 50 percent chance of the take involving males (far less impactful to the population), the potential impacts on population rates are even less. Based on all of the considerations described above, including consideration of the fact that the M/SI of 0.29 proposed for authorization would not delay the time to recovery by more than 1 percent, we do not expect the potential lethal take from Navy activities, alone, to adversely affect the CA/OR/WA stock of humpback whales through effects on annual rates of recruitment or survival. Nonetheless, the fact that total human-caused mortality exceeds PBR necessitates close attention to the remainder of the impacts (*i.e.,* harassment) on the CA/OR/WA stock of humpback whales from the Navy's activities to ensure that the total authorized takes would have a negligible impact on the species and stock. Therefore, this information will be considered in combination with our assessment of the impacts of authorized harassment takes in the *Group and Species-Specific Analyses* section that follows.

Group and Species-Specific Analyses

The maximum amount and type of incidental take of marine mammals reasonably likely to occur and therefore proposed to be authorized from exposures to sonar and other active acoustic sources and explosions during the seven-year training and testing period are shown in Tables 32 and 33 along with the discussion in the *Estimated Take of Marine Mammals* section on Vessel Strike. 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.

In the discussions below, 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 some cases individuals may be taken more than one time. Below, we compare the total take numbers (including PTS, TTS, and behavioral disruption) for species or stocks to their associated abundance estimates to evaluate the magnitude of impacts across the species and to individuals. Specifically, when an abundance percentage comparison is below 100, it means that that percentage or less of the individuals 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 as many as 16 times. Those comparisons are included in the sections below.

To assist in understanding what this analysis means, we clarify a few issues related to estimated takes and the analysis here. An individual that incurs a PTS or TTS take may sometimes, for example, also be subject to behavioral disturbance at the same time. As described above in this section, the degree of PTS, and the degree and duration of TTS, expected to be incurred from the Navy's activities are not expected to impact marine mammals such that their reproduction or survival could be affected. Similarly, data do not suggest that a single instance in which an animal accrues PTS or TTS and is also subjected to behavioral disturbance would result in impacts to reproduction or survival. Alternately, we recognize that if an individual is subjected to behavioral disturbance repeatedly for a longer duration and on consecutive days, effects could accrue to the point that reproductive success is jeopardized, although those sorts of impacts are generally not expected to result from these activities. Accordingly, in analyzing the number of takes and the likelihood of repeated and sequential takes, we consider the total takes, not just the Level B harassment takes by behavioral disruption, so that individuals potentially exposed to both threshold shift and behavioral disruption are appropriately considered. The number of Level A harassment takes by PTS are so low (and zero in most cases) compared to abundance numbers that it is considered highly unlikely that any individual would be taken at those levels more than once.

Use of sonar and other transducers would typically be transient and temporary. The majority of acoustic effects to marine mammals from sonar and other active sound sources during testing and training activities would be primarily from ASW events. It is important to note that unlike other Navy Training and Testing Study Areas, there are no MTEs proposed for the NWTT Study Area. On the less severe end, exposure to comparatively lower levels of 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 fed 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 response, 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, as noted previously, the death of an adult female has significantly more impact on population growth rates than reductions in reproductive success, while the death of an adult male 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 would be no effect on rates of recruitment or survival.

The analyses below in some cases address species collectively if they occupy the same functional hearing group (*i.e.,* low, mid, and high-frequency cetaceans), share similar life history strategies, and/or are known to behaviorally respond similarly to acoustic stressors. Because some of these groups or species share characteristics that inform the impact analysis similarly, it would be duplicative to repeat the same analysis for each species. In addition, similar species typically have the same hearing capabilities and behaviorally respond in the same manner.

Thus, our analysis below considers the effects of the Navy's activities on each affected species or stock even where discussion is organized by functional hearing group and/or information is evaluated at the group level. Where there are meaningful differences between a species or stock that would further differentiate the analysis, they are either described within the section or the discussion for those species or stocks is included as a separate subsection. Specifically below, we first give broad descriptions of the mysticete, odontocete, and pinniped groups and then differentiate into further groups as appropriate.

Mysticetes

This section builds on the broader discussion above and brings together the discussion of the different types and amounts of take that different species and stocks could potentially or would likely incur, the applicable mitigation, and the status of the species and stocks to support the preliminary negligible impact determinations for each species or stock. We have described (earlier in this section) the unlikelihood of any masking having effects that would impact the reproduction or survival of any of the individual marine mammals affected by the Navy's activities. We have also described above in the *Potential Effects of Specified Activities on Marine Mammals and their Habitat* section the unlikelihood of any habitat impacts having effects that would impact the reproduction or survival of any of the individual marine mammals affected by the Navy's activities. For mysticetes, there is no predicted PTS from sonar or explosives and no predicted tissue damage from explosives for any species. Much of the discussion below focuses on the behavioral effects and the mitigation measures that reduce the probability or severity of effects. Because there are species-specific and stock-specific considerations as well as M/SI take proposed for several stocks, at the end of the section we break out our findings on a species-specific and, for one species, stock-specific basis.

In Table 52 below for mysticetes, we indicate for each species and stock the total annual numbers of take by mortality, Level A and Level B harassment, and a number indicating the instances of total take as a percentage of abundance.

Table 52 -- Annual estimated takes by Level B harassment, Level A harassment, and mortality for mysticetes and number indicating the instances of total take as a percentage of species abundance.

		Instances of indicated types of incidental take (not all takes represent separate individuals, especially for disturbance)					Total takes	Abundance (NMFS SARs)*	Instances of total take as percentage of abundance
		Level B Harassment		Level A Harassment		Mortality			
Species	Stock	Behavioral Disturbance	TTS (may also include disturbance)	PTS	Tissue Damage				
Suborder Mysticeti (baleen whales)									
Family Balaenopteridae (rorquals)									
Blue whale	Eastern North Pacific	6	4	0	0	0	10	1,496	<1
Fin whale	Northeast Pacific	1	1	0	0	0.29	2.29	3,168	<1
	CA/OR/WA	91	44	0	0	0.29	135.29	9,029	2
Humpback whale	Central North Pacific	47	68	0	0	0.29	115.29	10,103	1
	CA/OR/WA	40	53	0	0	0.29	93.29	2,900	3
Minke whale	Alaska	1	1	0	0	0	2	389 [1]	<1
	CA/OR/WA	111	191	0	0	0.14	302.14	636	48
Sei whale	Eastern North Pacific	33	50	0	0	0	83	519	16
Family Eschrichtiidae									
Gray whale	Eastern North Pacific	28	15	0	0	0.14	43.14	26,960	<1

*Presented in the 2019 draft SARs or most recent SAR.

1 The 2018 final SAR (most recent SAR) for the Alaska stock of minke whales reports the stock abundance as unknown because only a portion of the stock's range has been surveyed. To be conservative, for this stock we report the smallest estimated abundance produced during recent surveys.

The majority of takes by harassment of mysticetes in the NWTT Study Area are caused by anti-submarine warfare (ASW) activities in the Offshore portion of the Study Area. Anti-submarine activities include sources from the MFAS bin (which includes hull-mounted sonar) because they are high level, narrowband sources in the 1–10 kHz range, which intersect what is estimated to be the most sensitive area of hearing for mysticetes. They also are used in a large portion of exercises (see Tables 3 and 4). Most of the takes (90 percent) from the MF1 bin in the NWTT Study Area would result from received levels between 160 and 178 dB SPL, while another 9 percent would result from exposure between 178 and 184 dB SPL. For the remaining active sonar bin types, the percentages are as follows: LF4 = 97 percent between 124 and 142 dB SPL, MF4 = 95 percent between 136 and 148 dB SPL, MF5 = 97 percent between 112 and 142 dB SPL, and HF4 = 91 percent between 100 and 154 dB SPL. For mysticetes, explosive training activities do not result in any take. Explosive testing activities result in a small number of behavioral Level B harassment takes (0–6 per stock) and TTS takes (0–2 per stock). 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. No PTS or tissue damage from training and testing activities is anticipated or proposed for authorization for any species or stock.

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 feeding or breeding grounds. Behavioral reactions may include alerting, breaking off feeding dives and surfacing, diving or swimming away, or no response at all (DOD, 2017; Nowacek, 2007; Richardson, 1995; Southall *et al.,* 2007). 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, while males en route to breeding grounds have been shown to be less responsive to disturbances. Although some may pause temporarily, they will resume migration shortly after the exposure ends. 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. Alternately, adult females with calves may be more responsive to stressors. 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 MFAS. Southall *et al.* (2019b) observed that after exposure to simulated and operational mid-frequency active sonar, more than 50 percent of blue whales in deep-diving states responded to the sonar, while no behavioral response was observed in shallow-feeding blue whales. Southall *et al.* (2019b) noted that the behavioral responses they observed were generally brief, of low to moderate severity, and highly dependent on exposure context (behavioral state, source-to-whale horizontal range, and prey availability). Most Level B behavioral harassment of mysticetes is likely to be short-term and of low to sometimes moderate severity, with no anticipated effect on reproduction or survival.

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 as they move through an area, although the Navy's activities do not typically use the same training locations day-after-day during multi-day activities, except periodically in instrumented ranges. Therefore, displaced animals could return quickly after even a large activity is completed. In the ocean, the use of Navy 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 procedural 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), which is reflected in the amount and type of incidental take that is anticipated to occur and proposed for authorization.

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 shifts caused by Navy sonar sources will typically occur in the range of 2–20 kHz (from the 1–10 kHz MF bin, though in a specific narrow band within this range as the sources are narrowband), and if resulting from hull-mounted sonar, will be in the range of 3.5–7 kHz. The majority of mysticete vocalizations occur 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.

All the mysticete species discussed in this section would benefit from the procedural mitigation measures described earlier in the *Proposed Mitigation Measures* section. Additionally, the Navy would limit activities and employ other measures in mitigation areas that would avoid or reduce impacts to mysticetes. Where these mitigation areas are designed to mitigate impacts to particular species or stocks (gray whales and humpback whales), they are discussed in detail below. Below we compile and summarize the information that supports our preliminary determination that the Navy's activities would not adversely affect any species or stock through effects on annual rates of recruitment or survival for any of the affected mysticete stocks.

Blue Whale (Eastern North Pacific Stock)

Blue whales are listed as endangered under the ESA throughout their range, but there is no ESA designated critical habitat or biologically important areas identified for this species in the NWTT Study Area. The SAR identifies this stock as ''stable''. We further note that this stock was originally listed under the ESA as a result of the impacts from commercial whaling, which is no longer affecting the species. Blue whales are anticipated to be present in summer and winter months and only in the Offshore Area of the Study Area. No mortality from either explosives or vessel strike and no Level A harassment is anticipated or proposed for authorization.

Regarding the magnitude of Level B harassment takes (TTS and behavioral disruption), the number of estimated total instances of take compared to the abundance is less than 1 percent. Given the range of blue whales, this information indicates that only a very small portion of individuals in the stock are likely impacted and repeated exposures of individuals are not anticipated. Regarding the severity of those individual takes by behavioral Level B 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 small portion up to 184 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, of short duration, and mostly not in a frequency band that would be expected to interfere with blue 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.

Altogether, this population is stable, only a very small portion of the stock is anticipated to be impacted, and any individual blue whale is likely to be disturbed at a low-moderate level. No mortality and no Level A harassment is anticipated or proposed for authorization. The low magnitude and severity of harassment effects is not expected to result in impacts on the reproduction or survival of any individuals, let alone have impacts on annual rates of recruitment or survival. For these reasons, we have preliminarily determined, in consideration of all of the effects of the Navy's activities combined, that the proposed authorized take would have a negligible impact on the Eastern North Pacific stock of blue whales.

Fin Whale (Northeast Pacific Stock and California/Oregon/Washington Stock)

Fin whales are listed as endangered under the ESA throughout their range, but no ESA designated critical habitat or biologically important areas are identified for this species in the NWTT Study Area. The SAR identifies these stocks as ''increasing.'' NMFS is proposing to authorize two mortalities of fin whales over the seven years covered by this rule, but because it is not possible to determine from which stock these potential takes would occur, that is 0.29 mortality annually for each stock. The addition of this 0.29 annual mortality still leaves the total annual human-caused mortality well under residual PBR (37.1 for the CA/OR/WA stock and 4.7 for the Northeast Pacific stock) and below the insignificance threshold for both stocks. No mortality from explosives and no Level A

harassment is anticipated or proposed for authorization.

Regarding the magnitude of Level B harassment takes (TTS and behavioral disruption), the number of estimated total instances of take compared to the abundance is less than 1 percent for the Northeast Pacific stock and 1.5 percent for the CA/OR/WA stock. This information indicates that only a very small portion of individuals in each stock are likely impacted and repeated exposures of individuals are not anticipated. Regarding the severity of those individual Level B harassment takes by behavioral disruption, 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 small portion up to 184 dB (*i.e.,* of a moderate or lower level, less likely to evoke a severe response). Regarding the severity of TTS takes, 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 the associated lost opportunities and capabilities are not at a level that would impact reproduction or survival.

Altogether, these populations are increasing, only a small portion of each stock is anticipated to be impacted, and any individual fin whale is likely to be disturbed at a low-moderate level. No Level A harassment is anticipated or proposed to be authorized. This low magnitude and severity of harassment effects is not expected to result in impacts on individual reproduction or survival for any individuals, nor are these harassment takes combined with the proposed authorized mortality expected to adversely affect these stocks through impacts on annual rates of recruitment or survival. For these reasons, we have preliminarily determined, in consideration of all of the effects of the Navy's activities combined, that the proposed authorized take would have a negligible impact on both the Northeast Pacific and CA/OR/WA stocks of fin whales.

Humpback Whale (Central North Pacific Stock)

The Central North Pacific stock of humpback whales consists of winter/spring humpback whale populations of the Hawaiian Islands which migrate primarily to foraging habitat in northern British Columbia/Southeast Alaska, the Gulf of Alaska, and the Bering Sea/Aleutian Islands (Muto *et al.* 2019). Three Feeding Area biologically important areas for humpback whales overlap with the NWTT Study Area: Northern Washington Feeding Area for humpback whales (May–November); Stonewall and Heceta Bank Feeding Area for humpback whales (May–November); and Point St. George Feeding Area for humpback whales (July–November) (Calambokidis *et al.,* 2015). The Marine Species Coastal, Olympic Coast National Marine Sanctuary, Stonewall and Hecta Bank Humpback Whale, and Point St. George Humpback Whale Mitigation Areas overlap with these important foraging areas. The mitigation measures implemented in each of these areas including no MF1 MFAS use seasonally or limited MFAS use year round, no explosive training, *etc.* (see details for each area in the *Proposed Mitigation* section), would reduce the severity of impacts to humpback whales by reducing interference in feeding that could result in lost feeding opportunities or necessitate additional energy expenditure to find other good opportunities.

The SAR identifies this stock as ''increasing'' and the associated Hawaii DPS is not listed under the ESA. No mortality from explosives and no Level A harassment is anticipated or proposed for authorization. NMFS proposes to authorize two mortalities of humpback whales over the seven years covered by this rule, but because it is not possible to determine from which stock these potential takes would occur, that is 0.29 mortality annually for both this stock and the CA/OR/WA stock (discussed separately below). The addition of this 0.29 annual mortality still leaves the total annual human-caused mortality well under both the insignificance threshold and residual PBR (57.6).

Regarding the magnitude of Level B harassment takes (TTS and behavioral disruption), the number of estimated instances of take compared to the abundance is 1 percent. This information and the complicated far-ranging nature of the stock structure indicates that only a very small portion of the stock is likely impacted and repeated exposures of individuals are not anticipated. Regarding the severity of those individual Level B harassment takes by behavioral disruption, 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 small portion up to 184 dB (*i.e.,* of a moderate or lower level, less likely to evoke a severe response). Regarding the severity of TTS takes, they are expected to be low-level, of short duration, and mostly not in a frequency band that would be expected to interfere with humpback 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.

Altogether, this population is increasing and the associated DPS is not listed as endangered or threatened under the ESA. Only a very small portion of the stock is anticipated to be impacted and any individual humpback whale is likely to be disturbed at a low-moderate level. No Level A harassment is anticipated or proposed to be authorized. 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 proposed authorized mortality expected to adversely affect this stock through effects on annual rates of recruitment or survival. For these reasons, we have preliminarily determined, in consideration of all of the effects of the Navy's activities combined, that the proposed authorized take would have a negligible impact on the Central North Pacific stock of humpback whales.

Humpback Whale (California/Oregon/Washington Stock)

The CA/OR/WA stock of humpback whales includes individuals from three ESA DPSs: Central America (endangered), Mexico (threatened), and Hawaii (not listed). There is no ESA-designated critical habitat for humpback whales, however NMFS recently proposed to designate critical habitat for humpback whales (84 FR 54354; October 9, 2019). Three Feeding Area biologically important areas for humpback whales overlap with the NWTT Study Area: Northern Washington Feeding Area for humpback whales (May–November); Stonewall and Heceta Bank Feeding Area for humpback whales (May–November); and Point St. George Feeding Area for humpback whales (July–November) (Calambokidis *et al.,* 2015). The Marine Species Coastal, Olympic Coast National Marine Sanctuary, Stonewall and Hecta Bank Humpback Whale, and Point St. George Humpback Whale Mitigation Areas overlap with these important foraging areas. The mitigation measures implemented in each of these areas including no MF1 MFAS use seasonally or limited MFAS use year round, no explosive training, *etc.* (see details for each area in the *Proposed Mitigation* section), would reduce the severity of impacts to humpback whales by reducing interference in feeding that could result in lost feeding

opportunities or necessitate additional energy expenditure to find other good opportunities.

The SAR identifies this stock as stable (having shown a long-term increase from 1990 and then leveling off between 2008 and 2014). NMFS proposes to authorize two mortalities over the seven years covered by this rule, or 0.29 mortality annually. With the addition of this 0.29 annual mortality, the total annual human-caused mortality exceeds residual PBR by 9.19. However, as described in more detail in the *Serious Injury or Mortality* section, when total human-caused mortality exceeds PBR, we consider whether the incremental addition of a small amount of mortality proposed for authorization from the specified activity may still result in a negligible impact, in part by identifying whether it is less than 10 percent of PBR. In this case, the mortality proposed for authorization is well below 10 percent of PBR (less than one percent, in fact) and management measures are in place to reduce mortality from other sources. More importantly, as described above in the *Serious Injury or Mortality* section, the mortality of 0.29 proposed for authorization would not delay the time to recovery by more than 1 percent. Given these considerations, the incremental addition of two mortalities over the course of the seven-year Navy rule is not expected to, alone, lead to adverse impacts on the stock through effects on annual rates of recruitment or survival. No mortality from explosives and no Level A harassment is anticipated or proposed for authorization.

Regarding the magnitude of Level B harassment takes (TTS and behavioral disruption), the number of estimated total instances of take compared to the abundance is 3 percent. Given the range of humpback whales, this information indicates that only a very small portion of individuals in the stock are likely impacted and repeated exposures of individuals are not anticipated. Regarding the severity of those individual Level B harassment takes by behavioral disruption, 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 small portion up to 184 dB (*i.e.,* of a moderate or lower level, less likely to evoke a severe response). Regarding the severity of TTS takes, they are expected to be low-level, of short duration, and mostly not in a frequency band that would be expected to interfere with humpback whale communication or other important low-frequency cues and the associated lost opportunities and capabilities are not at a level that would impact reproduction or survival.

Altogether, this population is stable (even though two of the three associated DPSs are listed as endangered or threatened under the ESA), only a small portion of the stock is anticipated to be impacted, and any individual humpback whale is likely to be disturbed at a low-moderate level. No Level A harassment is anticipated or proposed to be authorized. This low magnitude and severity of harassment effects is not expected to result in impacts on the reproduction or survival of any individuals and, therefore, when combined with the proposed authorized mortality (which our earlier analysis indicated will not, alone, have more than a negligible impact on this stock of humpback whales), the total take is not expected to adversely affect this stock through impacts on annual rates of recruitment or survival. For these reasons, we have preliminarily determined, in consideration of all of the effects of the Navy's activities combined, that the proposed authorized take would have a negligible impact on the CA/OR/WA stock of humpback whales.

Minke Whale (Alaska and California/Oregon/Washington Stocks)

The status of these stocks is unknown and the species is not listed under the ESA. No biologically important areas have been identified for this species in the NWTT Study Area. NMFS proposes to authorize one mortality over the seven years covered by this rule, or 0.14 mortality annually. The addition of this 0.14 annual mortality still leaves the total annual human-caused mortality well under the residual PBR (2.2) and below the insignificance threshold. No mortality from explosives and no Level A harassment is anticipated or proposed for authorization.

Regarding the magnitude of Level B harassment takes (TTS and behavioral disruption), the number of estimated total instances of take compared to the abundance is less than 1 percent for the Alaska stock (based on, to be conservative, the smallest available provisional estimate in the SAR, which is derived from surveys that cover only a portion of the stock's range) and 47.5 percent for the CA/OR/WA stock. Given the range of minke whales, this information indicates that only a portion of individuals in these stocks are likely to be impacted and repeated exposures of individuals are not anticipated. Regarding the severity of those individual Level B harassment takes by behavioral disruption, 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 small portion up to 184 dB (*i.e.,* of a moderate or lower level, less likely to evoke a severe response). Regarding the severity of TTS takes, they are expected to be low-level, of short duration, and mostly not in a frequency band that would be expected to interfere with minke whale communication or other important low-frequency cues—and the associated lost opportunities and capabilities are not at a level that would impact reproduction or survival.

Altogether, although the status of the stocks is unknown, the species is not listed under the ESA as endangered or threatened, only a portion of these stocks is anticipated to be impacted, and any individual minke whale is likely to be disturbed at a low-moderate level. No Level A harassment is anticipated or proposed to be authorized. 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 proposed authorized mortality expected to adversely affect these stocks through effects on annual rates of recruitment or survival. For these reasons, we have preliminarily determined, in consideration of all of the effects of the Navy's activities combined, that the proposed authorized take would have a negligible impact on the Alaska and CA/OR/WA stocks of minke whales.

Sei Whale (Eastern North Pacific Stock)

The status of this stock is unknown, however sei whales are listed as endangered under the ESA throughout their range. There is no ESA designated critical habitat or biologically important areas identified for this species in the NWTT Study Area. No mortality from either explosives or vessel strikes and no Level A harassment is anticipated or proposed for authorization.

Regarding the magnitude of Level B harassment takes (TTS and behavioral disruption), the number of estimated total instances of take compared to the abundance is 16 percent. This information and the large range of sei whales suggests that only a small portion of individuals in the stock are likely impacted and repeated exposures of individuals are not anticipated. Regarding the severity of those individual Level B harassment takes by behavioral disruption, 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 small portion up to 184 dB (*i.e.,* of a moderate or lower level, less likely to evoke a severe response). Regarding the severity of TTS takes, they are expected to be low-level, of short duration, and mostly not in a frequency band that would be expected to interfere with sei whale communication or other important low-frequency cues and the associated lost opportunities and capabilities are not at a level that would impact reproduction or survival.

Altogether, the status of the stock is unknown and the species is listed as endangered, but only a small portion of the stock is anticipated to be impacted and any individual sei whale is likely to be disturbed at a low-moderate level. No mortality and no Level A harassment is anticipated or proposed for authorization. This low magnitude and severity of harassment effects is not expected to result in impacts on individual reproduction or survival, much less annual rates of recruitment or survival. For these reasons, we have preliminarily determined, in consideration of all of the effects of the Navy's activities combined, that the proposed authorized take would have a negligible impact on the Eastern North Pacific stock of sei whales.

Gray Whale (Eastern North Pacific Stock)

The SAR identifies this stock as ''increasing'' and the associated DPS is not listed under the ESA. The NWTT Study Area overlaps with the offshore Northwest Washington and the Northern Puget Sound gray whale Feeding biologically important areas, and a portion of the Northwest coast of Washington approximately from Pacific Beach (WA) and extending north to the Strait of Juan de Fuca overlaps with the gray whale Migrations Corridor biologically important area. The Marine Species Coastal, Olympic Coast National Marine Sanctuary, Stonewall and Hecta Bank Humpback Whale, and Point St. George Humpback Whale, and Northern Puget Sound Gray Whale Mitigation Areas overlap with these important foraging and migration areas. The mitigation measures implemented in each of these areas including no MF1 MFAS use seasonally or limited MFAS use year round, no explosive training, *etc.* (see details for each area in the *Proposed Mitigation* section), would reduce the severity of impacts to gray whales by reducing interference in feeding and migration that could result in lost feeding opportunities or necessitate additional energy expenditure to find other good foraging opportunities or move migration routes.

NMFS proposes to authorize one mortality over the seven years covered by this rule, or 0.14 mortality annually. The addition of this 0.14 annual mortality still leaves the total annual human-caused mortality well under both the insignificance threshold and residual PBR (661.6). No mortality from explosives and no Level A harassment is anticipated or proposed for authorization.

Regarding the magnitude of Level B harassment takes (TTS and behavioral disruption), the number of estimated total instances of take compared to the abundance is less than 1 percent. This information indicates that only a very small portion of individuals in the stock are likely to be impacted and repeated exposures of individuals are not anticipated. Regarding the severity of those individual Level B harassment takes by behavioral disruption, 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 small portion up to 184 dB (*i.e.,* of a moderate or lower level, less likely to evoke a severe response). Regarding the severity of TTS takes, they are expected to be low-level, of short duration, and mostly not in a frequency band that would be expected to interfere with gray 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.

Altogether, while we have considered the impacts of the gray whale UME, this population of gray whales is not endangered or threatened under the ESA and the stock is increasing. No Level A harassment is anticipated or proposed to be authorized. Only a very small portion of the stock is anticipated to be impacted by Level B harassment and any individual gray whale is likely to be disturbed at a low-moderate level. This low magnitude and severity of harassment effects is not expected to result in impacts to reproduction or survival for any individuals, nor are these harassment takes combined with the proposed authorized mortality of one whale over the seven-year period expected to adversely affect this stock through impacts on annual rates of recruitment or survival. For these reasons, we have preliminarily determined, in consideration of all of the effects of the Navy's activities combined, that the proposed authorized take would have a negligible impact on the Eastern North Pacific stock of gray whales.

Odontocetes

This section builds on the broader discussion above and brings together the discussion of the different types and amounts of take that different species and stocks could potentially or would likely incur, the applicable mitigation, and the status of the species and stock to support the negligible impact determinations for each species or stock. We have described (earlier in this section) the unlikelihood of any masking having effects that would impact the reproduction or survival of any of the individual marine mammals affected by the Navy's activities. We have also described above in the Potential Effects of Specified Activities on Marine Mammals and their Habitat section the unlikelihood of any habitat impacts having effects that would impact the reproduction or survival of any of the individual marine mammals affected by the Navy's activities. For odontocetes, there is no anticipated M/SI or tissue damage from sonar or explosives for any species. Here, we include information that applies to all of the odontocete species, which are then further divided and discussed in more detail in the following subsections: Sperm whales, dwarf sperm whales, and pygmy sperm whales; beaked whales; dolphins and small whales; and porpoises. These subsections include more specific information about the groups, as well as conclusions for each species or stock represented.

The majority of takes by harassment of odontocetes in the NWTT Study Area are caused by sources from the MFAS bin (which includes hull-mounted sonar) because they are high level, typically narrowband sources at a frequency (in the 1–10 kHz range) that overlaps a more sensitive portion (though not the most sensitive) of the MF hearing range and they are used in a large portion of exercises (see Tables 3 and 4). For odontocetes other than beaked whales and porpoises (for which these percentages are indicated separately in those sections), most of the takes (96 percent) from the MF1 bin in the NWTT 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: LF4 = 99 percent between 124 and 154 dB SPL, MF4 = 99 percent between 136 and 166 dB SPL, MF5 = 98 percent between 112 and 148 dB SPL, and HF4 = 95 percent between 100 and 160 dB SPL. 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) comprise a very small fraction (and low number) of those caused by exposure to active sonar. For the following odontocetes, zero takes from explosives are expected to occur: Common bottlenose dolphins, killer whales, short-beaked common dolphins, short-finned pilot whales, the Alaska stock of Dall's porpoises, Southeast Alaska stock of harbor porpoises, sperm whales, Baird's beaked whale, Cuvier's beaked whale, and *Mesoplodon* species. For Level B behavioral disruption from explosives, with the exception of porpoises, one take is anticipated for the remaining species/stocks. For the CA/OR/WA stock of Dall's porpoise and the remaining three harbor porpoise stocks 1–91 Level B behavioral takes from explosives are anticipated. Similarly the instances of TTS and PTS expected to occur from explosives for all remaining species/stocks, with the exception of porpoises, are anticipated to be low (1–3 for TTS and 1 for PTS). Because of the lower TTS and PTS thresholds for HF odontocetes, for the CA/OR/WA stock of Dall's porpoise and the remaining three harbor porpoise stocks, TTS takes range from 61–214 and PTS takes range from 27–86.

Because the majority of harassment takes of odontocetes result from the sources in the MFAS bin, the vast majority of threshold shift would occur at a single frequency within the 1–10 kHz range and, therefore, the vast majority of threshold shift caused by Navy sonar sources would be at a single frequency within the range of 2–20 kHz. The frequency range within which any of the anticipated narrowband threshold shift would occur would fall directly within the range of most odontocete vocalizations (2–20 kHz). For example, the most commonly used hull-mounted sonar has a frequency around 3.5 kHz, and any associated threshold shift would be expected to be at around 7 kHz. 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 their 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 shift that might be incurred by individuals exposed to explosives 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 one day, or over a few days at most, and therefore they are unlikely to incur impacts on reproduction or survival. PTS takes from these sources are very low, and while spanning a wider frequency band, are still expected to be of a low degree (*i.e.,* low amount of hearing sensitivity loss) and unlikely to affect reproduction or survival.

The range of potential behavioral effects of sound exposure on marine mammals generally, and odontocetes specifically, has been discussed in detail previously. There are behavioral patterns that differentiate the likely impacts on odontocetes as compared to mysticetes however. 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, studies demonstrate that odontocetes may cease their 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). Second, while 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), odontocetes forage more homogeneously on one fish or squid at a time. Therefore, if odontocetes are interrupted while feeding, it is often possible to find more prey relatively nearby.

Sperm Whale, Dwarf Sperm Whale, and Pygmy Sperm Whale

This section builds on the broader odontocete discussion above and brings together the discussion of the different types and amounts of take that different species and stocks could potentially or would likely incur, the applicable mitigation, and the status of the species and stocks to support the preliminary negligible impact determinations for each species or stock. For sperm whales, there is no predicted PTS from sonar or explosives and no predicted tissue damage from explosives. For dwarf sperm whales and pygmy sperm whales (described as *Kogia* species below) no mortality or tissue damage from sonar or explosives is anticipated or proposed for authorization and only one PTS take is predicted.

In Table 53 below for sperm whales and *Kogia* species, we indicate the total annual numbers of take by mortality, Level A and Level B harassment, and a number indicating the instances of total take as a percentage of abundance.

Table 53 -- Annual estimated takes by Level B harassment, Level A harassment, and mortality for sperm whales, dwarf sperm whales, and pygmy sperm whales in the NWTT 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 (NMFS SARs)*	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			
Suborder Odontoceti (toothed whales)									
Family Physeteridae (sperm whale)									
Sperm whale	CA/OR/WA	834	5	0	0	0.14	839	1,997	42
Family Kogiidae (sperm whales)									
Kogia species	CA/OR/WA	364	518	1	0	0	883	4,111	21

*Presented in the 2019 draft SARs or most recent SAR.

As discussed above, the majority of Level B harassment behavioral takes of odontocetes, and thereby sperm whales and *Kogia* species, is 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, as is expected here, is unlikely to cause long-term consequences for either 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.

We note that *Kogia* species (dwarf and pygmy sperm whales), as HF-sensitive species, have a lower PTS threshold than all other groups and therefore are generally likely to experience larger amounts of TTS and PTS, and NMFS accordingly has evaluated and would 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. Therefore, even though the number of TTS takes are higher than for other odontocetes, for all of the reasons described above, TTS and PTS are not expected to impact reproduction or survival of any individual.

Below we compile and summarize the information that supports our preliminary determination that the Navy's activities would not adversely affect sperm whales and pygmy and dwarf sperm whales through effects on annual rates of recruitment or survival.

Sperm Whale (California/Oregon/Washington Stock)

The SAR identifies the CA/OR/WA stock of sperm whales as ''stable'' and the species is listed as endangered under the ESA. No critical habitat has been designated for sperm whales under the ESA and there are no biologically important areas for sperm whales in the NWTT Study Area. NMFS proposes to authorize one mortality for the CA/OR/WA stock of sperm whales over the seven years covered by this rule, or 0.14 mortality annually. The addition of this 0.14 annual mortality still leaves the total human-caused mortality under residual PBR (2.1) and below the insignificance threshold. No mortality from explosives and no Level A harassment is anticipated or proposed for authorization.

Regarding the magnitude of Level B harassment takes (TTS and behavioral disruption), the number of estimated total instances of take compared to the abundance is 42 percent for sperm whales. Given the range of this stock (which extends the entire length of the West Coast, as well as beyond the U.S. EEZ boundary), this information indicates that only a portion of the individuals in the stock are likely to be impacted and repeated exposures of individuals are not anticipated. 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 those individual Level B harassment takes by behavioral disruption, 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 lower, to occasionally moderate, level and less likely to evoke a severe response). Regarding the severity of TTS takes, they are expected to be low-level, of short duration, and mostly not in a frequency band that would be expected to interfere with sperm whale communication or other important low-frequency cues, and that the associated lost opportunities and capabilities are not at a level that will impact reproduction or survival.

Altogether, this population is stable (even though the species is listed under the ESA), only a portion of the stock is anticipated to be impacted, and any individual sperm whale is likely to be disturbed at a low-moderate level. No Level A harassment is anticipated or proposed to be authorized. This low magnitude and severity of harassment effects is not expected to result in impacts on individual reproduction or survival for any individuals, nor are these harassment takes combined with the proposed authorized mortality expected to adversely affect this stock through impacts on annual rates of recruitment or survival. For these reasons, we have preliminarily determined, in consideration of all of the effects of the Navy's activities combined, that the proposed authorized take would have a negligible impact on the CA/OR/WA stock of sperm whales.

Kogia Species (California/Oregon/Washington Stocks)

The status of the CA/OR/WA stocks of pygmy and dwarf sperm whales (*Kogia*

species) is unknown and neither are listed under the ESA. There are no biologically important areas for *Kogia* in the NWTT Study Area. No mortality or Level A harassment from tissue damage are anticipated or proposed for authorization, and one PTS Level A harassment take is expected and proposed for authorization. Due to their pelagic distribution, small size, and cryptic behavior, pygmy sperm whales and dwarf sperm whales (*Kogia* species) are rarely sighted during at-sea surveys and are difficult to distinguish between when visually observed in the field. Many of the relatively few observations of *Kogia* species off the U.S. West Coast were not identified to species. All at-sea sightings of Kogia species have been identified as pygmy sperm whales or *Kogia* species generally. Stranded dwarf sperm and pygmy sperm whales have been found on the U.S. West Coast, however dwarf sperm whale strandings are rare. NMFS SARs suggest that the majority of *Kogia* sighted off the U.S. West Coast were likely pygmy sperm whales. As such, the stock estimate in the NMFS SAR for pygmy sperm whales is the estimate derived for all *Kogia* species in the region (Barlow, 2016), and no separate abundance estimate can be determined for dwarf sperm whales, though some low number likely reside in the U.S. EEZ. Due to the lack of an abundance estimate it is not possible to predict the amount of Level A and Level B harassment take of dwarf sperm whales and therefore take estimates are identified as *Kogia* whales (including both pygmy and dwarf sperm whales). We assume only a small portion of those takes are likely to be dwarf sperm whales as the available information indicates that the density and abundance in the U.S. EEZ is low.

Regarding the magnitude of Level B harassment takes (TTS and behavioral disruption), the number of estimated total instances of take compared to the abundance is 21 percent. Given the range of these stocks (which extends the entire length of the West Coast, as well as beyond the U.S. EEZ boundary), this information indicates that only a portion of the individuals in the stocks are likely to be impacted and repeated exposures of individuals are not anticipated. 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 those individual Level B harassment takes by behavioral disruption, 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 lower, to occasionally moderate, level and less likely to evoke a severe response). Regarding the severity of TTS takes, they are expected to be low-level, of short duration, and mostly not in a frequency band that would be expected to interfere with sperm whale communication or other important low-frequency cues, and that the associated lost opportunities and capabilities are not at a level that will impact reproduction or survival. For these same reasons (low level and frequency band), while a small permanent loss of hearing sensitivity (PTS) 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 estimated one Level A harassment take by PTS would be unlikely to impact behaviors, opportunities, or detection capabilities to a degree that would interfere with reproductive success or survival of the affected individual. Thus, the one Level A harassment take by PTS for these stocks would be unlikely to affect rates of recruitment and survival for the stock.

Altogether, although the status of the stocks is unknown, these species are not listed under the ESA as endangered or threatened, only a portion of these stocks is anticipated to be impacted, and any individual *Kogia* whale is likely to be disturbed at a low-moderate level. This low magnitude and severity of harassment effects is not expected to result in impacts on the reproduction or survival of any individuals, let alone have impacts on annual rates of recruitment or survival. One individual could be taken by PTS annually of likely low severity. A small permanent loss of hearing sensitivity (PTS) may include some degree of energetic costs for compensating or may mean some small loss of opportunities or detection capabilities, but at the expected scale the estimated one Level A harassment take by PTS would be unlikely to impact behaviors, opportunities, or detection capabilities to a degree that would interfere with reproductive success or survival of that individual, let alone affect annual rates of recruitment or survival. For these reasons, we have preliminarily determined, in consideration of all of the effects of the Navy's activities combined, that the proposed authorized take would have a negligible impact on the CA/OR/WA stocks of *Kogia* whales.

Beaked Whales

This section builds on the broader odontocete discussion above and brings together the discussion of the different types and amounts of take that different beaked whale species and stocks would likely incur, the applicable mitigation for stocks, and the status of the species and stocks to support the preliminary negligible impact determinations for each species or stock. For beaked whales, there is no anticipated Level A harassment by PTS or tissue damage from sonar or explosives, and no mortality is anticipated or proposed for authorization.

In Table 54 below for beaked whales, we indicate the total annual numbers of take by mortality, Level A and Level B harassment, and a number indicating the instances of total take as a percentage of abundance.

Table 54 -- Annual estimated takes by Level B harassment, Level A harassment, and mortality for beaked whales in the NWTT 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 (NMFS SARs)*	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			
Suborder Odontoceti (toothed whales)									
Family Ziphiidae (beaked whales)									
Baird's beaked whale	CA/OR/WA	976	0	0	0	0	976	2,697	36
Cuvier's beaked whale	CA/OR/WA	2,535	4	0	0	0	2,539	3,274	78
Mesoplodon species	CA/OR/WA	1,119	3	0	0	0	1,122	3,044	37

*Presented in the 2019 draft SARs or most recent SAR.

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 NWTT Study Area are caused by sources from the MFAS bin (which includes hull-mounted sonar) because they are high level narrowband sources that fall within the 1–10 kHz range, which overlap a more sensitive portion (though not the most sensitive) of the MF hearing range. Also, of the sources expected to result in take, they are used in a large portion of exercises (see Tables 3 and 4). Most of the takes (95 percent) from the MF1 bin in the NWTT Study Area would result from received levels between 142 and 160 dB SPL. For the remaining active sonar bin types, the percentages are as follows: LF4 = 99 percent between 118 and 148 dB SPL, MF4 = 97 percent between 124 and 148 dB SPL, MF5 = 99 percent between 100 and 148 dB SPL, and HF4 = 97 percent between 100 and 154 dB SPL. Given the levels they are exposed to and beaked whale sensitivity, some responses would be of a lower severity, but many would likely be considered moderate, but still of generally short duration.

Research has shown that beaked whales are especially sensitive to the presence of human activity (Pirotta *et al.,* 2012; Tyack *et al.,* 2011) and therefore have been assigned a lower harassment threshold, with lower received levels resulting in a higher percentage of individuals being harassed and a more distant distance cutoff (50 km for high source level, 25 km for moderate source level).

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, although few definitive causal relationships between MFAS use and strandings have been documented (see *Potential Effects of Specified Activities on Marine Mammals and their Habitat* section).

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: 1 µPa. 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. 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; McCarthy *et al.,* 2011; Moretti *et al.,* 2009, 2010; Tyack *et al.,* 2010, 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. Cuvier's beaked whale responses suggested particular sensitivity to sound exposure consistent

with results for Blainville's beaked whale.

Populations of beaked whales and other odontocetes on the Bahamas and other Navy fixed ranges that have been operating for decades appear to be stable. Behavioral reactions (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 (De Ruiter *et al.,* 2013; Manzano-Roth *et al.,* 2013; Moretti *et al.,* 2014; Tyack *et al.,* 2011). 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, a Navy range that is utilized for training and testing, have identified approximately 100 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 long-term consequences as a result of exposure to Navy training and testing activities. More than eight years of passive acoustic monitoring on the Navy's instrumented range west of San Clemente Island documented no significant changes in annual and monthly beaked whale echolocation clicks, with the exception of repeated fall declines likely driven by natural beaked whale life history functions (DiMarzio *et al.,* 2018). Finally, results from passive acoustic monitoring estimated that regional Cuvier's beaked whale densities were higher than indicated by NMFS' broad scale visual surveys for the United States West Coast (Hildebrand and McDonald, 2009).

Below we compile and summarize the information that supports our preliminary determination that the Navy's activities would not adversely affect beaked whales through effects on annual rates of recruitment or survival.

Baird's and Cuvier's Beaked Whales and Mesoplodon Species (California/Oregon/Washington Stocks)

The CA/OR/WA stocks of Baird's beaked whale, Cuvier's beaked whale, and *Mesoplodon* species are not listed as endangered or threatened species under the ESA, and have been identified as ''stable,'' ''decreasing,'' and ''increasing,'' respectively, in the SARs. There are no biologically important areas for beaked whales in the NWTT Study Area. No mortality or Level A harassment from sonar or explosives is expected or proposed for authorization.

No methods are available to distinguish between the six species of *Mesoplodon* beaked whales from the CA/OR/WA stocks (Blainville's beaked whale (*M. densirostris*), Perrin's beaked whale (*M. perrini*), Lesser beaked whale (*M. peruvianus*), Stejneger's beaked whale (*M. stejnegeri*), Gingko-toothed beaked whale (*M. gingkodens*), and Hubbs' beaked whale (*M. carlhubbsi*)) when observed during at-sea surveys (Carretta *et al.,* 2019). Bycatch and stranding records from the region indicate that Hubb's beaked whale is the most commonly encountered (Carretta *et al.,* 2008, Moore and Barlow, 2013). As indicated in the SAR, no species-specific abundance estimates are available, the abundance estimate includes all CA/OR/WA *Mesoplodon* species, and the six species are managed as one unit. Due to the lack of species-specific abundance estimates it is not possible to predict the take of individual species and take estimates are identified as *Mesoplodon* species. Therefore our analysis considers these *Mesoplodon* species together.

Regarding the magnitude of Level B harassment takes (TTS and behavioral disruption), the number of estimated total instances of take compared to the abundance is 36 to 78 percent. This information indicates that up to 78 percent of the individuals in these stocks are likely to be impacted, depending on the stock, though the more likely scenario is that a smaller portion than that would be taken, and a subset of them would be taken on a few days, with no indication that these days would be sequential. Regarding the severity of those individual Level B harassment takes by behavioral disruption, 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 166 dB, though with beaked whales, which are considered somewhat more sensitive, this could mean that some individuals will leave preferred habitat for a day (*i.e.,* moderate level takes). However, while interrupted feeding bouts are a known response and concern for odontocetes, we also know that there are often viable alternative habitat options nearby. Regarding the severity of TTS takes, they are expected to be low-level, of short duration, and mostly not in a frequency band that would be expected to interfere with beaked 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. 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.

Altogether, none of these species are listed as threatened or endangered under the ESA, only a portion of the stocks are anticipated to be impacted, and any individual beaked whale is likely to be disturbed at a moderate or sometimes low level. This low magnitude and low to moderate severity of harassment effects is not expected to result in impacts on individual reproduction or survival, let alone annual rates of recruitment or survival. No mortality and no Level A harassment is anticipated or proposed for authorization. For these reasons, we have preliminarily determined, in consideration of all of the effects of the Navy's activities combined, that the proposed authorized take would have a negligible impact on the CA/OR/WA stocks of beaked whales.

Dolphins and Small Whales

This section builds on the broader odontocete discussion above and brings together the discussion of the different types and amounts of take that different dolphin and small whale species and stocks would likely incur, the applicable mitigation for stocks, and the status of the species and stocks to support the preliminary negligible impact determinations for each species or stock. For all dolphin and small whale stocks discussed here except for the CA/OR/WA stocks of Northern right whale dolphin and Pacific white-sided dolphin there is no predicted PTS from sonar or explosives, and no mortality or tissue damage from sonar or explosives is anticipated or proposed for authorization. For the CA/OR/WA stocks of Northern right whale dolphin and Pacific white-sided dolphin no mortality or tissue damage from sonar or explosives is anticipated or proposed for authorization and one Level A

harassment by PTS from testing activities is predicted for each stock.

In Table 55 below for dolphins and small whales, we indicate the total annual numbers of take by mortality, Level A harassment and Level B harassment, and a number indicating the instances of total take as a percentage of abundance.

Table 55. Annual estimated takes by Level B harassment, Level A harassment, and mortality for dolphins and small whales in the NWTT 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 (NMFS SARs)*	Instances of total take as percentage of abundance
		Level B Harassment		Level A Harassment		Mortality			
Species	Stock	Behavioral Disturbance	TTS (may also include disturbance)	PTS	Tissue Damage				
Family Delphinidae (dolphins)									
Common bottlenose dolphin	CA/OR/WA Offshore	8	0	0	0	0	8	1,924	<1
Killer whale	Eastern North Pacific Alaskan Resident	34	0	0	0	0	34	2,347	1
	West Coast Transient	210	22	0	0	0	232	243	95
	Eastern North Pacific Offshore	152	5	0	0	0	157	300	52
	Eastern North Pacific Southern Resident	49	2	0	0	0	51	75	68
Northern right whale dolphin	CA/OR/WA	20,671	1,029	1	0	0	21,701	26,556	82
Pacific white-sided dolphin	North Pacific	101	0	0	0	0	101	26,880	<1
	CA/OR/WA	19,593	1,372	1	0	0	20,966	26,814	78
Risso's dolphin	CA/OR/WA	6,080	275	0	0	0	6,355	6,336	100
Short-beaked common dolphin	CA/OR/WA	2,103	46	0	0	0	2,149	969,861	<1
Short-finned pilot whale	CA/OR/WA	87	1	0	0	0	88	836	11
Striped dolphin	CA/OR/WA	763	20	0	0	0	783	29,211	3

*Presented in the 2019 draft SARs or most recent SAR.

As described above, the large majority of Level B behavioral harassment to odontocetes, and thereby dolphins and small whales, from hull-mounted sonar (MFAS) in the NWTT 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.

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, such as bottlenose dolphins, spotted dolphins, spinner dolphins, rough-toothed dolphins, *etc.,* but not Risso's dolphin), 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. Dolphins and small whales 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.

Below we compile and summarize the information that supports our preliminary determination that the Navy's activities would not adversely affect dolphins and small whales through effects on annual rates of recruitment or survival.

Killer Whales (Eastern North Pacific Alaskan Resident, West Coast Transient, Eastern North Pacific Offshore, and Eastern North Pacific Southern Resident Stocks)

With the exception of the Eastern North Pacific Southern Resident stock (Southern Resident killer whale DPS) which is listed as endangered under the ESA, killer whale stocks in the NWTT Study Area are not listed under the ESA. ESA-designated critical habitat for the Southern Resident killer whale DPS overlaps with the NWTT Study area in the Strait of Juan de Fuca. No biologically important areas for killer whales have been identified in the NWTT Study Area. The Eastern North Pacific Southern Resident stock is small (75 individuals) and has been decreasing in recent years. The Eastern North Pacific Offshore stock is reported as ''stable'', and the other stocks have unknown population trends. No mortality or Level A harassment is anticipated or proposed for authorization for any of these stocks.

The proposed Marine Species Coastal, Olympic Coast National Marine Sanctuary, Stonewall and Heceta Bank Humpback Whale, Point St. George Humpback Whale, and Puget Sound and Strait of Juan de Fuca Mitigation Areas overlap with important Eastern North Pacific Southern Resident (Southern Resident DPS) killer whale foraging and migration habitat. Procedural mitigation along with the mitigation measures implemented in each of these areas include no MF1 MFAS use seasonally or limited MFAS use year round, no explosive training, *etc.* (see details for each area in the *Proposed Mitigation Measures* section), would reduce the severity of impacts to Eastern North Pacific Southern Resident (Southern Resident DPS) killer whales by reducing interference in feeding and migration that could result in lost feeding opportunities or necessitate additional energy expenditure to find other good foraging opportunities or migration routes.

Regarding the magnitude of Level B harassment takes (TTS and behavioral disruption), the number of estimated total instances of take compared to the abundance ranges from 1 percent (Eastern North Pacific Alaskan Resident) to 95 percent (West Coast Transient). The number of estimated total instances of take compared to the abundance for the Eastern North Pacific Southern Resident is 68 percent. This information indicates that only a very small portion of the Eastern North Pacific Alaskan Resident stock is likely impacted and repeated exposures of individuals are not anticipated. This information also indicates that a few to up to 95 percent of individuals of the remaining three stocks could be impacted, if each were taken only one day per year, though the more likely scenario is that a smaller portion than that would be taken, and a subset of them would be taken multiple days with no indication that these days would be sequential. Regarding the severity of those individual Level B harassment takes by behavioral disruption, 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 lower, to occasionally moderate, level and less likely to evoke a severe response). Regarding the severity of TTS takes, they are expected to be low-level, of short duration, and mostly not in a frequency band that would be expected to interfere with killer 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.

Altogether, with the exception of the Eastern North Pacific Southern Resident stock which is listed as endangered under the ESA, these killer whale stocks are not listed under the ESA. Only a portion of these killer whale stocks is anticipated to be impacted, and any individual is likely to be disturbed at a low-moderate level, with the taken individuals likely exposed on one day or a few days. Even acknowledging the small and declining stock size of the Eastern North Pacific Southern Resident stock, this low magnitude and severity of harassment effects is unlikely to result in impacts on individual reproduction or survival, much less annual rates of recruitment or survival of any of the stocks. No mortality or Level A harassment is anticipated or proposed for authorization for any of the stocks. For these reasons, we have preliminarily determined, in consideration of all of the effects of the Navy's activities combined, that the proposed authorized take would have a negligible impact on these killer whale stocks.

All other dolphin and small whale stocks

None of these stocks is listed under the ESA and their stock statuses are considered ''unknown,'' except for the CA/OR/WA stock of short-beaked common dolphin which is described as ''increasing''. No biologically important areas for these stocks have been identified in the NWTT Study Area. No mortality or serious injury is anticipated or proposed for authorization. With the exception of one Level A harassment PTS take to the CA/OR/WA stocks of Northern right whale dolphin and Pacific white-sided dolphin, no Level A harassment by PTS or tissue damage is expected or proposed for authorization for these stocks.

Regarding the magnitude of Level B harassment takes (TTS and behavioral disruption), the number of estimated total instances of take compared to the abundance ranges from less than 1 percent (North Pacific stock of Pacific white-sided dolphins, CA/OR/WA Offshore stock of common bottlenose dolphins, and CA/OR/WA stock of short-beaked common dolphin) to 100 percent (CA/OR/WA stock of Risso's dolphins). All stocks except for the CA/OR/WA stocks of Risso's dolphin, Pacific white-sided dolphin, and Northern right whale dolphin have estimated total instances of take compared to the abundances less than or equal to 11 percent. This information indicates that only a small portion of these stocks is likely impacted and repeated exposures of individuals are not anticipated. The CA/OR/WA stocks of Risso's dolphins, Pacific white-sided dolphin, and Northern right whale dolphin have estimated total instances of take compared to the abundances that range from 78 to 100 percent. This information indicates that up to 100 percent of the individuals of these stocks could be impacted, if each were taken only one day per year, though the more likely scenario is that a smaller portion than that would be taken, and a subset of them would be taken on a few days, with no indication that these days would be sequential. Regarding the severity of those individual Level B harassment takes by behavioral disruption, 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

lower, to occasionally moderate, level and less likely to evoke a severe response). However, while interrupted feeding bouts are a known response and concern for odontocetes, we also know that there are often viable alternative habitat options nearby. Regarding the severity of TTS takes, they are expected to be low-level, of short duration, and mostly not in a frequency band that would be expected to interfere with dolphin and small 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 (PTS) 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 estimated one Level A harassment take by PTS for the CA/OR/WA stocks of Northern right whale dolphin and Pacific white-sided dolphin would be unlikely to impact behaviors, opportunities, or detection capabilities to a degree that would interfere with reproductive success or survival of that individual. Thus the one Level A harassment take by PTS for these stocks would be unlikely to affect rates of recruitment and survival for the stock.

Altogether, though the status of these stocks is largely unknown, none of these stocks is listed under the ESA and any individual is likely to be disturbed at a low-moderate level, with the taken individuals likely exposed on one to a few days. This low magnitude and severity of harassment effects is not expected to result in impacts on individual reproduction or survival. One individual each from the CA/OR/WA stocks of Northern right whale dolphin and Pacific white-sided dolphin could be taken by PTS annually of likely low severity. A small permanent loss of hearing sensitivity (PTS) may include some degree of energetic costs for compensating or may mean some small loss of opportunities or detection capabilities, but at the expected scale the estimated Level A harassment takes by PTS for the CA/OR/WA stocks of Northern right whale dolphin and Pacific white-sided dolphin would be unlikely to impact behaviors, opportunities, or detection capabilities to a degree that would interfere with reproductive success or survival of any individuals, let alone annual rates of recruitment or survival. No mortality is anticipated or proposed for authorization. For these reasons, we have preliminarily determined, in consideration of all of the effects of the Navy's activities combined, that the proposed authorized take would have a negligible impact on these stocks of small whales and dolphins.

Porpoises

This section builds on the broader odontocete discussion above and brings together the discussion of the different types and amounts of take that different porpoise species or stocks would likely incur, the applicable mitigation, and the status of the species and stock to support the negligible impact determinations for each species or stock. For porpoises, there is no anticipated M/SI or tissue damage from sonar or explosives for any species.

In Table 56 below for porpoises, we indicate the total annual numbers of take by mortality, Level A harassment and Level B harassment, and a number indicating the instances of total take as a percentage of abundance.

Table 56 -- Annual estimated takes by Level B harassment, Level A harassment, and mortality for porpoises in the NWTT 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 (NMFS SARs)*	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			
Family Phocoenidae (porpoises)									
Dall's porpoise	Alaska	179	459	0	0	0	638	83,400	<1
	CA/OR/WA	13,407	20,290	98	0	0	33,795	25,750	131
Harbor porpoise	Southeast Alaska	92	38	0	0	0	130	1,354	10
	Northern OR/WA Coast	31,602	20,810	103	0	0	52,515	21,487	244
	Northern CA/ Southern OR	1,691	348	86	0	0	2,125	35,769	6
	Washington Inland Waters	15,146	14,397	180	0	0	29,723	11,233	265

*Presented in the 2019 draft SARs or most recent SAR.

The majority of takes by harassment of harbor porpoises in the NWTT Study Area are caused by sources from the MFAS 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 Tables 3 and 4). Most of the takes (90

percent) from the MF1 bin in the NWTT Study Area would result from received levels between 148 and 166 dB SPL. For the remaining active sonar bin types, the percentages are as follows: LF4 = 99 percent between 124 and 142 dB SPL, MF4 = 97 percent between 124 and 148 dB SPL, MF5 = 97 percent between 118 and 142 dB SPL, and HF4 = 97 percent between 118 and 160 dB SPL. Given the levels they are exposed to and harbor porpoise sensitivity, some responses would be of a lower severity, but many would likely be considered moderate, but still of generally short duration.

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 NWTT Study Area is generally higher than the other species. 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 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 stocks.

While harbor porpoises have been observed to be especially sensitive to human activity, the same types of responses have not been observed in Dall's porpoises. Dall's porpoises are typically notably longer than, and weigh more than twice as much as, harbor porpoises, making them generally less likely to be preyed upon and likely differentiating their behavioral repertoire somewhat from harbor porpoises. Further, they are typically seen in large groups and feeding aggregations, or exhibiting bow-riding behaviors, which is very different from the group dynamics observed in the more typically solitary, cryptic harbor porpoises, which are not often seen bow-riding. For these reasons, Dall's porpoises are not treated as an especially sensitive species (versus harbor porpoises which have a lower behavioral harassment threshold and more distant cutoff) but, rather, are analyzed similarly to other odontocetes (with takes from the sonar bin in the NWTT Study Area resulting from the same received levels reported in the *Odontocete* section above). Therefore, the majority of Level B takes are expected to be in the form of milder responses compared to higher level exposures. As mentioned earlier in this section, we anticipate more severe effects from takes when animals are exposed to higher received levels.

All Porpoise Stocks

These Dall's and harbor porpoise stocks are not listed under the ESA and the status of these stocks is considered ''unknown.'' There are no biologically important areas for Dall's and harbor porpoises in the NWTT Study Area. However, a known important feeding area for harbor porpoises overlaps with the Stonewall and Heceta Bank Humpback Whale Mitigation Area. No MF1 MFAS or explosives would be used in this mitigation area from May 1—November 30, which would reduce the severity of impacts to harbor porpoises by reducing interference in feeding that could result in lost feeding opportunities or necessitate additional energy expenditure to find other good opportunities. No mortality or Level A harassment from tissue damage is expected or proposed to be authorized for any of these stocks.

Regarding the magnitude of Level B harassment takes (TTS and behavioral disruption), the number of estimated total instances of take compared to the abundance ranges from less than 1 percent for the Alaska stock of Dall's porpoises to 265 percent for the Washington Inland Waters stock of harbor porpoises. The Alaska stock of Dall's porpoises, and Southeast Alaska and Northern California/Southern Oregon stocks of harbor porpoises have estimated total instances of take compared to the abundances less than or equal to 10 percent. This information indicates that only a small portion of these stocks is likely impacted and repeated exposures of individuals are not anticipated. The CA/OR/WA stock of Dall's porpoises and the Northern Washington/Oregon Coast and Washington Inland Waters stocks of harbor porpoises have estimated total instances of take compared to the abundances that range from 131 to 265 percent. This information indicates that all individuals of these stocks could be impacted, if each were taken two to three days per year, though the more likely scenario is that a smaller portion would be taken, and a subset of those would be on more days (maybe 5 or 6), with no indication that these days would 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. However, foregone reproduction (especially for only one year within seven, which is the maximum predicted because the small number anticipated in any one year makes the probability that any individual will be impacted in this way twice in seven years very low) 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. All indications are that the number of times in which reproduction would be likely to be foregone would not affect the stocks' annual rates of recruitment or survival.

Regarding the severity of those individual Level B harassment takes by

behavioral disruption for harbor porpoises, 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 166 dB, which for harbor porpoise (which have a lower behavioral Level B harassment threshold) would mostly be considered a moderate level. Regarding the severity of those individual Level B harassment takes by behavioral disruption for Dall's porpoises, 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 lower, to occasionally moderate, level and less likely to evoke a severe response). Regarding the severity of TTS takes, they are expected to be low-level, of short duration, and mostly not in a frequency band that would be expected to interfere with communication or other important low-frequency cues. The associated lost opportunities and capabilities are not at a level that would impact reproduction or survival.

No Level A harassment by PTS is anticipated or proposed for the Southeast Alaska stock of harbor porpoise or the Alaska stock of Dall's porpoise. For the remaining porpoise stocks, for the same reasons explained above for TTS (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 annual Level A harassment takes by PTS for these three stocks of harbor porpoises and one stock of Dall's porpoises (86 to 180) 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 higher number of PTS takes, however, 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. Given the large population sizes of these stocks, even if these occurred, it would not adversely impact rates of recruitment or survival.

Altogether, the status of the harbor porpoise stocks is unknown, however harbor porpoises are not listed as endangered or threatened under the ESA. Because harbor porpoises are particularly sensitive, it is likely that a fair number of the Level B behavioral responses of individuals will be of a moderate nature. Additionally, as noted, some portion of the stocks may be taken repeatedly on up to several days within a year, however this is not anticipated to affect the stocks' annual rates of recruitment or survival. Some individuals (86 to 180) from the Northern Oregon/Washington Coast, Northern California/Southern Oregon, and Washington Inland Waters stocks of harbor porpoises could be taken by PTS annually of likely low severity. A small permanent loss of hearing sensitivity (PTS) may include some degree of energetic costs for compensating or may mean some small loss of opportunities or detection capabilities, but at the expected scale the estimated Level A harassment takes by PTS for these stocks would be unlikely to impact behaviors, opportunities, or detection capabilities to a degree that would interfere with reproductive success or survival of any individuals, let alone annual rates of recruitment or survival. No mortality is anticipated or proposed for authorization. For these reasons, we have preliminarily determined, in consideration of all of the effects of the Navy's activities combined, that the proposed authorized take would have a negligible impact on all four stocks of harbor porpoises. Altogether, the status of the Dall's porpoise stocks is unknown, however Dall's porpoises are not listed as endangered or threatened under the ESA. Any individual Dall's porpoise is likely to be disturbed at a low-moderate level, with the taken individuals likely exposed on one to a few days. This low magnitude and severity of Level B harassment effects is not expected to result in impacts on individual reproduction or survival, much less annual rates of recruitment or survival. Some individuals (98) from the CA/OR/WA stock of Dall's porpoises could be taken by PTS annually of likely low severity. A small permanent loss of hearing sensitivity (PTS) may include some degree of energetic costs for compensating or may mean some small loss of opportunities or detection capabilities, but at the expected scale the estimated Level A harassment takes by PTS for this stock would be unlikely to impact behaviors, opportunities, or detection capabilities to a degree that would interfere with reproductive success or survival of any individuals, let alone annual rates of recruitment or survival. No mortality is anticipated or proposed for authorization. For these reasons, we have preliminarily determined, in consideration of all of the effects of the Navy's activities combined, that the proposed authorized take would have a negligible impact on these stocks of Dall's porpoises.

Pinnipeds

This section builds on the broader discussion above and brings together the discussion of the different types and amounts of take that different species and stocks would likely incur, the applicable mitigation, and the status of the species and stocks to support the negligible impact determinations for each species or stock. We have described (earlier in this section) the unlikelihood of any masking having effects that would impact the reproduction or survival of any of the individual marine mammals affected by the Navy's activities. We have also described above in the *Potential Effects of Specified Activities on Marine Mammals and their Habitat* section the unlikelihood of any habitat impacts having effects that would impact the reproduction or survival of any of the individual marine mammals affected by the Navy's activities. For pinnipeds, there is no mortality or serious injury and no Level A harassment from tissue damage from sonar or explosives anticipated or proposed to be authorized for any species. Here, we include information that applies to all of the pinniped species.

In Table 57 below for pinnipeds, we indicate the total annual numbers of take by mortality, Level A harassment and Level B harassment, and a number indicating the instances of total take as a percentage of abundance.

Table 57 -- Annual estimated takes by Level B harassment, Level A harassment, and mortality for pinnipeds in the NWTT 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 (NMFS SARs)*	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			
Suborder Pinnipedia									
Family Phocidae (eared seals and sea lions)									
California sea lion	U.S.	23,756	342	1	0	0	24,099	257,606	9
Guadelupe fur seal	Mexico to California	1,482	13	0	0	0	1,495	34,187	4
Northern fur seal	Eastern Pacific	11,462	130	0	0	0	11,592	620,660	2
	California	231	1	0	0	0	232	14,050	2
Steller sea lion	Eastern U.S.	2,231	7	0	0	0	2,238	43,201	5
Family Phocidae (true seals)									
Harbor seal	Southeast Alaska (Clarence Strait)	2,077	275	0	0	0	2,352	27,659	9
	OR/WA Coast	540	640	2	0	0	1,182	24,732	5
	Washington Northern Inland Waters	870	377	5	0	0	1,252	8,198 [1]	15
	Hood Canal	38,430	23,040	1	0	0	61,471	1,933 [1]	3,084
	Southern Puget Sound	3,274	3,564	4	0	0	6,842	4,068 [1]	168
Northern Elephant seal	California	4,134	710	4	0	0	4,848	179,000	3

*Presented in the 2019 draft SARs or most recent SAR.

[1] Recent survey data in the inland waters has not been incorporated into the SARs for these specific stocks, therefore we have used recent Navy Abundance (COA-1) estimates for these stocks for the NID analysis.

The majority of takes by harassment of pinnipeds in the NWTT Study Area are caused by sources from the MFAS 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 Tables 3 and 4). Most of the takes (97 percent) from the MF1 bin in the NWTT Study Area would result from received levels between 166 and 178 dB SPL. For the remaining active sonar bin types, the percentages are as follows: LF4 = 97 percent between 130 and 160 dB SPL, MF4 = 99 percent between 142 and 172 dB SPL, MF5 = 97 percent between 130 and 160 dB SPL, and HF4 = 99 percent between 100 and 172 dB SPL. Given the levels they are exposed to and pinniped sensitivity, most responses would be of a lower severity, with only occasional responses likely to be considered moderate, but still of generally short duration.

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.

Because the majority of harassment take of pinnipeds results from narrowband sources in the range of 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, pinniped 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 a 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 shifts either. The very low number of takes by threshold shifts that might be incurred by individuals exposed to explosives 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 (Costa *et al.,* 2003; Jacobs and Terhune, 2002; 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 (Blackwell *et al.,* 2004; Harris *et al.,* 2001; 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 that are taken by Level B harassment in the NWTT Study Area, 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 individuals 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.

Of these stocks, only Guadalupe fur seals are listed as threatened under the ESA and the SAR indicates the stock is ''increasing.'' No critical habitat under the ESA is designated for the Guadalupe fur seal. The other stocks are not ESA-listed. Biologically important areas have not been identified for pinnipeds. There are active UMEs for Guadalupe fur seals and California sea lions. Since 2015 there have been 400 strandings of Guadalupe fur seals (including live and dead seals). The California sea lion UME is anticipated to be closed soon as elevated strandings occurred from 2013–2016. All of the other pinniped stocks are considered ''increasing,'' ''stable,'' or ''unknown'' except for Northern fur seals (Eastern Pacific stock), which is considered ''declining''. No mortality or Level A harassment from tissue damage is anticipated or proposed for authorization. All the pinniped species discussed in this section would benefit from the procedural mitigation measures described earlier in the *Proposed Mitigation Measures* section.

Regarding the magnitude of Level B harassment takes (TTS and behavioral disruption), for Guadalupe fur seals, the estimated instances of takes as compared to the stock abundance is 4 percent. This information indicates that only a small portion of individuals in the stock are likely impacted and repeated exposures of individuals are not anticipated. With the exception of the Hood Canal and Southern Puget Sound stocks of harbor seals, for the remaining stocks the number of estimated total instances of take compared to the abundance is 2–15 percent. Given the ranges of these stocks (*i.e.,* large ranges, but with individuals often staying in the vicinity of haulouts), this information indicates that a small portion of individuals in the stock are likely impacted and repeated exposures of individuals are not anticipated. For the Southern Puget Sound stock of harbor seals, the number of estimated total instances of take compared to the abundance is 168 percent. This information indicates that all individuals in this stock could be impacted, if each were taken up to 1–2 days per year, though the more likely scenario is that a smaller portion than that would be taken, and a subset of them would be taken on 3 or 4 days, with no indication that these days would be sequential.

For the Hood Canal stock of harbor seals, the number of estimated total instances of take compared to the abundance is 3,084 percent. This information indicates that all individuals of this stock could be impacted, if each were taken up to 31 days per year, though the more likely scenario is that a subset of them would be taken on fewer than 31 days and a subset would be taken on more than 31 days, and for those taken on a higher number of days, some of those days may be sequential. Though the majority of impacts are expected to be of a lower to sometimes moderate severity, the repeated takes over a potentially fair number of sequential days for some individuals in the Hood Canal stock of harbor seals makes it more likely that some 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 only one year within seven, which is the maximum predicted because the small number anticipated in any one year makes the probability that

any individual will be impacted in this way twice in seven years very low) has far less of an impact on population rates than mortality and a relatively small number of instances of foregone reproduction would not be expected to adversely affect the stock through effects on annual rates of recruitment or survival. Regarding the severity of those individual takes by Level B behavioral harassment for all pinniped stocks, 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 178 dB, which is considered a relatively low to occasionally moderate level for pinnipeds. However, as noted, for the Hood Canal stock, some of these takes could occur on some number of sequential days.

Regarding the severity of TTS takes, they are expected to be low-level, of short duration, and mostly not in a frequency band that would be expected to interfere with pinniped 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, the 1–5 estimated Level A harassment takes by PTS for California sea lions, Northern elephant seals, and the Washington Northern inland waters, Hood Canal, OR/WA Coast, and Southern Puget Sound stocks of harbor seals 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, all pinniped stocks are considered ''increasing,'' ''stable,'' or ''unknown'' except for Northern fur seals (Eastern Pacific stock), which is considered ''declining'' but is not listed under the ESA. Only the Guadalupe fur seal is listed under the ESA, with a population that is considered increasing. No mortality for pinnipeds is anticipated or proposed for authorization. For nearly all pinniped stocks (with the exception of the Hood Canal harbor seals) only a portion of the stocks are anticipated to be impacted and any individual is likely to be disturbed at a low-moderate level. Even considering the effects of the UMEs on the Guadalupe fur seal and California sea lion stocks, this low magnitude and severity of harassment effects is not expected to result in impacts on individual reproduction or survival, much less annual rates of recruitment or survival. For the Hood Canal stock of harbor seals, a fair portion of individuals will be taken by Level B harassment (at a moderate or sometimes low level) over a comparatively higher number of days within a year, and some smaller portion of those individuals may be taken on sequential days, however this is not expected to adversely affect the stock through effects on annual rates of recruitment or survival. Accordingly, we do not anticipate the relatively small number of individual harbor seals that might be taken over repeated days within the year in a manner that results in one year of foregone reproduction to adversely affect the stock through effects on rates of recruitment or survival, given the status of the stock. For these reasons, in consideration of all of the effects of the Navy's activities combined, we have preliminarily determined that the proposed authorized take would have a negligible impact on all stocks of pinnipeds.

Preliminary Determination

Based on the analysis contained herein of the likely effects of the specified activity on marine mammals and their habitat, and taking into consideration the implementation of the proposed monitoring and mitigation measures, NMFS preliminarily finds that the total marine mammal take from the Specified Activities will have a negligible impact on all affected marine mammal species or stocks.

Subsistence Harvest of Marine Mammals

In order to issue an incidental take authorization, NMFS must find that the specified activity will not have an ''unmitigable adverse impact'' on the subsistence uses of the affected marine mammal species or stocks by Alaskan Natives. NMFS has defined ''unmitigable adverse impact'' in 50 CFR 216.103 as an impact resulting from the specified activity: (1) That is likely to reduce the availability of the species to a level insufficient for a harvest to meet subsistence needs by: (i) Causing the marine mammals to abandon or avoid hunting areas; (ii) Directly displacing subsistence users; or (iii) Placing physical barriers between the marine mammals and the subsistence hunters; and (2) That cannot be sufficiently mitigated by other measures to increase the availability of marine mammals to allow subsistence needs to be met.

To our knowledge there are no relevant subsistence uses of the affected marine mammal stocks or species implicated by this action. Therefore, NMFS has preliminarily determined that the total taking of affected species or stocks would not have an unmitigable adverse impact on the availability of the species or stocks for taking for subsistence purposes. However, we have limited information on marine mammal subsistence use in the Western Behm Canal area of southeastern Alaska and seek additional information pertinent to making the final determination.

Classification

Endangered Species Act

There are seven marine mammal species under NMFS jurisdiction that are listed as endangered or threatened under the ESA with confirmed or possible occurrence in the NWTT Study Area: Blue whale, fin whale, humpback whale (Mexico and Central America DPSs), sei whale, sperm whale, killer whale (Southern Resident killer whale DPS), and Guadalupe fur seal. The Southern Resident killer whale has critical habitat designated under the ESA in the NWTT Study Area. NMFS has recently published two proposed rules, proposing new or revised ESA-designated critical habitat for humpback whales (84 FR 54354; October 9, 2019) and Southern Resident killer whales (84 FR 49214; September 19, 2019).

The Navy will consult with NMFS pursuant to section 7 of the ESA for NWTT Study Area activities. NMFS will also consult internally on the issuance of the regulations and LOAs under section 101(a)(5)(A) of the MMPA.

National Marine Sanctuaries Act

NMFS will work with NOAA's Office of National Marine Sanctuaries to fulfill our responsibilities under the National Marine Sanctuaries Act as warranted and will complete any NMSA requirements prior to a determination on the issuance of the final rule and LOAs.

National Environmental Policy Act

To comply with the National Environmental Policy Act of 1969 (NEPA; 42 U.S.C. 4321 *et seq.*) and NOAA Administrative Order (NAO) 216–6A, NMFS must evaluate our proposed actions and alternatives with respect to potential impacts on the human environment. Accordingly, NMFS plans to adopt the NWTT SEIS/OEIS for the NWTT Study Area provided our independent evaluation of the document finds that it includes adequate information analyzing the effects on the human environment of issuing regulations and LOAs under the

MMPA. NMFS is a cooperating agency on the 2019 NWTT DSEIS/OEIS and has worked extensively with the Navy in developing the document. The 2019 NWTT DSEIS/OEIS was made available for public comment at *https://www.nwtteis.com* in April, 2019. We will review all comments submitted in response to this notice prior to concluding our NEPA process or making a final decision on the MMPA rule and request for LOAs.

Regulatory Flexibility Act

The Office of Management and Budget has determined that this proposed 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 proposed rule, if adopted, would 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 would 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, would be 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, if adopted, would directly affect the Navy and not a small entity, NMFS concludes that the action would not result in a significant economic impact on a substantial number of small entities.

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: April 17, 2020.

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 proposed to be 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 O to read as follows:

Subpart O—Taking and Importing Marine Mammals; U.S. Navy's Northwest Training and Testing (NWTT)

Sec.

Subpart O—Taking and Importing Marine Mammals; U.S. Navy's Northwest Training and Testing (NWTT)

§ 218.140 Specified activity and geographical region.

(a) Regulations in this subpart apply only to the U.S. Navy (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 is only authorized if it occurs within the NWTT Study Area, which is composed of established maritime operating and warning areas in the eastern North Pacific Ocean region, including areas of the Strait of Juan de Fuca, Puget Sound, and Western Behm Canal in southeastern Alaska. The Study Area includes air and water space within and outside Washington state waters, and outside state waters of Oregon and Northern California. The eastern boundary of the Offshore Area portion of the Study Area is 12 nautical miles (nmi) off the coastline for most of the Study Area, including southern Washington, Oregon, and Northern California. The Offshore Area includes the ocean all the way to the coastline only along that part of the Washington coast that lies beneath the airspace of W–237 and the Olympic Military Operating Area (MOA) and the Washington coastline north of the Olympic MOA. The Study Area includes four existing range complexes and facilities: The Northwest Training Range Complex (NWTRC), the Keyport Range Complex, the Carr Inlet Operations Area, and the Southeast Alaska Acoustic Measurement Facility (SEAFAC). In addition to these range complexes, the Study Area also includes Navy pierside locations where sonar maintenance and testing occurs as part of overhaul, modernization, maintenance, and repair activities at Naval Base Kitsap, Bremerton; Naval Base Kitsap, Bangor; and Naval Station Everett.

(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) Anti-submarine warfare;

(2) Expeditionary warfare;

(3) Mine warfare;

(4) Surface warfare; and

(5) Other training and testing activities.

§ 218.141 Effective dates.

Regulations in this subpart are effective from November 9, 2020 through November 8, 2027.

§ 218.142 Permissible methods of taking.

(a) Under Letters of Authorization (LOAs) issued pursuant to §§ 216.106 of this chapter and 218.146, the Holder of the LOAs (hereinafter ''Navy'') may incidentally, but not intentionally, take marine mammals within the area described in § 218.140(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 vessel strikes, provided the activity is in compliance with all terms, conditions, and requirements of this subpart and the applicable LOAs.

(b) The incidental take of marine mammals by the activities listed in § 218.140(c) is limited to the following species:

TABLE 1 TO § 218.142

Species	Stock
Blue whale	Eastern North Pacific.
Fin whale	Northeast Pacific.
Fin whale	California/Oregon/Washington.
Sei whale	Eastern North Pacific.
Minke whale	Alaska.
Minke whale	California/Oregon/Washington.
Humpback whale	Central North Pacific.
Humpback whale	California/Oregon/Washington.
Gray whale	Eastern North Pacific.
Bottlenose dolphin	California/Oregon/Washington Offshore.
Killer whale	Alaska Resident.
Killer whale	Eastern North Pacific Offshore.
Killer whale	West Coast Transient.
Killer whale	Southern Resident.
Northern right whale dolphin	California/Oregon/Washington.
Pacific white-sided dolphin	North Pacific.
Pacific white-sided dolphin	California/Oregon/Washington.
Risso's dolphin	California/Oregon/Washington.
Short-beaked common dolphin	California/Oregon/Washington.
Short-finned pilot whale	California/Oregon/Washington.
Striped dolphin	California/Oregon/Washington.
Pygmy sperm whale	California/Oregon/Washington.
Dwarf sperm whale	California/Oregon/Washington.
Dall's porpoise	Alaska.
Dall's porpoise	California/Oregon/Washington.
Harbor porpoise	Southeast Alaska.
Harbor porpoise	Northern Oregon & Washington Coast.
Harbor porpoise	Northern California/Southern Oregon.
Harbor porpoise	Washington Inland Waters.
Sperm whale	California/Oregon/Washington.
Baird's beaked whale	California/Oregon/Washington.
Cuvier's beaked whale	California/Oregon/Washington.
Mesoplodon species	California/Oregon/Washington.
California sea lion	U.S. Stock.
Steller sea lion	Eastern U.S.
Guadalupe fur seal	Mexico.
Northern fur seal	Eastern Pacific.
Northern fur seal	California.
Harbor seal	Southeast Alaska—Clarence Strait.
Harbor seal	Oregon & Washington Coastal.
Harbor seal	Washington Northern Inland Waters.
Harbor seal	Hood Canal.
Harbor seal	Southern Puget Sound.
Northern elephant seal	California.

§ 218.143 Prohibitions.

Notwithstanding incidental takings contemplated in § 218.142(a) and authorized by LOAs issued under §§ 216.106 of this chapter and 218.146, no person in connection with the activities listed in § 218.140(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 218.146;

(b) Take any marine mammal not specified in § 218.142(b);

(c) Take any marine mammal specified in § 218.142(b) in any manner other than as specified in the LOAs; or

(d) Take a marine mammal specified in § 218.142(b) if NMFS determines such taking results in more than a negligible impact on the species or stocks of such marine mammal.

§ 218.144 Mitigation requirements.

When conducting the activities identified in § 218.140(c), the mitigation measures contained in any LOAs issued under §§ 216.106 of this chapter and 218.146 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 NWTT Study Area for acoustic stressors (*i.e.,* active sonar, weapons firing noise), explosive stressors (*i.e.,* sonobuoys, torpedoes, medium-caliber and large-caliber projectiles, missiles, bombs, mine countermeasure and neutralization activities, mine neutralization involving Navy divers), 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, non-explosive bombs and mine shapes).

(1) *Environmental awareness and education.* Appropriate Navy 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 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).

(i) *Number of Lookouts and observation platform*—(A) For 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); and two Lookouts for platforms without space or manning restrictions while underway (at the forward part of the ship).

(B) For sources that are not hull mounted, One Lookout on the ship or aircraft conducting the activity.

(ii) *Mitigation zone and requirements.* (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 and marine mammals; if floating vegetation or a marine mammals is observed, Navy personnel must relocate or delay the start of active sonar transmission until the mitigation zone is clear of floating vegetation or until the conditions in paragraph (a)(2)(ii)(D) of this section are met for marine mammals.

(B) During the activity, for 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. If a marine mammal is observed within 1,000 yd of the sonar source, Navy personnel must power down active sonar transmission by 6 dB. If a marine mammal is observed within 500 yd of the sonar source, Navy personnel must power down active sonar transmission an additional 4 dB (10 dB total). Navy personnel must cease transmission if a cetacean or pinniped in the NWTT Offshore Area or Western Behm Canal is observed within 200 yd of the active sonar source and must cease transmission if a pinniped in NWTT Inland Waters is observed within 100 yd of the active sonar source (except if hauled out on, or in the water near, man-made structures and vessels).

(C) During the activity, for low-frequency active sonar below 200 dB, mid-frequency active sonar sources that are not hull-mounted, and high-frequency sonar, Navy personnel must observe the mitigation zone for marine mammals. Navy personnel must cease transmission if a cetacean in the NWTT Offshore Area, NWTT Inshore Area, or Western Behm Canal is observed within 200 yd of the sonar source. Navy personnel must cease transmission if a pinniped in the NWTT Offshore Area or Western Behm Canal is observed within 200 yd of the sonar source and must cease transmission if a pinniped in NWTT Inland Waters is observed within 100 yd of the active sonar source (except if hauled out on, or in the water near, man-made structures and vessels).

(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 where a dolphin(s) is observed in the mitigation zone, the Lookout concludes that the dolphin(s) is 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) *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)(6)(i) and (a)(13)(i) of this section.

(ii) *Mitigation zone and requirements.* (A) Thirty degrees on either side of the firing line out to 70 yd from the muzzle of the weapon being fired.

(B) Prior to the initial start of the activity, Navy personnel must observe the mitigation zone for floating vegetation and marine mammals; if floating vegetation or a marine mammal is observed, Navy personnel must relocate or delay the start of weapons firing until the mitigation zone is clear of floating vegetation or until the conditions in paragraph (a)(3)(ii)(D) of this section are met for marine mammals.

(C) During the activity, Navy personnel must observe the mitigation zone for marine mammals; if marine mammals are observed, Navy personnel must cease weapons firing.

(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 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.

(4) *Explosive sonobuoys*—(i) *Number of Lookouts and observation platform.* One Lookout must be positioned in an aircraft or on a small boat. 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) 600 yd around an explosive sonobuoy.

(B) 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 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 floating vegetation and marine mammals; if floating vegetation or a

marine mammal is observed, Navy personnel must relocate or delay the start of sonobuoy or source/receiver pair detonations until the mitigation zone is clear of floating vegetation or until the conditions in paragraph (a)(4)(ii)(D) of this section are met for marine mammals.

(C) During the activity, Navy personnel must observe the mitigation zone for marine mammals; if marine mammals are observed, Navy personnel must cease sonobuoy or source/receiver pair detonations.

(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 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, or 30 min when the activity involves aircraft that are not typically fuel constrained.

(E) After completion of the activity (*e.g.,* prior to maneuvering off station), Navy personnel must, 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, 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.

(5) *Explosive torpedoes*—(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 marine mammals while performing their regular duties.

(ii) *Mitigation zone and requirements.* (A) 2,100 yd around the intended impact location.

(B) Prior to the initial start of the activity (*e.g.,* during deployment of the target), Navy personnel must conduct passive acoustic monitoring for marine mammals and use the information from detections to assist visual observations. Navy personnel also must visually observe the mitigation zone for floating vegetation and marine mammals; if floating vegetation or a marine mammal is observed, Navy personnel must relocate or delay the start of firing until the mitigation zone is clear of floating vegetation or until the conditions in paragraph (a)(5)(ii)(D) of this section are met for marine mammals.

(C) During the activity, Navy personnel must observe the mitigation zone for marine mammals. If a marine mammal is observed, Navy personnel must cease firing.

(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 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.

(E) After completion of the activity (*e.g.,* prior to maneuvering off station), Navy personnel must, 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, 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.

(6) *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 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)(3)(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 marine mammals while performing their regular duties.

(ii) *Mitigation zone and requirements.* (A) 600 yd around the intended impact location for explosive medium-caliber projectiles.

(B) 1,000 yd around the intended impact location for explosive large-caliber projectiles.

(C) Prior to the initial start of the activity (*e.g.,* when maneuvering on station), Navy personnel must observe the mitigation zone for floating vegetation and marine mammals; if floating vegetation or a marine mammal is observed, Navy personnel must relocate or delay the start of firing until the mitigation zone is clear of floating vegetation or until the conditions in paragraph (a)(6)(ii)(E) are met for marine mammals.

(D) During the activity, Navy personnel must observe the mitigation zone for marine mammals; if a marine mammal is 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; the mitigation zone has been clear from any additional sightings for 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.

(F) After completion of the activity (*e.g.,* prior to maneuvering off station), Navy personnel must, 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, 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 missiles.* Aircraft-deployed explosive missiles. 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 marine mammals while performing their regular duties.

(ii) *Mitigation zone and requirements.* (A) 2,000 yd around the intended impact location.

(B) 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 and marine mammals; if floating vegetation or a marine mammal is observed, Navy personnel must relocate or delay the start of firing until the mitigation zone is clear of floating vegetation or until the conditions in paragraph (a)(7)(ii)(D) are met for marine mammals.

(C) During the activity, Navy personnel must observe the mitigation zone for marine mammals; if marine mammals are observed, Navy personnel must cease firing.

(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 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.

(E) After completion of the activity (*e.g.,* prior to maneuvering off station), Navy personnel must, 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, 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 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 marine mammals while performing their regular duties.

(ii) *Mitigation zone and requirements.* (A) 2,500 yd around the intended target.

(B) Prior to the initial start of the activity (*e.g.,* when arriving on station), Navy personnel must observe the mitigation zone for floating vegetation and marine mammals; if floating vegetation or a marine mammals is observed, Navy personnel must relocate or delay the start of bomb deployment until the mitigation zone is clear of floating vegetation or until the conditions in paragraph (a)(8)(ii)(D) of this section are met for marine mammals.

(C) During the activity (*e.g.,* during target approach), Navy personnel must observe the mitigation zone for marine mammals; if a marine mammal is observed, Navy personnel must cease bomb deployment.

(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 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.

(E) After completion of the activity (*e.g.,* prior to maneuvering off station), Navy personnel must, 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, 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 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.

(B) Two Lookouts must be positioned (one in an aircraft and one on a small boat) when implementing the larger mitigation zone.

(C) 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 marine mammals while performing their regular duties.

(ii) *Mitigation zone and requirements.* (A) 600 yd around the detonation site for activities using ≤5 lb net explosive weight.

(B) 2,100 yd around the detonation site for activities using >5–60 lb net explosive weight.

(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 and marine mammals; if floating vegetation or a marine mammal is observed, Navy personnel must relocate or delay the start of detonations until the mitigation zone is clear of floating vegetation or until the conditions in paragraph (ii)(E) are met for marine mammals.

(D) During the activity, Navy personnel must observe the mitigation zone for marine mammals; if a marine mammal is observed, Navy personnel 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 must assist in the visual observation of the area where detonations occurred.

(10) *Explosive mine neutralization activities involving Navy divers*—(i) *Number of Lookouts and observation platform.* (A) Two Lookouts (two small boats with one Lookout each (one of which must be a Navy biologist)).

(B) All divers placing the charges on mines must support the Lookouts while performing their regular duties and will report applicable sightings to their supporting small boat or Range Safety Officer.

(C) 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 marine mammals while performing their regular duties.

(ii) *Mitigation zone and requirements.* (A) 500 yd around the detonation site during activities using >0.5–2.5 lb net explosive weight.

(B) Prior to the initial start of the activity (*e.g.,* starting 30 min before the first planned detonation), Navy personnel must observe the mitigation zone for floating vegetation and marine mammals; if floating vegetation is observed, Navy personnel must relocate or delay the start of detonations until the mitigation zone is clear of floating vegetation. If a marine mammal is observed, Navy personnel must ensure the area is clear of marine mammals for 30 min prior to commencing a detonation. A Navy biologist must serve as the lead Lookout and must make the final determination that the mitigation zone is clear of any floating vegetation or marine mammals prior to the commencement of a detonation. The Navy biologist must maintain radio communication with the unit conducting the event and the other Lookout.

(C) During the activity, Navy personnel must observe the mitigation zone for marine mammals; if a marine mammal is observed, Navy personnel must cease detonations. To the maximum extent practicable depending on mission requirements, safety, and environmental conditions, Navy personnel must position boats near the midpoint 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. Navy personnel must only use positively controlled charges (*i.e.,* no time-delay fuses). Navy personnel must use the smallest practicable charge size for each activity. All activities must be conducted in Beaufort sea state number 2 conditions or better and must not be conducted in low visibility conditions.

(D) Commencement/recommencement conditions after a marine mammal sighting before or during the activity. Navy personnel must allow a sighted animal 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 30 min.

(E) After each detonation and completion of an activity the Navy must observe for marine mammals for 30 min Navy personnel must observe for marine mammals in the vicinity of where detonations occurred and immediately downstream of the detonation location; 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.

(F) At the Hood Canal Explosive Ordnance Disposal Range and Crescent Harbor Explosive Ordnance Disposal Range, Navy personnel must obtain permission from the appropriate designated Command authority prior to conducting explosive mine neutralization activities involving the use of Navy divers.

(G) At the Hood Canal Explosive Ordnance Disposal Range, during February, March, and April (the juvenile migration period for Hood Canal Summer Run Chum), Navy personnel must not use explosives in bin E3 (>0.5–2.5 lb net explosive weight), and must instead use explosives in bin E0 (<0.1 lb net explosive weight).

(H) At the Hood Canal Explosive Ordnance Disposal Range, during August, September, and October (the adult migration period for Hood Canal summer-run chum and Puget Sound Chinook), Navy personnel must avoid the use of explosives in bin E3 (>0.5–2.5 lb net explosive weight), and must instead use explosive bin E0 (<0.1 lb net explosive weight) to the maximum extent practicable unless necessitated by mission requirements.

(I) At the Crescent Harbor Explosive Ordnance Disposal Range, Navy personnel must conduct explosive activities at least 1,000 meters (m) from the closest point of land to avoid or reduce impacts on fish (*e.g.,* bull trout) in nearshore habitat areas.

(11) *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, during Transit Protection Program exercises, and other events involving escort vessels); the vessel is operated autonomously; or when impractical based on mission requirements (*e.g.,* during test body retrieval by range craft).

(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 for surface vessels other than small boats.

(B) 200 yd around all marine mammals other than whales (except bow-riding dolphins and pinnipeds hauled out on man-made navigational structures, port structures, and vessels) for surface vessels other than small boats.

(C) 100 yd around marine mammals (except bow-riding dolphins and pinnipeds hauled out on man-made navigational structures, port structures, and vessels) for small boats, such as range craft.

(D) During the activity (when underway), Navy personnel must observe the mitigation zone for marine mammals; if a marine mammal is observed, Navy personnel must maneuver to maintain distance.

(E) Prior to Small Boat Attack exercises at Naval Station Everett, Naval Base Kitsap Bangor, or Naval Base

Kitsap Bremerton, Navy event planners must coordinate with Navy biologists during the event planning process. Navy biologists must work with NMFS to determine the likelihood of marine mammal presence in the planned training location. Navy biologists must notify event planners of the likelihood of species presence as they plan specific details of the event (*e.g.,* timing, location, duration). Navy personnel must provide additional environmental awareness training to event participants. The training must alert participating ship crews to the possible presence of marine mammals in the training location. Lookouts must use the information to assist their visual observation of applicable mitigation zones and to aid in the implementation of procedural mitigation.

(iii) *Incident reporting procedures.* If a marine mammal vessel strike occurs, Navy personnel must follow the established incident reporting procedures.

(12) *Towed in-water devices.* Mitigation applies to devices that are towed from a manned surface platform or manned aircraft, or when a manned support craft is already participating in an activity involving in-water devices being towed by unmanned platforms. 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 or support craft.

(ii) *Mitigation zone and requirements.* (A) 250 yd around marine mammals (except bow-riding dolphins and pinnipeds hauled out on man-made navigational structures, port structures, and vessels) for in-water devices towed by aircraft or surface vessels other than small boats.

(B) 100 yd around marine mammals (except bow-riding dolphins and pinnipeds hauled out on man-made navigational structures, port structures, and vessels) for in-water devices towed by small boats, such as range craft.

(C) During the activity (*i.e.,* when towing an in-water device), Navy personnel must observe the mitigation zone for marine mammals; if a marine mammal is observed, Navy personnel must maneuver to maintain distance.

(13) *Small-, medium-, and large-caliber non-explosive practice munitions.* Gunnery activities using 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)(3)(i) of this section.

(ii) *Mitigation zone and requirements.* (A) 200 yd around the intended impact location.

(B) Prior to the initial start of the activity (*e.g.,* when maneuvering on station), Navy personnel must observe the mitigation zone for floating vegetation and marine mammals; if floating vegetation or a marine mammal is observed, Navy personnel must relocate or delay the start until the mitigation zone is clear of floating vegetation or until the conditions in paragraph (a)(13)(ii)(D) of this section are met for marine mammals.

(C) During the activity, Navy personnel must observe the mitigation zone for marine mammals; if a marine mammal is observed, Navy personnel must cease firing.

(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 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.

(14) *Non-explosive missiles.* Aircraft-deployed non-explosive missiles. 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.* (A) 900 yd around the intended impact location.

(B) 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 and marine mammals; if floating vegetation or a marine mammal is observed, Navy personnel must relocate or delay the start of firing until the mitigation zone is clear of floating vegetation or until the conditions in paragraph (a)(14)(ii)(D) of this section are met for marine mammals.

(C) During the activity, Navy personnel must observe the mitigation zone for marine mammals; if a marine mammal is observed, Navy personnel must cease firing.

(D) 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.

(15) *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.* (A) 1,000 yd around the intended target.

(B) Prior to the initial start of the activity (*e.g.,* when arriving on station), Navy personnel must observe the mitigation zone for floating vegetation and marine mammals; if floating vegetation or a marine mammal is observed, Navy personnel must relocate or delay the start of bomb deployment or mine laying until the mitigation zone is clear of floating vegetation or until the conditions in paragraph (a)(15)(ii)(D) of section are met for marine mammals.

(C) During the activity (*e.g.,* during approach of the target or intended minefield location), Navy personnel must observe the mitigation zone for marine mammals and, if a marine mammal is observed, Navy personnel must cease bomb deployment or mine laying.

(D) 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, Navy personnel must implement mitigation measures within mitigation areas to avoid or reduce potential impacts on marine mammals.

(1) Mitigation areas for marine mammals for NWTT Study Area for sonar, explosives, and physical disturbance and vessel strikes—(i) *Mitigation area requirements*—(A) *Marine Species Coastal Mitigation Area (year round).* (*1*) Within 50 nmi from shore in the Marine Species Coastal Mitigation Area, Navy personnel must not conduct: Explosive training activities; explosive testing activities (with the exception of explosive Mine Countermeasure and Neutralization Testing activities); and non-explosive missile training activities. Should national security require conducting these activities in the mitigation area, Navy personnel must obtain permission from the appropriate designated Command authority prior to commencement of the activity. Navy personnel must provide NMFS with advance notification and include information about the event in its annual activity reports to NMFS.

(*2*) Within 20 nmi from shore in the Marine Species Coastal Mitigation Area, Navy personnel must not conduct non-explosive large-caliber gunnery training activities and non-explosive bombing training activities. Should national security require conducting these activities in the mitigation area, Navy personnel must obtain permission from the appropriate designated Command authority prior to commencement of the activity. Navy personnel must provide NMFS with advance notification and include information about the event in its annual activity reports to NMFS.

(*3*) Within 12 nmi from shore in the Marine Species Coastal Mitigation Area, Navy personnel must not conduct: Non-explosive small- and medium-caliber gunnery training activities; non-explosive torpedo training activities; and Anti-Submarine Warfare Tracking Exercise—Helicopter, Maritime Patrol Aircraft, Ship, or Submarine training activities. Should national security require conducting these activities in the mitigation area, Navy personnel must obtain permission from the appropriate designated Command authority prior to commencement of the activity. Navy personnel must provide NMFS with advance notification and include information about the event in its annual activity reports to NMFS.

(B) *Olympic Coast National Marine Sanctuary Mitigation Area (year-round).* (*1*) Within the Olympic Coast National Marine Sanctuary Mitigation Area, Navy personnel must not conduct more than 32 hours of MF1 mid-frequency active sonar during training annually and will not conduct non-explosive bombing training activities. Should national security require conducting more than 32 hours of MF1 mid-frequency active sonar during training annually or conducting non-explosive bombing training activities in the mitigation area, Navy personnel must obtain permission from the appropriate designated Command authority prior to commencement of the activity. Navy personnel must provide NMFS with advance notification and include information about the event in its annual activity reports to NMFS.

(*2*) Within the Olympic Coast National Marine Sanctuary Mitigation Area, Navy personnel must not conduct more than 33 hours of MF1 mid-frequency active sonar during testing annually (except within the portion of the mitigation area that overlaps the Quinault Range Site) and must not conduct explosive Mine Countermeasure and Neutralization Testing activities. Should national security require conducting more than 33 hours of MF1 mid-frequency active sonar during testing annually (except within the portion of the mitigation area that overlaps the Quinault Range Site) or conducting explosive Mine Countermeasure and Neutralization Testing activities in the mitigation area, Navy personnel must obtain permission from the appropriate designated Command authority prior to commencement of the activity. Navy personnel must provide NMFS with advance notification and include information about the event in its annual activity reports to NMFS.

(C) *Stonewall and Heceta Bank Humpback Whale Mitigation Area (May 1–November 30).* Within the Stonewall and Heceta Bank Humpback Whale Mitigation Area, Navy personnel must not use MF1 mid-frequency active sonar or explosives during training and testing from May 1 to November 30. Should national security require using MF1 mid-frequency active sonar or explosives during training and testing from May 1 to November 30, Navy personnel must obtain permission from the appropriate designated Command authority prior to commencement of the activity. Navy personnel must provide NMFS with advance notification and include information about the event in its annual activity reports to NMFS.

(D) *Point St. George Humpback Whale Mitigation Area (July 1–November 30).* Within the Point St. George Humpback Whale Mitigation Area, Navy personnel must not use MF1 mid-frequency active sonar or explosives during training and testing from July 1 to November 30. Should national security require using MF1 mid-frequency active sonar or explosives during training and testing from July 1 to November 30, Navy personnel must obtain permission from the appropriate designated Command authority prior to commencement of the activity. Navy personnel must provide NMFS with advance notification and include information about the event in its annual activity reports to NMFS.

(E) *Puget Sound and Strait of Juan de Fuca Mitigation Area (year-round).* (*1*) Within the Puget Sound and Strait of Juan de Fuca Mitigation Area, Navy personnel must obtain approval from the appropriate designated Command authority prior to: The use of hull-mounted mid-frequency active sonar during training while underway or conducting ship and submarine active sonar pierside maintenance or testing.

(*2*) Within the Puget Sound and Strait of Juan de Fuca Mitigation Area for Civilian Port Defense—Homeland Security Anti-Terrorism/Force Protection Exercises, Navy personnel must coordinate with Navy biologists during the event planning process. Navy biologists must work with NMFS to determine the likelihood of gray whale and Southern Resident Killer Whale presence in the planned training location. Navy biologists must notify Navy event planners of the likelihood of species presence as they plan specific details of the event (*e.g.,* timing, location, duration). Navy personnel must ensure environmental awareness of event participants. Environmental awareness will help alert participating ship and aircraft crews to the possible presence of marine mammals in the training location, such as gray whales and Southern Resident Killer Whales.

(F) *Northern Puget Sound Gray Whale Mitigation Area (March 1–May 31).* Within the Northern Puget Sound Gray Whale Mitigation Area, Navy personnel must not conduct Civilian Port Defense—Homeland Security Anti-Terrorism/Force Protection Exercises from March 1 to May 31. Should national security require conducting

Civilian Port Defense—Homeland Security Anti-Terrorism/Force Protection Exercises from March 1 to May 31, Navy personnel must obtain permission from the appropriate designated Command authority prior to commencement of the activity. Navy personnel must provide NMFS with advance notification and include information about the event in its annual activity reports to NMFS.

(ii) [Reserved]

§ 218.145 Requirements for monitoring and reporting.

(a) *Unauthorized take.* Navy personnel must notify NMFS immediately (or as soon as operational security considerations allow) if the specified activity identified in § 218.140 is thought to have resulted in the mortality or serious injury of any marine mammals, or in any Level A harassment or Level B harassment of marine mammals not identified in this subpart.

(b) *Monitoring and reporting under the LOAs.* The Navy must conduct all monitoring and reporting required under the LOAs, including abiding by the U.S. Navy's Marine Species 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 *https://www.fisheries.noaa.gov/national/marine-mammal-protection/incidental-take-authorizations-military-readiness-activities.*

(d) *Annual NWTT Study Area marine species monitoring report.* The Navy must submit an annual report of the NWTT 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, NMFS, either within three months after the end of the calendar year, or within three months after the conclusion of the monitoring year, to be determined by the Adaptive Management process. NMFS will submit comments or questions on the report, if any, within one month of receipt. The report will be considered final after the Navy has addressed NMFS' comments, or one month after submittal of the draft if NMFS does not provide comments on the draft report. This report will describe progress of knowledge made with respect to intermediate scientific objectives within the NWTT Study Area associated with the Integrated Comprehensive Monitoring Program (ICMP). 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. As an alternative, the Navy may submit a multi-range complex annual monitoring plan report to fulfill this requirement. Such a report will describe progress of knowledge made with respect to monitoring study questions across multiple Navy ranges associated with the ICMP. Similar study questions must be treated together so that progress on each topic can be summarized across multiple Navy ranges. The report need not include analyses and content that does not provide direct assessment of cumulative progress on the monitoring study question. This will continue to allow the Navy to provide a cohesive monitoring report covering multiple ranges (as per ICMP goals), rather than entirely separate reports for the NWTT, Hawaii-Southern California, Gulf of Alaska, and Mariana Islands Study Areas.

(e) *Annual NWTT Study Area training exercise report and testing activity reports.* Each year, the Navy must submit two preliminary reports (Quick Look Report) detailing the status of applicable 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 to the Director, Office of Protected Resources, NMFS, within three months after the one-year anniversary of the date of issuance of the LOA. NMFS will submit comments or questions on the report, if any, within one month of receipt. The report will be considered final after the Navy has addressed NMFS' comments, or one month after submittal of the draft if NMFS does not provide comments on the draft report. The NWTT Annual Training Exercise Report and Testing Activity Report can be consolidated with other exercise reports from other range complexes in the Pacific Ocean for a single Pacific Exercise Report, if desired. The annual report must contain information on the total hours of operation of MF1 surface ship hull-mounted mid-frequency active sonar used during training and testing activities in the Olympic Coast National Marine Sanctuary Mitigation Area and a summary of all sound sources used, including within specific mitigation reporting areas as described in paragraph (e)(2) 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 previous annual reports. The annual report will also contain cumulative sonar and explosive use quantity from previous years' reports through the current year. Additionally, if there were any changes to the sound source allowance in a given year, or cumulatively, the report must include a discussion of why the change was made and include analysis to support how the change did or did not affect the analysis in the NWTT SEIS/OEIS and MMPA final rule. The annual report must also include details regarding specific requirements associated with the mitigation areas listed in § 218.144(b). The analysis in the detailed report will be based on the accumulation of data from the current year's report and data collected from previous reports. The final annual/close-out report at the conclusion of the authorization period (year seven) will serve as the comprehensive close-out report and include both the final year annual incidental take compared to annual authorized incidental take as well as a cumulative seven-year incidental take compared to seven-year authorized incidental take. The detailed reports must contain information identified in paragraphs (e)(1) through (3) of this section.

(1) *Summary of sources used.* This section of the report 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 and other transducers, and

(ii) Total annual expended/detonated ordinance (missiles, bombs, sonobuoys, *etc.*) for each explosive bin.

(2) *NWTT Study Area Mitigation Areas.* The report must include any Navy activities that occurred as specifically described in areas identified in § 218.144(b). Information included in the classified annual reports may be used to inform future adaptive management of activities within the NWTT Study Area.

(3) *Geographic information presentation.* The reports must present an annual (and seasonal, where practical) depiction of training and

testing bin usage geographically across the NWTT Study Area.

(f) *Seven-year close-out report.* The final (year seven) draft annual/close-out report must be submitted within three months after the expiration of this subpart to the Director, Office of Protected Resources, NMFS. NMFS will 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 three months after submittal of the draft if NMFS does not provide comments on the draft report.

§ 218.146 Letters of Authorization.

(a) To incidentally take marine mammals pursuant to this subpart, the Navy must apply for and obtain an LOA in accordance with § 216.106 of this chapter.

(b) An LOA, unless suspended or revoked, may be effective for a period of time not to exceed the expiration date of this subpart.

(c) If an LOA expires prior to the expiration date of 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 § 218.147(c)(1)) required by an LOA issued under this subpart, the Navy must apply for and obtain a modification of the LOA as described in § 218.147.

(e) Each LOA will set forth:

(1) Permissible methods of incidental taking;

(2) Geographic areas for incidental taking;

(3) Means of effecting the least practicable adverse impact (*i.e.,* mitigation) on the species and 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 is consistent with the findings made for the total taking allowable under 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.

§ 218.147 Renewals and modifications of Letters of Authorization.

(a) An LOA issued under §§ 216.106 of this chapter and 218.146 for the activity identified in § 218.140(c) 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 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) 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 this subpart 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 218.146 may be modified by NMFS under the following circumstances:

(1) Through 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 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) 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 218.146, 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.

§ 218.148 [Reserved]

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Part IV

Department of the Treasury

Internal Revenue Service

26 CFR Part 1
Credit for Carbon Oxide Sequestration; Proposed Rule

DEPARTMENT OF THE TREASURY

Internal Revenue Service

26 CFR Part 1

[REG–112339–19]

RIN 1545–BP42

Credit for Carbon Oxide Sequestration

AGENCY: Internal Revenue Service (IRS), Treasury.

ACTION: Notice of proposed rulemaking.

SUMMARY: This document contains proposed regulations regarding the credit for carbon oxide sequestration under section 45Q of the Internal Revenue Code (Code). These proposed regulations will affect persons who physically or contractually ensure the capture and disposal of qualified carbon oxide, use of qualified carbon oxide as a tertiary injectant in a qualified enhanced oil or natural gas recovery project, or utilization of qualified carbon oxide in a manner that qualifies for the credit.

DATES: Written or electronic comments and requests for a public hearing must be received by August 3, 2020. Requests for a public hearing must be submitted as prescribed in the ''Comments and Requests for a Public Hearing'' section.

ADDRESSES: Commenters are strongly encouraged to submit public comments electronically. Submit electronic submissions via the Federal eRulemaking Portal at *www.regulations.gov* (indicate IRS and REG–112339–19) by following the online instructions for submitting comments. Once submitted to the Federal eRulemaking Portal, comments cannot be edited or withdrawn. The IRS expects to have limited personnel available to process public comments that are submitted on paper through mail. Until further notice, any comments submitted on paper will be considered to the extent practicable. The Department of the Treasury (Treasury Department) and the IRS will publish for public availability any comment submitted electronically, and to the extent practicable on paper, to its public docket.

Send paper submissions to: CC:PA:LPD:PR (REG–112339–19), Room 5203, Internal Revenue Service, P.O. Box 7604, Ben Franklin Station, Washington, DC 20044.

FOR FURTHER INFORMATION CONTACT: Concerning the proposed regulations, Maggie Stehn of the Office of Associate Chief Counsel (Passthroughs & Special Industries) at (202) 317–6853; concerning submissions of comments and/or requests for a public hearing, Regina L. Johnson at (202) 317–5177 (not toll-free numbers).

SUPPLEMENTARY INFORMATION:

Background

This document contains proposed amendments to the Income Tax Regulations (26 CFR part 1) under section 45Q of the Code (proposed regulations).

Section 45Q was enacted on October 3, 2008, by section 115 of Division B of the Energy Improvement and Extension Act of 2008, Public Law 110–343, 122 Stat. 3765, 3829, to provide a credit for the sequestration of carbon oxide. On February 17, 2009, section 45Q was amended by section 1131 of Division B of the American Recovery and Reinvestment Tax Act of 2009, Public Law 111–5, 123 Stat. 115, 325. Section 45Q was further amended on December 19, 2014, by section 209(j)(1) of Division A of the Tax Increase Prevention Act of 2014, Public Law 113–295, 128 Stat. 4010, 4030, and most recently on February 9, 2018, by section 41119 of Division D of the Bipartisan Budget Act of 2018 (BBA), Public Law 115–123, 132 Stat. 64, 162, to encourage the construction and use of carbon capture and sequestration projects.

On May 20, 2019, the IRS published Notice 2019–32, 2019–21 I.R.B. 1187. The notice requested general comments on issues arising under section 45Q, as well as specific comments concerning secure geological storage, the measurement of qualified carbon oxide, the recapture of the benefit of the credit for carbon oxide sequestration, the types of utilization that qualify for the credit, the beginning of construction, partnership arrangements, definitions of terms, and other issues related to the credit. The IRS received 116 comments from industry participants, environmental groups, and other stakeholders.

In response to comments submitted pursuant to Notice 2019–32, on March 9, 2020, the Treasury Department and the IRS published Revenue Procedure 2020–12, 2020–11 I.R.B. 511, and Notice 2020–12, 2020–11 I.R.B. 495. Revenue Procedure 2020–12 provides a safe harbor under which the IRS will treat partnerships as properly allocating the section 45Q credit in accordance with section 704(b). Notice 2020–12 provides guidance on the determination of when construction has begun on a qualified facility or on carbon capture equipment that may be eligible for the section 45Q credit. As requested by commenters, the safe harbor in Revenue Procedure 2020–12 and the rules in Notice 2020–12 are similar to those provided in prior guidance.

Pursuant to section 45Q(h), the Secretary of the Treasury or his delegate (Secretary) may prescribe such regulations and other guidance as may be necessary or appropriate to carry out section 45Q, including regulations or other guidance to (i) ensure proper allocation under section 45Q(a) for qualified carbon oxide captured by a taxpayer during the taxable year ending after the date of the enactment of the BBA, and (ii) determine whether a facility satisfies the requirements under section 45Q(d)(1).

Summary of Comments and Explanation of Provisions

1. General Credit Provisions

a. Credit Amount in General

Section 45Q(a)(1) allows a credit of $20 per metric ton of qualified carbon oxide (i) captured by the taxpayer using carbon capture equipment which is originally placed in service at a qualified facility before the date of the enactment of the BBA (February 9, 2018); (ii) disposed of by the taxpayer in secure geological storage; and (iii) neither used by the taxpayer as a tertiary injectant in a qualified enhanced oil or natural gas recovery project nor utilized in a manner described in section 45Q(f)(5).

Section 45Q(a)(2) allows a credit of $10 per metric ton of qualified carbon oxide (i) captured by the taxpayer using carbon capture equipment which is originally placed in service at a qualified facility before February 9, 2018; and (ii) either (A) used by the taxpayer as a tertiary injectant in a qualified enhanced oil or natural gas recovery project and disposed of by the taxpayer in secure geological storage; or (B) utilized by the taxpayer in a manner described in section 45Q(f)(5).

Section 45Q(a)(3) allows a credit of the applicable dollar amount (as determined under section 45Q(b)(1)) per metric ton of qualified carbon oxide (i) captured by the taxpayer using carbon capture equipment which is originally placed in service at a qualified facility on or after February 9, 2018, during the 12-year period beginning on the date the equipment was originally placed in service; (ii) disposed of by the taxpayer in secure geological storage; and (iii) neither used by the taxpayer as a tertiary injectant in a qualified enhanced oil or natural gas recovery project nor utilized in a manner described in section 45Q(f)(5).

Section 45Q(a)(4) allows a credit of the applicable dollar amount (as determined under section 45Q(b)(1)) per

metric ton of qualified carbon oxide (i) captured by the taxpayer using carbon capture equipment which is originally placed in service at a qualified facility on or after February 9, 2018, during the 12-year period beginning on the date the equipment was originally placed in service; and (ii) either (A) used by the taxpayer as a tertiary injectant in a qualified enhanced oil or natural gas recovery project and disposed of by the taxpayer in secure geological storage, or (B) utilized by the taxpayer in a manner described in section 45Q(f)(5).

Section 45Q(b)(1)(A)(i)(I) and (ii)(I) provides that the applicable dollar amount for activities under section 45Q(a)(3) for any taxable year beginning in a calendar year (1) after 2016 and before 2027 is an amount equal to the dollar amount established by linear interpolation between $22.66 and $50 for each calendar year during such period, and (2) after 2026 is an amount equal to the product of $50 and the inflation adjustment factor for such calendar year determined under section 43(b)(3)(B) for such calendar year, determined by substituting ''2025'' for ''1990.''

Section 45Q(b)(1)(A)(i)(II) and (ii)(II) provides that the applicable dollar amount for activities under section 45Q(d)(4) for any taxable year beginning in a calendar year (1) after 2016 and before 2027 is an amount equal to the dollar amount established by linear interpolation between $12.83 and $35 for each calendar year during such period, and (2) after 2026 is an amount equal to the product of $35 and the inflation adjustment factor for such calendar year determined under section 43(b)(3)(B) for such calendar year, determined by substituting ''2025'' for ''1990.'' Section 45Q(b)(1)(B) provides that the applicable dollar amount determined under section 45Q(b)(1)(A) is rounded to the nearest cent.

Section 45Q(b)(2) provides a method to compute the amount of qualified carbon oxide captured at a qualified facility that was placed in service before February 9, 2018, and for which additional carbon capture equipment is placed in service on or after February 9, 2018. For purposes of section 45Q(a)(1)(A) and (2)(A), the amount of qualified carbon oxide that is captured by the taxpayer is equal to the lesser of (i) the total amount of qualified carbon oxide captured at such facility for the taxable year, or (ii) the total amount of the carbon dioxide capture capacity of the carbon capture equipment in service at such facility on February 8, 2018 (the day before the date of enactment of the BBA). For purposes of section 45Q(a)(3)(A) and (4)(A), the amount of qualified carbon oxide captured by the taxpayer is an amount (not less than zero) equal to the excess of (i) the total amount of qualified carbon oxide captured at such facility for the taxable year, over (ii) the total amount of the carbon dioxide capture capacity of the carbon capture equipment in service at such facility on February 8, 2018. These proposed regulations explain the difference between a physical modification or equipment addition that results in an increase in the carbon dioxide capture capacity of existing carbon capture equipment, which will be treated as newly placed in service, and a mere increase in the amount of carbon dioxide captured by existing carbon capture equipment, which will not be treated as newly placed in service.

Pursuant to section 45Q(b)(3), a taxpayer may elect to have the dollar amounts applicable under section 45Q(a)(1) or (2) apply in lieu of the dollar amounts applicable under section 45Q(a)(3) or (4) for each metric ton of qualified carbon oxide which is captured by the taxpayer using carbon capture equipment which is originally placed in service at a qualified facility on or after February 9, 2018. These proposed regulations provide that the election will apply to all metric tons of qualified carbon oxide captured by the taxpayer at the qualified facility for the full 12-year credit period.

Section 45Q(f)(6)(A) provides that for any taxable year in which an applicable facility captures not less than 500,000 metric tons of qualified carbon oxide, the person described in section 45Q(f)(3)(A)(ii) may elect to have such applicable facility, and any carbon capture equipment placed in service at such applicable facility, deemed as having been placed in service on February 9, 2018. The term ''applicable facility'' means a qualified facility (i) which was placed in service before February 9, 2018, and (ii) for which no taxpayer claimed a section 45Q credit for any taxable year ending before February 9, 2018.

Section 45Q(f)(7) provides that in the case of any taxable year beginning in a calendar year after 2009, there is substituted for each dollar amount contained in section 45Q(a)(1) and (2) an amount equal to the product of (i) such dollar amount, multiplied by (ii) the inflation adjustment factor for such calendar year determined under section 43(b)(3)(B) for such calendar year, determined by substituting ''2008'' for ''1990.''

Section 45Q(g) provides that in the case of any carbon capture equipment placed in service before February 9, 2018, the section 45Q credit applies with respect to qualified carbon oxide captured using such equipment before the end of the calendar year in which the Secretary, in consultation with the Administrator of the Environmental Protection Agency (EPA), certifies that a total of 75,000,000 metric tons of qualified carbon oxide have been taken into account in accordance with former section 45Q(a) (as in effect before February 9, 2018) and sections 45Q(a)(1) and (2).

These proposed regulations reflect the statutory provisions relating to credit amounts.

b. Contractually Ensuring Capture and Disposal, Injection, or Utilization of Qualified Carbon Oxide

Section 45Q(f)(3)(A)(i) provides that in the case of qualified carbon oxide captured using carbon capture equipment which is originally placed in service at a qualified facility before February 9, 2018, the section 45Q credit is attributable to the person that captures and physically or contractually ensures the disposal through secure geological storage (referred to as disposal), use for tertiary injection and disposal through secure geological storage (referred to as injection) or utilization in a manner consistent with section 45Q(f)(5) (referred to as utilization).

Section 45Q(f)(3)(A)(ii) provides that in the case of qualified carbon oxide captured using carbon capture equipment which is originally placed in service at a qualified facility on or after February 9, 2018, the section 45Q credit is attributable to the person that owns the carbon capture equipment and physically or contractually ensures the capture and disposal, injection, or utilization of such qualified carbon oxide.

Commenters requested that the Treasury Department and the IRS clarify which contract provisions are necessary to contractually ensure the capture and disposal, injection, or utilization of qualified carbon oxide. Several commenters requested broad guidance on commercially reasonable terms rather than specifying exact language. One commenter requested guidance regarding the assurance of capture, remedies, guarantees, and the prevention of leakage.

In response, the proposed regulations provide a framework for the types of contracts, terms, and reporting requirements that will demonstrate the contractual assurance of the capture and disposal, injection, or utilization of qualified carbon oxide. The proposed regulations provide that a taxpayer may

enter into multiple contracts with multiple parties for the disposal, injection, or utilization of qualified carbon oxide. For example, a taxpayer that captures qualified carbon oxide may contract with one party to dispose of a portion of its captured qualified carbon oxide in a deep saline formation, with another party to use another portion of its captured qualified carbon oxide as a tertiary injectant in multiple enhanced oil recovery (EOR) sites, and with several parties to utilize the remaining portion of its captured qualified carbon oxide. The existence of each contract and the parties involved must be reported to the IRS on an annual basis on Form 8933, *Carbon Oxide Sequestration Credit* (or successor forms, or pursuant to instructions and other guidance). For contracts for the disposal of carbon oxide or use as a tertiary injectant in enhanced oil or natural gas recovery, the following information must be included: Identifying information (name of operator, field, unit and reservoir), the location (county and state) and the identification number assigned to the facility by the EPA's electronic Greenhouse Gas Reporting Tool (e-GGRT ID number). The e-GGRT ID number will allow the IRS to reconcile information with data reported to the EPA's Greenhouse Gas Reporting Program (GHGRP) and otherwise receive technical assistance from the EPA.

The proposed regulations require taxpayers to contractually ensure the disposal, injection, or utilization of qualified carbon oxide in a binding written contract that includes commercially reasonable terms that provides for enforcement. The proposed regulations provide that taxpayers may include information regarding how much carbon oxide the parties agree to dispose of, inject, or utilize in their contracts. Contracts may also include various other specific provisions relating to enforcement, such as long-term liability provisions, indemnity provisions, or penalties for breach of contract or liquidated damages. While the proposed regulations require that the contract include a mechanism for enforcement, no specific enforcement-related provision, or other particular kind of enforcement provision, are mandated by these proposed regulations. This is consistent with allowing contracting parties to tailor their agreements to a wide variety of business needs and circumstances.

Under the proposed regulations, a taxpayer does not elect to allow all or a portion of the section 45Q credit to any of the contracting parties merely by contracting with that party to ensure the disposal, injection, or utilization of qualified carbon oxide. Any election to allow all or a portion of the credit to another taxpayer must be made separately in the manner provided in these proposed regulations.

c. Election To Allow the Credit to Another Taxpayer

Section 45Q(f)(3)(B) provides that a person that is entitled to claim the credit under section 45Q(f)(3)(A)(i) or section 45Q(f)(3)(A)(ii) may elect to allow the person that disposes of the qualified carbon oxide, utilizes the qualified carbon oxide, or uses the qualified carbon oxide as a tertiary injectant to claim the credit (section 45Q(f)(3)(B) election).

Commenters requested guidance regarding the section 45Q(f)(3)(B) election. Commenters generally sought to maximize the ability of the taxpayer to whom the section 45Q credit is attributable (electing taxpayer) to make the section 45Q credit allowable to one or more other taxpayers (credit claimants) pursuant to the section 45Q(f)(3)(B) election. Commenters also generally requested that guidance provide that section 45Q(f)(3)(B) elections may be made on an annual basis. One commenter requested that guidance provide for a broader range of permissible credit claimants, including an owner, operator, service company, supplier, partner, or tax equity or other project finance participant.

One commenter suggested that the section 45Q(f)(3)(B) election should be made in the taxable year that the qualified carbon oxide is disposed of, utilized, or used as a tertiary injectant. The commenter recommended that the election procedures follow the procedures for making a section 338(h)(10) election. Further, commenters suggested that Forms 8933 should be filed by all parties to the section 45Q(f)(3)(B) election with their respective tax returns for the taxable year in which the qualifying activity is completed.

Other commenters suggested that a taxpayer should make a section 45Q(f)(3)(B) election for a taxable year by attaching a statement to a timely filed income tax return (including extensions) for the taxable year. Further, commenters suggested that a taxpayer should be permitted to make a section 45Q(f)(3)(B) election for a portion of the section 45Q credit. The portion allowed to a credit claimant would be specified in the electing taxpayer's annual election as a percentage of the total credit claimed.

One commenter noted that when a taxpayer makes a section 45Q(f)(3)(B) election, the electing taxpayer should no longer claim the section 45Q credit subject to the election. To ensure compliance with this rule, the commenter suggested that the guidance and the relevant tax forms (*i.e.,* Form 8933) require coordination between the electing taxpayer and the credit claimant. For example, the credit claimant could be required to include a copy of the electing taxpayer's section 45Q(f)(3)(B) election to allow the credit.

In response to these comments, the proposed regulations provide guidance regarding who may make a section 45Q(f)(3)(B) election and the time and manner for making a section 45Q(f)(3)(B) election. The proposed regulations also provide that section 45Q(f)(3)(B) elections must be made on an annual basis no later than the time prescribed by law (including extensions) for filing the Federal income tax return or Form 1065 and may not be made on an amended Federal income tax return. However, a section 45Q(f)(3)(B) election may be made on an amended Federal income tax return, an amended Form 1065 or an administrative adjustment request under section 6227 of the Code (AAR), for any taxable year ending after February 9, 2018, but not for taxable years beginning after June 2, 2020.

The proposed regulations also set forth information to be provided as part of a section 45Q(f)(3)(B) election, requiring both an electing taxpayer and a credit claimant to include a Form 8933 (or successor forms, or pursuant to instructions and other guidance) with its timely filed Federal income tax return or Form 1065, U.S. Return of Partnership Income (including extensions) as applicable. An electing taxpayer must provide each credit claimant with a copy of the electing taxpayer's Form 8933, and each credit claimant must attach that copy of the electing taxpayer's Form 8933 to its own Form 8933.

The proposed regulations further provide that section 45Q(f)(3)(B) elections may be made for all or a portion of the available section 45Q credit and may be made for a single or multiple credit claimants. If an electing taxpayer elects to allow multiple credit claimants to claim section 45Q credits, the proposed regulations provide that the maximum amount of section 45Q credits allowable to each credit claimant is proportional to the amount of qualified carbon oxide disposed of, utilized, or used as a tertiary injectant by the credit claimant. In addition, as provided in Revenue Procedure 2020–23, 2020–18 I.R.B.1 (April 27, 2020), the exception applies regarding the time to

file an amended return by a partnership subject to the centralized partnership audit regime enacted as part of the BBA (BBA partnership) for the 2018 and 2019 taxable years. The amended Federal income tax return or the amended Form 1065 must be filed, in no event, later than the applicable period of limitations on assessment for the taxable year for which the amended Federal income tax return or Form 1065 is being filed. In the case of a BBA partnership that chooses not to file an amended Form 1065 as permitted under Revenue Procedure 2020–23, the BBA partnership may make a late election by filing an AAR on or before October 15, 2021, but in no event, later than the applicable period of limitations on making adjustments under section 6235 for the reviewed year, as defined in § 301.6241–1(a)(8) of the Procedure and Administration Regulations (26 CFR part 301).

d. Amended Returns

Taxpayers may claim section 45Q credits on an amended Federal income tax return, an amended Form 1065, or an AAR, as applicable, for taxable years beginning on or after February 9, 2018, provided that the requirements described in the proposed regulations are satisfied. In addition, as provided in Revenue Procedure 2020–23, the exception applies regarding the time to file an amended return by a BBA partnership for the 2018 and 2019 taxable years. The amended Federal income tax return or the amended Form 1065 must be filed, in no event, later than the applicable period of limitations on assessment for the taxable year for which the amended Federal income tax return or Form 1065 is being filed. In the case of a BBA partnership that chooses not to file an amended Form 1065 as permitted under Revenue Procedure 2020–23, the BBA partnership may make a late election by filing an AAR on or before October 15, 2021, but in no event, later than the applicable period of limitations on making adjustments under section 6235 for the reviewed year, as defined in § 301.6241–1(a)(8) of the Procedure and Administration Regulations (26 CFR part 301). However, section 45Q(f)(3)(B) elections may not be made on amended returns for taxable years beginning after the date of issuance of these proposed regulations.

2. Definitions

a. Qualified Carbon Oxide

Section 45Q(c) provides that ''qualified carbon oxide'' means (A) any carbon dioxide which (i) is captured from an industrial source by carbon capture equipment which is originally placed in service before February 9, 2018; (ii) would otherwise be released into the atmosphere as industrial emission of greenhouse gas or lead to such release; and (iii) is measured at the source of capture and verified at the point of disposal, injection, or utilization; (B) any carbon dioxide or other carbon oxide which (i) is captured from an industrial source by carbon capture equipment which is originally placed in service on or after February 9, 2018; (ii) would otherwise be released into the atmosphere as industrial emission of greenhouse gas or lead to such release; and (iii) is measured at the source of capture and verified at the point of disposal, injection, or utilization; or (C) in the case of a direct air capture facility, any carbon dioxide which (i) is captured directly from ambient air; and (ii) is measured at the source of capture and verified at the point of disposal, injection, or utilization.

While ''qualified carbon oxide'' includes the initial deposit of captured carbon oxide used as a tertiary injectant, section 45Q(c)(2) provides that the term does not include carbon oxide that is recaptured, recycled, and re-injected as part of the qualified enhanced oil or natural gas recovery process. Additionally, section 45Q(f)(1) provides that the section 45Q credit apples only with respect to qualified carbon oxide the capture and disposal, injection, or utilization of which is within the United States (within the meaning of section 638(1)), or a possession of the United States (within the meaning of section 638(2)).

Commenters suggested generally that the statutory definition of qualified carbon oxide is sufficient, and did not seek additional clarification. The Treasury Department and the IRS agree that the statutory definition of qualified carbon oxide is clear due to the broad acceptance and use of the term by industry participants, environmental groups, and stakeholders. Therefore, the proposed regulations generally conform to the statutory definition of qualified carbon oxide, including the provision that only qualified carbon oxide captured and disposed of, injected, or utilized within the United States or a possession of the United States is taken into account. Therefore, the proposed regulations generally conform to the statutory definition of qualified carbon oxide, including the provision that only qualified carbon oxide captured and disposed of, injected, or utilized within the United States or a possession of the United States is taken into account.

b. Carbon Capture Equipment

Section 45Q does not define carbon capture equipment. One commenter suggested that carbon capture equipment be broadly defined as, ''any system that but for its presence and application, the carbon oxides captured at a qualifying industrial facility and on which a section 45Q credit is earned would have been vented into the atmosphere.'' Another commenter suggested that the definition allow for maximum flexibility to encompass a complete configuration of equipment including separate units, processing units, processing plants, pipe, buildings, pumps, compressors, meters, facilities, motors, fixtures, materials, and machinery, and all other improvements used for the purpose of: (1) Separating and/or capturing carbon dioxide that would otherwise be released into the atmosphere from a qualifying facility; (2) compressing or otherwise increasing the pressure of carbon dioxide; or (3) transporting, disposing, injecting, and/or utilizing qualified carbon oxide.

Finally, some commenters suggested that the definition of carbon capture equipment should be limited to the equipment that functions to capture the carbon oxides from any industrial source. The commenters explained that once the carbon oxides are captured, equipment having a separate function such as compression, liquefaction, transportation, or pumping, should not be included in the definition of carbon capture equipment.

The Treasury Department and the IRS agree that carbon capture equipment generally should be defined in terms of its functionality. The proposed regulations provide that in general, carbon capture equipment includes all components of property that are used to capture or process carbon oxide until the carbon oxide is transported for disposal, injection, or utilization. Further, the proposed regulations list specific items that are included in, or excluded from the definition of carbon capture equipment. Components of property related to the function of capturing carbon oxides, such as components of property necessary to compress, treat, process, liquefy, or pump carbon oxides, are included within the definition of carbon capture equipment. Components of property related to transporting carbon oxides for disposal, injection, or utilization are not included in the general definition.

c. Qualified Facility

Section 45Q(d) provides that ''qualified facility'' means any industrial facility or direct air capture facility, the

construction of which begins before January 1, 2024, and (i) the construction of carbon capture equipment begins before such date; or (ii) the original planning and design for such facility includes installation of carbon capture equipment. In addition, a qualified facility must capture: (i) In the case of a facility which emits not more than 500,000 metric tons of carbon oxide into the atmosphere during the taxable year, not less than 25,000 metric tons of qualified carbon oxide during the taxable year which is utilized in a manner described in section 45Q(f)(5) (Section 45Q(d)(2)(A) Facility); (ii) in the case of an electricity generating facility which is not a Section 45Q(d)(2)(A) Facility (Section 45Q(d)(2)(B) Facility), not less than 500,000 metric tons of qualified carbon oxide during the taxable year; or (iii) in the case of a direct air capture facility or any facility which is not a Section 45Q(d)(2)(A) Facility or a Section 45Q(d)(2)(B) Facility, not less than 100,000 metric tons of qualified carbon oxide during the taxable year.

Some commenters requested that the proposed regulations incorporate the ''80/20 Rule'' set forth in Rev. Rul. 94–31, 1994–1 C.B. 16, which held that for section 45 purposes a facility that contains some used property would still qualify as originally placed in service, provided the fair market value of the used property is not more than 20 percent of the facility's total value. Commenters requested the inclusion of this rule because the section 45Q credit amounts depend on whether carbon capture equipment is placed in service before February 9, 2018, or on or after that date.

The proposed regulations adopt the 80/20 Rule and provide that a qualified facility or carbon capture equipment may qualify as originally placed in service even though it contains some used components of property, provided the fair market value of the used components of property is not more than 20 percent of the qualified facility or carbon capture equipment's total value (the cost of the new components of property plus the value of the used components of property). For purposes of the 80/20 Rule, the cost of a new qualified facility or carbon capture equipment includes all properly capitalized costs of the new qualified facility or carbon capture equipment. Solely for purposes of the 80/20 Rule, properly capitalized costs of a new qualified facility or carbon capture equipment may, at the option of the taxpayer, include the cost of new equipment for a pipeline owned and used exclusively by that taxpayer to transport carbon oxides captured from that taxpayer's qualified facility that would otherwise be emitted into the atmosphere.

d. Industrial Facility

Section 45Q does not define the term ''industrial facility.'' Commenters suggested that an ''industrial facility'' should be defined as a facility that produces a carbon oxide stream from a fuel combustion source, a manufacturing process, or a fugitive carbon oxide-emission source that, absent capture and disposal, injection, or utilization, would otherwise be released into the atmosphere. They also recommended that the term not include a facility that produces carbon dioxide through carbon dioxide production wells at natural carbon dioxide-bearing formations. This definition is consistent with the definition of industrial facility provided in section 3.03 of Notice 2020–12. The proposed regulations adopt this definition.

e. Direct Air Capture Facility

Section 45Q(e)(1) provides that the term ''direct air capture facility'' means any facility which uses carbon capture equipment to capture carbon dioxide directly from the ambient air, except the term does not include any facility which captures carbon dioxide that is deliberately released from naturally occurring subsurface springs or using natural photosynthesis.

Generally, commenters did not request that the definition of ''direct air capture facility'' be clarified. One commenter suggested that ''direct air capture facility'' include certain algae. Although section 45Q(f)(5)(A)(i) provides that photosynthesis or chemosynthesis is a permitted type of utilization of qualified carbon oxide, the statutory definition of a ''direct air capture facility'' excludes any facility that captures carbon dioxide using natural photosynthesis. Therefore, the proposed regulations do not adopt the commenter's suggestion.

3. Secure Geological Storage

Section 45Q(f)(2) provides that the Secretary, in consultation with the Administrator of the EPA, the Secretary of Energy, and the Secretary of the Interior, must establish regulations for determining adequate security measures for the geological storage of qualified carbon oxide under section 45Q(a) such that the qualified carbon oxide does not escape into the atmosphere. Such term includes storage at deep saline formations, oil and gas reservoirs, and unminable coal seams under such conditions as the Secretary may determine under such regulations.

Injection of carbon oxide into any underground reservoir, onshore or offshore under submerged lands within the territorial jurisdiction of States, requires the operator to comply with Underground Injection Control (UIC) program regulations and to obtain the appropriate UIC well permits. Under 40 CFR 146.5 (Classification of injection wells) Class II may be an appropriate UIC well permit for wells which inject fluids (including carbon dioxide) brought to the surface in connection with conventional oil or natural gas production and may be commingled with waste waters from gas plants that are an integral part of production operations, unless those fluids are classified as a hazardous waste at the time of injection, and for wells which inject fluids (including carbon oxides) for enhanced recovery of oil or natural gas. Class VI is an appropriate UIC well permit for wells that are not experimental in nature that are used for geologic sequestration of carbon dioxide beneath the lowermost formation containing an underground source of drinking water; or, for wells used for geologic sequestration of carbon dioxide that have been granted a waiver of the injection depth requirements pursuant to requirements at 40 CFR 146.95; or, for wells used for geologic sequestration of carbon dioxide that have received an expansion to the areal extent of an existing Class II enhanced oil recovery or enhanced gas recovery aquifer exemption pursuant to §§ 146.4 and 144.7(d) of 40 CFR.

Operators that inject carbon dioxide underground are also subject to the EPA's GHGRP requirements set forth at 40 CFR part 98. Under 40 CFR part 98 subpart RR (Geologic Sequestration of Carbon Dioxide source category, referred to as *subpart RR*), certain facilities, including UIC Class VI wells, are required to report basic information on carbon dioxide received for injection, develop and implement an EPA-approved site-specific Monitoring, Reporting, and Verification Plan (MRV Plan), and report the amount of carbon dioxide geologically sequestered using a mass balance approach and annual monitoring activities. Under 40 CFR part 98 subpart UU (Injection of Carbon Dioxide source category, referred to as *subpart UU*), all other facilities that inject carbon dioxide underground such as for EOR or any other purpose, are required to report basic information on carbon dioxide received for injection. Facilities that conduct EOR are not required by 40 CFR part 98 to report under subpart RR unless (1) the owner

or operator chooses to opt into subpart RR or, (2) the facility holds a UIC Class VI permit for the well or group of wells used for EOR. Annual reports that are submitted under 40 CFR part 98 to the EPA's GHGRP undergo verification by the EPA, and non-confidential data from these reports are published on the EPA's website.

Commenters noted that Form 8933 defines ''secure geological storage'' for purposes of section 45Q as requiring approval by the EPA of an MRV Plan. Thus, meeting the Form 8933 conditions would be achieved currently by receiving either (i) a UIC Class VI permit plus an EPA-approved MRV Plan, which UIC Class VI permit holders are already required to have because they are subject to subpart RR; or (ii) a UIC Class II permit plus an EPA-approved MRV Plan. The Form 8933 requirement that UIC Class II permit holders receive an approved MRV Plan for purposes of the section 45Q credit creates an additional burden on such holders. Some commenters expressed concern that being required to opt into subpart RR may create a misalignment with state mineral property and natural resource conservation laws, as well as accepted industry practices and commercial arrangements. Therefore, the commenters generally requested that the Treasury Department and the IRS provide alternatives to opting into subpart RR for demonstrating secure geological storage for EOR projects.

Many commenters suggested that a standard adopted by the International Organization for Standardization (ISO) and endorsed by the American National Standards Institute (ANSI), CSA/ANSI ISO 27916:19, ''Carbon Dioxide Capture, Transportation and Geological Storage—Carbon Dioxide Storage Using Enhanced Oil Recovery (CO_2-EOR),'' is a viable alternative to subpart RR for establishing secure geological storage for the use of qualified carbon oxide for EOR.

The CSA/ANSI ISO 27916:19 standard was developed for the purpose of quantifying and documenting the total carbon dioxide that is stored in association with EOR. In general, reporting under CSA/ANSI ISO 27916:19 uses mass balance accounting, has established reporting and documentation requirements, and includes requirements for documenting a monitoring program and a containment assurance plan.

Some of the commenters advocating for the application of the CSA/ANSI ISO 27916:19 standard emphasized the importance and need for public acceptance and input, transparent public filings, credible third-party audits and certifications, and government oversight and enforcement. For example, some commenters suggested that the proposed regulations require that all relevant documentation of the amount of qualified carbon oxide stored for purposes of the section 45Q credit be retained and made available for public review and the total quantity of qualified carbon oxide stored for long-term containment be reported annually. The Treasury Department and the IRS appreciate the importance of shared and open information in this context and encourage transparency. However, there is no statutory requirement in section 45Q for taxpayers, Federal agencies, or industry groups to pubicly display this information or otherwise make it available. In addition, the IRS is itself limited in what it can disclose because of the rules prohibiting the public disclosure of taxpayer information under section 6103.

Some commenters also requested that the Treasury Department and the IRS recognize the standards for secure geological storage required by government entities with regulatory primacy, and also recommended that states be allowed to certify the secure geological storage of qualified carbon oxide. The commenters noted that the EPA has approved primary enforcement authority (primacy) for UIC Class II wells for more than half the states. Primacy permits a state, tribe, or territory to implement and oversee its own EPA approved program. One commenter requested that the IRS clarify that a valid UIC Class VI permit issued under the authority of the EPA includes permits issued by a state that has received final approval from the EPA of its primacy application under section 1422 of the Safe Water Drinking Act to implement a Class VI UIC Program. The commenter also suggested that use of an accounting methodology consistent with the mass balance equation under subpart RR be adequate to establish secure geological storage.

The Treasury Department and the IRS, in consultation with the EPA, DOE, and the Department of Interior (Interior Department), agree that providing CSA/ANSI ISO 27916:19 as an alternative for UIC Class II wells is a viable quantification methodology that is appropriate for these purposes. Both subpart RR and CSA/ANSI ISO 27916:19 require an assessment and monitoring of potential leakage pathways; quantification of inputs, losses and storage through a mass balance approach; and documentation of steps and approaches. Operators of UIC Class II wells that follow the CSA/ANSI ISO 27916:19 standard could elect to report to the EPA's GHGRP under subpart RR but would not be required to do so. Rather, they could continue to report to the EPA under subpart UU.

The Treasury Department and the IRS, in consultation with the EPA, DOE, and the Interior Department, disagree with suggestions to allow the reporting rules promulgated by states as an alternative to subpart RR or CSA/ANSI ISO 27916:19. Reporting rules among states are not uniform and states may have different reporting requirements and different governing bodies to whom carbon dioxide injection projects are required to report. Adopting such rules would not promote uniformity, and would increase the administrative burden on the IRS significantly.

Consequently, the proposed regulations allow the CSA/ANSI ISO 27916:19 standard as an alternative to subpart RR for UIC Class II wells using qualified carbon oxide for EOR, but do not allow standards set by states as an alternative to subpart RR. In addition, the proposed regulations do not provide for an alternative to subpart RR reporting for UIC Class VI wells because all UIC Class VI wells are already subject to subpart RR reporting requirements. A taxpayer that reported volumes of carbon oxide to the EPA pursuant to subpart RR may self-certify the volume of carbon oxide claimed for purposes of section 45Q. Alternatively, if a taxpayer determined volumes pursuant to CSA/ANSI ISO 27916:19, the taxpayer may prepare documentation as outlined in CSA/ANSI 27916:2019 internally, but such documentation must be provided to a qualified independent engineer or geologist, who then must certify that the documentation provided, including the mass balance calculations as well as information regarding monitoring and containment assurance, is accurate and complete.

4. Utilization of Qualified Carbon Oxide

Section 45Q(f)(5)(A) provides that ''utilization of qualified carbon oxide'' means (i) the fixation of such qualified carbon oxide through photosynthesis or chemosynthesis, such as through the growing of algae or bacteria; (ii) the chemical conversion of such qualified carbon oxide to a material or chemical compound in which such qualified carbon oxide is securely stored; or (iii) the use of such qualified carbon oxide for any other purpose for which a commercial market exists (with the exception of use as a tertiary injectant in a qualified enhanced oil or natural gas recovery project), as determined by the Secretary.

Section 45Q(f)(5)(B) provides a methodology to determine the amount of qualified carbon oxide utilized by the taxpayer. Such amount is equal to the metric tons of qualified carbon oxide which the taxpayer demonstrates, based upon an analysis of lifecycle greenhouse gas emissions and subject to such requirements as the Secretary, in consultation with the Secretary of Energy and the Administrator of the EPA, determines appropriate, were (i) captured and permanently isolated from the atmosphere, or (ii) displaced from being emitted into the atmosphere, through use of a process described in section 45Q(f)(5)(A). The term ''lifecycle greenhouse gas emissions'' has the same meaning given such term under subparagraph (H) of section 211(o)(1) of the Clean Air Act (42 U.S.C. 7545(o)(1)(H)), as in effect on February 9, 2018, except that ''product'' is substituted for ''fuel'' each place it appears in such subparagraph.

Commenters generally sought guidance about the methodologies required to prepare an acceptable life cycle analysis (LCA) that demonstrates the amount of qualified carbon oxide utilized, as well as the boundaries required for the LCA.

One commenter requested that guidance establish clear guidelines for the preparation of an LCA by applicants to demonstrate the net reduction or avoidance of carbon dioxide achieved through its utilization by the taxpayer. Because LCA requires selection of comparative data, the commenter recommended that the LCA undergo a review by a third party, determined by the IRS, to assess the reasonableness of the assumptions, factors and calculations used by the applicant.

Other commenters suggested using the Greenhouse Gases, Regulated Emissions, and Energy Use in Transportation (GREET) model, or an adaptation of it adopted by the California Air Resources Board, to perform LCA of transportation fuels, and further suggested using both a basic method and a safe harbor method. The GREET model is a tool that examines the life-cycle impacts of vehicle technologies, fuels, products, and energy systems. It provides a transparent platform through which energy and vehicle producers, researchers, and regulators can evaluate energy and environmental effects of vehicle technologies and energy and product systems. For any given energy and vehicle system, GREET can calculate total energy consumption (non-renewable and renewable), emissions of air pollutants, emissions of greenhouse gases, and water consumption.

One commenter suggested that the LCA, as reviewed by the relevant governmental agency, should determine whether any release of embodied qualified carbon oxide is possible for a specific utilization project. If so, the commenter recommended that recapture be addressed in the LCA. The commenter requested guidance regarding the types of LCA models that are appropriate, and recommended the GREET model.

Another commenter suggested that the IRS should not adopt a specific methodology or approach to calculating lifecycle emissions. Instead, the commenter recommended that guidance make clear that models that are acceptable to the EPA will also be acceptable for purposes of section 45Q. The commenter suggested that the LCA model for section 45Q purposes should be one that is recognized by the EPA based on its use in the Renewable Fuel Standard or other program administered by the EPA. The commenter further recommended that if the capture and utilization of carbon oxides also generates other greenhouse gas detriments, such as an increase in emissions over the base case, those greenhouse gases caused by the utilization should be adjusted to account for the relative global warming potential. Similarly, if the capture and utilization of carbon oxides reduce greenhouse gas emissions over the base case, the commenter argued that those benefits should also be credited.

One commenter sought guidance on the boundaries for LCA to determine displacement of carbon dioxide and recommended that lifecycle emissions include the entirety of the lifecycle.

Several commenters expressed the view that an MRV Plan or any accredited LCA performed by a qualified firm as determined by the IRS could be suitable for establishing boundaries for lifecycle emissions for qualified carbon oxide utilization. Further, commenters suggested that there should be contractual proof to track the supply chain and ensure that the MRV Plan is followed according to the annual LCA.

Some commenters suggested that guidance require EOR operators to provide a full lifecycle greenhouse gas emissions analysis that, like the requirements for utilization, includes all stages of product and feedstock production and distribution, from feedstock generation or extraction through the distribution and delivery and use of the finished product to the ultimate consumer. The commenters requested that the IRS make public all lifecycle emissions calculations.

One commenter made the following suggestions. First, taxpayers should use an independent consulting firm or other similar independent entity to undertake the LCA. Second, taxpayers should insure that an LCA model is realistic and has been used widely by the LCA industry. Third, an LCA must be commercially available to anyone and must be able to be examined in any audit by the IRS. Fourth, taxpayers should use an LCA that compares a base case of making the product produced by utilization without carbon capture to the modeled utilization case using qualified carbon oxide to determine what greenhouse gases were displaced from being emitted into the atmosphere. Finally, taxpayers must use an LCA which models all ''greenhouse gases'' as defined in the Clean Air Act in determining the net impact of such greenhouse gases generated or reduced in utilization of qualified carbon oxide.

One commenter suggested that the IRS should provide a safe harbor for taxpayers that retain a third-party firm to undertake the LCA. However, the commenter stated that while a safe harbor would be helpful, third-party verification should not be mandatory, as many taxpayers may have sufficient engineering expertise in-house and some smaller projects may not support the extra cost of third-party verification.

In response to the commenters, the proposed regulations conform the definition of utilization to the statutory definition. The Treasury Department and the IRS, in consultation with the EPA and the DOE, concluded that the LCA must be in writing and either performed or verified by a professionally-licensed third party that uses generally-accepted standard practices of quantifying the greenhouse gas emissions of a product or process and comparing that impact to a baseline. In particular, the analysis must contain documentation consistent with the International Organization for Standardization (ISO) 14044:2006, ''Environmental management—Life cycle assessment—Requirements and Guidelines,'' as well as a statement documenting the qualifications of the third party. Although the section 45Q credit is only available with respect to qualified carbon oxides, all greenhouse gas emissions are taken into account under this analysis. The proposed regulations require a taxpayer to submit an LCA report to the IRS and the DOE. The LCA will be subject to a technical review by the DOE, and the IRS, in consultation with the DOE and the EPA, will determine whether to approve the

LCA. The Treasury Department and the IRS request comments on how to achieve consistency in boundaries and baselines so that similarly situated taxpayers will be treated consistently. The Treasury Department and the IRS are willing to consider issuing guidance on particular fact patterns.

The proposed regulations do not define commercial markets or provide for Standards of Lifecycle Analysis. The Treasury Department and the IRS continue to study these issues and request comments.

5. Credit Recapture

Section 45Q(f)(4) directs the Secretary to provide regulations for recapturing the benefit of any section 45Q credit allowable with respect to any qualified carbon oxide which ceases to be captured, disposed of, or used as a tertiary injectant in a manner consistent with the requirements of section 45Q.

Commenters sought guidance about the method for measuring the amount of leaked qualified carbon oxide subject to recapture (recapture amount), the method for calculating recapture, and the open period during which a recapture event may occur (recapture period).

All of these issues require a definition of the recapture period. The proposed regulations provide that the *recapture* period begins on the date of the first injection of qualified carbon oxide for disposal in secure geological storage or use as a tertiary injectant and ends the earlier of five years after the last taxable year in which the taxpayer claimed a section 45Q credit or the date monitoring ends under subpart RR requirements or the CSA/ANSI ISO 27916:19 standard.

For clarity we will describe two sub-portions of the recapture period, the ''post-credit-claiming period'' and the ''lookback period''. The ''post-credit-claiming period'' is the period after the end of the twelve year credit period during which a leak can result in recapture, whereas the ''lookback period'' is the portion of the recapture period during which the IRS can look back after a leakage event to recapture credits. Most commenters supported a lookback period of three to five years.

Commenters generally suggested that if a recapture event occurs with respect to storage of qualified carbon oxide, then the taxpayer must add the recapture amount to the amount of tax due in the taxable year in which the recapture event occurs, as opposed to attributing the leak to past tax years and amending those returns.

Commenters also suggested that a recapture event should occur when qualified carbon oxide, for which a section 45Q credit has been allowed, ceases to be stored in secure geological storage if the amount of leakage of qualified carbon oxide in a taxable year exceeds the amount of qualified carbon oxide stored in that same taxable year. In other words, they suggested that a leak would first offset the immediate tax year's claimed credits and then be an addition to tax, as opposed to auditing and amending past tax returns.

One commenter stated that the standard for measuring recapture of the section 45Q credit should be the mass balance calculations that are used for determining the amount of qualified carbon oxide stored in secure geological storage. The commenter noted that these mass balance calculations effectively establish a last-in/first-out (LIFO) accounting method that assumes current year releases offset current year injections for the qualified carbon oxide that is in secure geological storage.

Several commenters requested a safe harbor for recapture, providing that recapture will not apply so long as the injection operator is operating in compliance with any standards set by the Treasury Department and the IRS for secure geological storage of the qualified carbon oxide. These commenters asserted that if the injection operator is in compliance with the secure geological storage standards at the time of a release, any release or leakage of the qualified carbon oxide would be offset by current year injections of qualified carbon oxide. If the injection operator is not operating in compliance with the standards for secure geological storage at the time of the release, the commenters recommended that any recapture be calculated on a LIFO basis against previously taken section 45Q credits when the injection operator was in compliance with the secure geological storage standards.

The proposed regulations do not provide a recapture safe harbor, but do limit the recapture period similar to the recapture provisions for investment credit property under section 50(a)(1). Specifically, the proposed regulations provide that any recapture amount will be accounted for in the taxable year that it is identified and reported. If, during the recapture period, a taxpayer, operator, or regulatory agency determines that qualified carbon oxide has leaked to the atmosphere, the taxpayer will have a recapture amount if the leaked amount of qualified carbon oxide exceeds the amount of qualified carbon dioxide disposed of in secure geological storage or used as a tertiary injectant in that taxable year. That excess amount of leaked qualified carbon oxide will be recaptured at a credit rate calculated on a LIFO basis (that is, the excess leaked qualified carbon oxide will be deemed attributable first to the first preceding year, then to second preceding year, and then up to the fifth preceding year) to simplify the calculation of the recapture amount.

The taxpayer must add the amount of the recaptured section 45Q tax credit to the amount of tax due in the taxable year in which the recapture event occurs. Consistent with this five-year lookback period, the proposed regulations provide that the post-credit-claiming period ends the earlier of (i) five years after the last taxable year in which the taxpayer claimed a section 45Q credit or (ii) the date monitoring ends under the requirements of the subpart RR standard or the CSA/ANSI ISO 27916:19 standard.

The proposed regulations also provide that in the event of a recapture event with respect to a secure geological storage location in which the stored qualified carbon oxide had been captured from more than one unit of carbon capture equipment that was not under common ownership, the recapture amount must be allocated among the taxpayers that own the multiple units of carbon capture equipment pro rata on the basis of the amount of qualified carbon oxide captured from each of the multiple units of carbon capture equipment.

Similarly, the proposed regulations provide that in the event of a recapture event where the leaked amount of qualified carbon oxide is deemed attributable to qualified carbon oxide with respect to which multiple taxpayers claimed section 45Q credit amounts, the recapture amount is allocated on a pro rata basis among the taxpayers that claimed the section 45Q credits.

The proposed regulations provide a limited exception to recapture in the event of a leakage of qualified carbon oxide resulting from actions not related to the selection, operation, or maintenance of the storage facility, such as volcanic activity or a terrorist attack. Finally, the proposed regulations provide that if qualified carbon oxide is deliberately removed from a secure storage site, a recapture event occurs in the year in which the qualified carbon oxide is removed from its original storage.

As noted in section 4.08 of Revenue Procedure 2020–12, a taxpayer may obtain third-party recapture insurance to protect against recapture.

The Treasury Department and the IRS request comments on how to apply the

recapture provisions to section 45Q credits that are carried forward to future taxable years due to insuffificent income tax liability in the current taxable year.

Effect on Other Documents

Sections 1 through 5 of Notice 2009–83, 2009–2 C.B. 588, as modified by Notice 2011–25, 2011–1 C.B. 604, are obsoleted. The remaining sections of Notice 2009–83 provide reporting and recordkeeping requirements associated with the limitation on credits available under former section 45Q(a) (as in effect before February 9, 2018) and sections 45Q(a)(1) and (2). After the end of the calendar year in which the Secretary, in consultation with the Administrator of the EPA, certifies that a total of 75,000,000 metric tons of qualified carbon oxide have been taken into account under former section 45Q(a) (as in effect before February 9, 2018) and sections 45Q(a)(1) and (2), the remaining sections of Notice 2009–83 will be obsoleted.

Proposed Effective/Applicability Date

The regulations are proposed to apply to taxable years beginning on or after the date the Treasury decision adopting these regulations as final regulations is published in the **Federal Register**. However, taxpayers may choose to apply the final regulations for taxable years beginning on or after February 9, 2018, and before the date the Treasury decision adopting these regulations as final regulations is published in the **Federal Register**. See section 7805(b)(7). Alternatively, taxpayers may rely on these proposed regulations for taxable years beginning on or after February 9, 2018, and before the date the Treasury decision adopting these regulations as final regulations is published in the **Federal Register**, provided the taxpayers follow the proposed regulations in their entirety and in a consistent manner.

Statement of Availability for IRS Documents

For copies of recently issued Revenue Procedures, Revenue Rulings, Notices, and other guidance published in the Internal Revenue Bulletin, please visit the IRS website at *http://www.irs.gov.*

Special Analyses

I. Regulatory Planning and Review—Economic Analysis

Executive Orders 13563, 13771, and 12866 direct agencies to assess costs and benefits of available regulatory alternatives and, if regulation is necessary, to select regulatory approaches that maximize net benefits (including potential economic, environmental, public health and safety effects, distributive impacts, and equity). Executive Order 13563 emphasizes the importance of quantifying both costs and benefits, of reducing costs, of harmonizing rules, and of promoting flexibility. The preliminary E.O. 13771 designation is deregulatory.

These regulations have been designated by the Office of Management and Budget's Office of Information and Regulatory Affairs (OIRA) as economically significant under Executive Order 12866 pursuant to the Memorandum of Agreement (April 11, 2018) between the Treasury Department and the Office of Management and Budget regarding review of tax regulations.

A. Background and Overview

Section 45Q was enacted on October 3, 2008, by section 115 of Division B of the Energy Improvement and Extension Act of 2008, Public Law 110–343, 122 Stat. 3765, 3829, to provide a credit for the sequestration of carbon dioxide. On February 17, 2009, section 45Q was amended by section 1131 of Division B of the American Recovery and Reinvestment Tax Act of 2009, Public Law 111–5, 123 Stat. 115, 325. Section 45Q was further amended on December 19, 2014, by section 209(j)(1) of Division A of the Tax Increase Prevention Act of 2014, Public Law 113–295, 128 Stat. 4010, 4030, and most recently on February 9, 2018, by section 41119 of Division D of the Bipartisan Budget Act of 2018 (BBA), Public Law 115–123, 132 Stat. 64, 162.

On May 20, 2019, the IRS published Notice 2019–32, 2019–21 I.R.B. 1187. The notice requested general comments on issues arising under section 45Q, as well as specific comments concerning the secure geological storage and measurement of qualified carbon oxide, and the recapture of the benefit of the credit for carbon oxide sequestration. The IRS received 116 comments from industry members, environmental groups, and other stakeholders.

In addition, the Treasury Department and the IRS published Revenue Procedure 2020–12, 2020–11 I.R.B. 511, and Notice 2020–12, 2020–11 I.R.B. 495. Revenue Procedure 2020–12 provides a safe harbor under which the IRS will treat partnerships as properly allocating the section 45Q credit in accordance with section 704(b). Notice 2020–12 provides guidance on the determination of when construction has begun on a qualified facility or on carbon capture equipment that may be eligible for the section 45Q credit.

Section 45Q generally allows a credit of an amount per metric ton of qualified carbon oxide captured by the taxpayer using carbon capture equipment. This qualified carbon oxide must be captured according to the statute in one of three general manners. First, it may be disposed of in secure geological storage. This would occur if it were injected into a geologic formation, such as a deep saline formation, an oil and gas reservoir, or an unminable coal seam.

Second, the qualified carbon oxide may be used as a tertiary injectant in a qualified enhanced oil or natural gas recovery project and disposed of in secure geological storage. A ''tertiary injectant'' is qualified carbon oxide that is injected into and stored in a qualified enhanced oil or natural gas recovery project and contributes to the extraction of crude oil or natural gas.

Third, the qualified carbon oxide may be ''utilized'' by fixing it through photosynthesis or chemosynthesis, converting it to a material or chemical compound in which it is securely stored, or using it for any other purpose for which a commercial market exists. ''Utilization'' generally means the qualified carbon oxide was captured and permanently isolated from the atmosphere, or displaced from being emitted into the atmosphere. Calculation of the amount utilized is based on an analysis of lifecycle greenhouse gas emissions.

The amount of the credit depends on the date the carbon capture equipment is placed in service and whether the qualified carbon oxide is disposed of in secure storage, injected, or utilized. Different rules and credit amounts apply to qualified carbon oxide capture projects placed in service before and after the date the enactment of the BBA on February 9, 2018. Based on annual reports filed with the IRS as of May, 2019, the aggregate amount of qualified carbon oxide taken into account for purposes of section 45Q was 62,740,171 metric tons. This is an increase of 2,972,247 metric tons from the preceding year.[1] According to data reported to the EPA's Greenhouse Gas Reporting Program (GHGRP), there were 65 enhanced oil recovery (EOR) projects operating in the U.S. in 2018. As of 2019, the National Petroleum Council, an oil and natural gas advisory committee to the Secretary of Energy, reports that there were 10 carbon capture, utilization, and storage projects in the United States. DOE models project that the section 45Q credit may

[1] These data are available in Notice 2018–40, 2018–20 I.R.B. 583, and Notice 2019–31, 2019–20 I.R.B. 1181.

result in the sequestration of approximately 570 million metric tons of carbon oxides between 2018 and 2036.

B. Need for Regulation

The proposed regulations provide guidance regarding the application of section 45Q. Section 45Q requires regulations for determining adequate security measures for the secure geological storage of qualified carbon oxide such that it does not escape into the atmosphere, standards for recapture of section 45Q credits, and standards for carbon oxide utilization.

C. Economic Analysis

1. Baseline

The Treasury Department and the IRS have assessed the economic impacts of the final regulations relative to a no-action baseline reflecting anticipated Federal income tax-related behavior in the absence of these regulations.

2. Economic Rationale for Issuing Guidance for the 2018 BBA

The Treasury Department and the IRS anticipate that the issuance of guidance pertaining to section 45Q will provide greater clarity in definitions than the alternative of having no further descriptions than the statute; more flexibility in methods to establish qualifications for the credit relative to prior guidance; and more transparency regarding business arrangements related to the section 45Q credit relative to the baseline. These features may lower compliance burden and increase economic investment by lowering regulatory barriers to entry, compared to a baseline of having only the statue and not the regulations.

3. Economic Analysis of Specific Provisions

The final regulations embody certain regulatory decisions that reflect necessary regulatory discretion. These decisions specify more fully how the section 45Q credit is to be implemented.

i. Standard for Secure Geological Storage

a. Background

Section 45Q(f)(2) provides that the Secretary, in consultation with the Administrator of the EPA, the Secretary of Energy, and the Secretary of the Interior, must establish regulations for determining adequate security measures for the secure geological storage of qualified carbon oxide under section 45Q such that qualified carbon oxide does not escape into the atmosphere. Such term includes storage at deep saline formations, oil and gas reservoirs, and unminable coal seams under such conditions as the Secretary may determine under such regulations.

Under existing law, injection of carbon oxide into any underground reservoir requires the operator to comply with EPA's Underground Injection Control (UIC) program regulations and to obtain the appropriate UIC well permits. The UIC program is designed to protect underground sources of drinking water from underground injection. Operators that inject carbon dioxide underground are also subject to the EPA's GHGRP requirements set forth at 40 CFR part 98.

Under 40 CFR part 98, facilities that inject carbon dioxide underground for long-term containment of carbon dioxide in subsurface geologic formations are specifically subject to 40 CFR part 98 subpart RR (Geologic Sequestration of Carbon Dioxide source category, referred to as *subpart RR*). Facilities that are subject to subpart RR, including UIC Class VI wells, are required to report basic information on carbon dioxide received for injection, develop and implement an EPA-approved site-specific Monitoring, Reporting, and Verification Plan (MRV Plans); and report the amount of carbon dioxide geologically sequestered using a mass balance approach and annual monitoring activities.

Facilities that inject carbon dioxide underground for the purposes of enhanced oil (EOR) and gas recovery or any other purpose other than geologic sequestration are required to report basic information on carbon dioxide received for injection under 40 CFR part 98 subpart UU (Injection of Carbon Dioxide source category, referred to as *subpart UU*). At present, the EPA does not generally require facilities that conduct EOR to report under subpart RR. However, the owner or operator may voluntarily choose to opt in to subpart RR. For both subparts RR and UU, annual reports are submitted under 40 CFR part 98 to the EPA's GHGRP and undergo verification by the EPA. Non-confidential data from these reports are published on the EPA's website.

b. Comments Received

Commenters noted that in order to qualify for section 45Q credits, IRS Form 8933 defines ''secure geological storage'' as requiring approval by the EPA of an MRV Plan under 40 CFR part 98 subpart RR. Thus, meeting the Form 8933 conditions would currently be achieved by receiving either (i) a UIC Class VI permit plus an EPA-approved MRV Plan, which UIC Class VI permit holders are already required to have because they are subject to subpart RR; or (ii) a UIC Class II permit plus an EPA-approved MRV Plan, which requires UIC Class II permit holders to opt in to subpart RR. In this manner, the Form 8933 requirement that UIC Class II permit holders receive an approved MRV Plan creates an additional burden on such holders because– it requires them to opt in to subpart RR to receive section 45Q credits. In addition, some commenters expressed concern that a requirement that they opt in to subpart RR, in addition to being a supplementary requirement, may create a misalignment with state mineral property and natural resource conservation laws.

Commenters supported the continued use of subpart RR, but most commenters sought an alternative method in addition to subpart RR. Many of these commenters considered the subpart RR requirements burdensome, for the reasons noted immediately above.

Many commenters suggested that a standard adopted by the International Organization for Standardization (ISO) and endorsed by the American National Standards Institute (ANSI), CSA/ANSI ISO 27916:19 standard, ''Carbon dioxide capture, transportation and geological storage—Carbon dioxide storage using enhanced oil recovery (CO_2-EOR),'' (CSA/ANSI ISO 27916:19) is a viable alternative to subpart RR for establishing secure geological storage for the use of qualified carbon oxide for EOR.

The CSA/ANSI ISO 27916:19 was developed for the purpose of quantifying and documenting the total carbon dioxide that is stored in association with carbon dioxide-EOR. In general, reporting under CSA/ANSI ISO 27916:19 (i) uses mass balance accounting, (ii) has established reporting and documentation requirements, and (iii) includes requirements for documenting a monitoring program and a containment assurance plan. ANSI, a not-for-profit organization dedicated to supporting the U.S. voluntary standards and conformity assessment system, adopted the CSA/ANSI ISO 27916:19 standard in 2019.

c. Regulatory Alternatives and Analysis

The Treasury Department and the IRS considered three options for defining standards for secure geological storage: (i) The requirements set forth in 40 CFR part 98 subpart RR; (ii) an election for the taxpayer to comply with either the subpart RR standards or the requirements set forth in CSA/ANSI ISO 27916:19 and (iii) other alternatives to

subpart RR, including allowing use of state programs.

In evaluating option (ii), the Treasury Department and the IRS, in consultation with the EPA, the DOE, and the Interior Department, agree with commenters that CSA/ANSI ISO 27916:19 is a viable quantification methodology that is adequate for the intent and purpose of the statute. Both subpart RR and CSA/ANSI ISO 27916:19 require an assessment and monitoring of potential leakage pathways; quantification of inputs, losses and storage through a mass balance approach; and documentation of steps and approaches. Under option (ii), operators of UIC Class II wells that follow the CSA/ANSI ISO 27916:19 standard could elect to report under subpart RR but would not be required to do so. Rather, they could continue to report to the EPA under subpart UU.

The Treasury Department and the IRS, in consultation with the EPA, the DOE, and the Interior Department, disagree with commenter suggestions to allow the reporting rules promulgated by states as an alternative to subpart RR or CSA/ANSI ISO 27916:19. Reporting rules among states are not uniform and states may have different reporting requirements and different governing bodies to whom carbon dioxide injection projects are required to report. The adoption of such rules by the Treasury Department and the IRS would substantially increase the administrative burden on the IRS. The Treasury Department and the IRS did not attempt to determine to what extent particular states' standards would fulfill the intent and purpose of the statute.

The ability for taxpayers to elect to use the CSA/ANSI ISO 27916:19 standard instead of subpart RR could yield economic differences in three ways. First, if the two standards are different in their costs of compliance, then allowing a choice allows EOR project operators to choose the less costly standard. This would reduce costs of compliance and regulatory burden. Second, to the extent that the difference in compliance costs between the two standards is high and that difference is a significant portion of start-up costs, then allowing a less expensive standard might lead to more investment and more new projects. Third, operators can use the option that best aligns with their project goals and timeframes. The Treasury Department and the IRS project that compliance costs for some taxpayers may be lower under the CSA/ANSI ISO 27916:19 standard than under subpart RR. Some commenters stated that subpart RR may create a misalignment for UIC Class II wells with both state mineral property and natural resource conservation laws; and that such potential misalignment would be costly to taxpayers. This stated misalignment would not be implicated with the use of the ISO standards.

The Treasury Department and the IRS recognize that the two standards differ in terms of who would be responsible for reviewing and approving a sequestration plan and for identifying leakage once a project is in place. In addition, the standards differ because unless otherwise required by law, the CSA/ANSI ISO 27916:19 standard does not require public reports of the amount of qualified carbon oxide sequestered, whereas the subpart RR standard does entail the public provision of such data. The Treasury Department and the IRS did not attempt to analyze the economic consequences of these differences.

The Treasury Department and the IRS did not attempt to provide quantitative estimates of the difference in compliance costs between the CSA/ANSI ISO 27916:19 standard and a regulatory alternative of requiring only subpart RR because suitable data are not readily available at this level of detail. Further, the Treasury Department and IRS did not attempt to estimate the effects of compliance cost differences on investment or sequestration.

The Treasury Department and the IRS solicit comments on these findings and particularly solicit data, models, or other evidence that could enhance the rigor with which the final regulations are developed.

ii. Credit Recapture

Section 45Q(f)(4) requires the Treasury Department and the IRS to promulgate regulations to provide for the recapture of section 45Q credits in the event of leakage. ''Recapture'' refers to the repayment of the tax credits claimed, and not to the capturing of CO_2 that may have leaked from the project after being injected.

In response to Notice 2019–32, 2019–21 I.R.B. 1187, several commenters requested clarification regarding credit recapture, including (i) when the tax would be due in relation to the year of a recapture event, (ii) how long the IRS can ''look back'' to recapture credits in the event of leakage (lookback period), and (iii) the length of time after ceasing to claim credits during which a leakage event would lead to recapture of credits.

All of these issues require a definition of the recapture period. The proposed regulations provide that the *recapture* period begins on the date of the first injection of qualified carbon oxide for disposal in secure geological storage or use as a tertiary injectant and ends the earlier of five years after the last taxable year in which the taxpayer claimed a section 45Q credit or the date monitoring ends under subpart RR requirements or the CSA/ANSI ISO 27916:19 standard.

For clarity we will describe two sub-portions of the recapture period, the ''post-credit-claiming period'' and the ''lookback period''. The ''post-credit-claiming period'' is the lesser of 5 years after the last taxable year in which the taxpayer claimed a section 45Q credit or the date monitoring ends under subpart RR requirements or the CSA/ANSI ISO 27916:19 standard. Depending on the project's individual requirements, the post-credit-claiming period is therefore between zero and five years. Whereas the ''lookback period'' is the portion of the recapture period during which the IRS can look back after a leakage event to recapture credits. Most commenters supported a lookback period of three to five years.

A leakage event that leads to recapture of credits can occur any time during the recapture period. A leakage event that occurs after the recapture period would not lead to recapture of credits.

The proposed regulations provide that any recapture amount will be accounted for in the taxable year that it is identified and reported. The amount of credits that can be recaptured in the event of leakage depends on the length of the lookback period and the amount of the leakage.

If, during the recapture period, it is determined that qualified carbon oxide has leaked to the atmosphere, the taxpayer will have a recapture amount if the leaked amount of qualified carbon oxide exceeds the amount of qualified carbon dioxide disposed of in secure geological storage or used as a tertiary injectant in that taxable year. That excess amount of leaked qualified carbon oxide will be recaptured at a credit rate calculated on a LIFO basis (that is, such excess leaked qualified carbon oxide will be deemed attributable first to the first preceding year, then to second preceding year, and so forth up to five years) for ease of administration. The taxpayer must add the amount of the recaptured section 45Q tax credit to the amount of tax due in the taxable year in which the recapture event occurs. This rule applies regardless of whether the project injected qualified carbon oxide in the taxable year.

In response to Notice 2019–32, commenters expressed concerns with how long the length of a lookback period after the project operator stops

claiming section 45Q credits (for example, if the project is finished or the period for claiming credits ends) that a leakage event can lead to recapture. Commenters were concerned that investors would deem the risk too high to invest if the end of the recapture period extended too long after the final year of claiming section 45Q credits. To address this concern the proposed regulations provide that the recapture period begins on the date of first injection of qualified carbon oxide for disposal in secure geological storage or use as a tertiary injectant and ends the earlier of three years after the last taxable year in which the taxpayer claimed a section 45Q credit or the date monitoring ends under subpart RR requirements or the CSA/ANSI ISO 27916:19 standard.

The Treasury Department and the IRS considered alternative specifications for the lookback period other than five years. Open-ended or undefined lookback periods would increase the financial risk associated with the project and dissuade investors, particularly for projects for which the section 45Q credit would constitute a sizeable share of revenue. The proposed regulations, by allowing for a specific and finite lookback period, will encourage more investment in projects relative to an unspecified or infinite period. The Treasury Department and the IRS, in consultation with the EPA, the DOE, and the Interior Department, have determined that for the period after the lookback period, existing environmental regulations and standards will ensure integrity consistent with the intent and purpose of the statute.

In examining possible lookback periods, the Treasury Department and the IRS have not developed a quantitative model to incorporate the costs of monitoring and the probability of leakage along with the tax administration burden involved in the lookback period.

The Treasury Department and the IRS welcome comments on the length of the lookback period and particularly solicit data, models, or other evidence that could enhance the rigor with which the final regulations are developed.

iii. Utilization of Qualified Carbon Oxide

Section 45Q(f)(5)(A) provides that ''utilization of qualified carbon oxide'' means (i) the fixation of such qualified carbon oxide through photosynthesis or chemosynthesis, such as through the growing of algae or bacteria; (ii) the chemical conversion of such qualified carbon oxide to a material or chemical compound in which such qualified carbon oxide is securely stored; or (iii) the use of such qualified carbon oxide for any other purpose for which a commercial market exists (with the exception of use as a tertiary injectant in a qualified enhanced oil or natural gas recovery project), as determined by the Secretary.

Section 45Q(f)(5)(B) provides a methodology to determine the amount of qualified carbon oxide utilized by the taxpayer. Such amount is equal to the metric tons of qualified carbon oxide which the taxpayer demonstrates, based upon an analysis of lifecycle greenhouse gas emissions and subject to such requirements as the Secretary, in consultation with the Secretary of Energy and the Administrator of the EPA, determines appropriate, were (i) captured and permanently isolated from the atmosphere, or (ii) displaced from being emitted into the atmosphere, through use of a process described in section 45Q(f)(5)(A). The term ''lifecycle greenhouse gas emissions'' has the same meaning given such term under subparagraph (H) of section 211(o)(1) of the Clean Air Act (42 U.S.C. 7545(o)(1)(H)), as in effect on the date of enactment of the BBA on February 9, 2018, except that ''product'' is substituted for ''fuel'' each place it appears in such subparagraph.

The term ''lifecycle greenhouse gas emissions'' means the aggregate quantity of greenhouse gas emissions (including direct emissions and significant indirect emissions such as significant emissions from land use changes), related to the full product lifecycle, including all stages of product and feedstock production and distribution, from feedstock generation or extraction through the distribution and delivery and use of the finished product to the ultimate consumer, where the mass values for all greenhouse gases are adjusted to account for their relative global warming potential.

Commenters proposed multiple methods for the Treasury Department and the IRS to allow for calculating ''utilization'' of qualified carbon oxide. The proposed regulations provide clarifications regarding: (i) Standards for the lifecycle analysis (LCA) of emissions that were captured or displaced for purposes of section 45Q(f)(5)(B); and (ii) the agency with responsibility to review the LCA.

The Treasury Department and the IRS, in consultation with the EPA and the DOE, have determined that the LCA must be in writing and either performed or verified by a professionally-licensed third party that uses generally-accepted standard practices of quantifying the greenhouse gas emissions of a product or process and comparing that impact to a baseline. In particular, the analysis must contain documentation consistent with the International Organization for Standardization (ISO) 14044:2006, ''Environmental management—Life cycle assessment—Requirements and Guidelines,'' as well as a statement documenting the qualifications of the third party.

The proposed regulations require a taxpayer submit an LCA report to the IRS and the DOE prior to the taxpayer claiming the section 45Q credit. The LCA will be subject to a technical review by the DOE, and the IRS, in consultation with the DOE and the EPA, will determine whether to approve the LCA.

The proposed regulations provide greater clarity and examples for calculating qualified carbon oxide utilization. This enhanced clarity should increase transparency and lower compliance burden. In addition, the proposed regulations allow for oversight of the LCA plans by a third party, the DOE, and the IRS (in consultation with the DOE and the EPA); evaluation and approval of the plans before the taxpayer claims the credit will potentially reduce taxpayer compliance costs and IRS administrative costs. Following industry-specific standards will also increase clarity in qualifying for the section 45Q credit.

The proposed regulations provide an economic gain arising from enhanced clarity regarding the rules of the section 45Q credit within the context of the intent and purpose of the statute. The Treasury Department and the IRS project that this clarity will encourage additional investment in carbon oxide utilization projects relative to the no-action baseline. The Treasury Department and the IRS have not estimated this gain because we do not have readily available data or models to predict (i) the interpretations that taxpayers might have made in the absence of this guidance, and (ii) the effect of such guidance on the investment that taxpayers would make, relative to alternative regulatory approaches or the no-action baseline.

The Treasury Department and the IRS solicit comments on the economic consequences of these decisions and particularly solicit data, models, or other evidence that could enhance the rigor with which the final regulations are developed.

II. Paperwork Reduction Act

The collection of information in these proposed regulations with respect to section 45Q are in proposed § 1.45Q–1(e), § 1.45Q–1(h)(3)(iv), § 1.45Q–

1(h)(2)(v), and § 1.45Q–2(h)(2), § 1.45Q–3(d), and § 1.45Q–4(c)(1).

The collection of information in proposed § 1.45Q–1(e) is an election to have the dollar amounts applicable under § 1.45Q–1(b) apply in lieu of the dollar amounts applicable under § 1.45Q–1(d) for each metric ton of qualified carbon oxide that a taxpayer captures using carbon capture equipment which is originally placed in service at a qualified facility on or after February 9, 2018. A new section 45Q(f)(3)(B) election must be made for each taxable year that the taxpayer wishes to allow a credit claimant to claim section 45Q credits. The election must be made on a Form 8933 (or successor forms, or pursuant to instructions and other guidance), and applies to all metric tons of qualified carbon oxide captured by the taxpayer at the qualified facility throughout the full 12-year credit period. The IRS is contemplating making additional changes to the Form 8933 to take these proposed regulations into account.

The collection of information in proposed § 1.45Q–1(h)(3)(iv) is an election that a taxpayer (electing taxpayer) eligible for the section 45Q credit may make to allow the person that disposes of the qualified carbon oxide, utilizes the qualified carbon oxide, or uses the qualified carbon oxide as a tertiary injectant to claim the credit (credit claimant). The electing taxpayer that makes the section 45Q(f)(3)(B) election must file a statement of election containing the information described in § 1.45Q–1(h)(3)(iv) with the electing taxpayer's Federal income tax return or Form 1065 for each taxable year in which the credit arises. The section 45Q(f)(3)(B) election must be made in accordance with Form 8933 (or successor forms, or pursuant to instructions and other guidance) no later than the time prescribed by law (including extensions) for filing the Federal income tax return for the year in which the credit arises. The election may not be filed with an amended Federal income tax return, an amended Form 1065, or an AAR, as applicable, after the prescribed date (including extensions) for filing the original Federal income tax return or Form 1065 for the year, with the exception of amended Federal income tax returns, amended Forms 1065, or AARs, as applicable, for any taxable year ending after February 9, 2018, and before taxable years beginning after the date of issuance of this proposed regulation. New section 45Q(f)(3)(B) elections must be made for each taxable year that the electing taxpayer wishes to allow credit claimants to claim section 45Q credits. The IRS is contemplating making additional changes to the Form 8933 to take these proposed regulations into account.

The collection of information in proposed § 1.45Q–1(h)(2)(v) requires that if a taxpayer enters into a binding written contract with a third party that physically carries out the disposal, injection, or utilization of qualified carbon oxide, the existence of each contract and the parties involved must be reported to the IRS annually on a Form 8933 (or successor forms, or pursuant to instructions and other guidance) by each party to the contract, regardless of the party claiming the credit. The IRS is contemplating making additional changes to the Form 8933 to take these proposed regulations into account.

The collection of information in proposed § 1.45Q–2(h)(2) requires that a taxpayer that claims a section 45Q credit for qualified carbon oxide that is captured and then used as a tertiary injectant in a qualified enhanced oil or natural gas recovery project certify such qualified enhanced oil or natural gas recovery project as required under § 1.43–3. This requires that the taxpayer obtain a petroleum engineer's certification under § 1.43–3(a)(3) for each project that must be attached to a Form 8933 (or successor forms, or pursuant to instructions and other guidance) and filed not later than the last date prescribed by law (including extensions) for filing the operator's or designated owner's Federal income tax return or Form 1065 for the first taxable year in which qualified carbon oxide is injected into the reservoir. If a section 45Q credit is claimed on an amended Federal income tax return, an amended Form 1065, or an AAR, as applicable, the petroleum engineer's certification will be treated as filed timely if it is attached to a Form 8933 that is submitted with such amended federal income tax return, amended Form 1065, or AAR. With respect to a section 45Q credit that is claimed on a timely filed Federal income tax return or Form 1065 for a taxable year ending after February 9, 2018 and beginning before the date of issuance of this proposed regulation, for which the petroleum engineer's certification was not submitted, the petroleum engineer's certification will be treated as filed timely if it is attached to an amended Form 8933 for any taxable year ending after February 9, 2018, but not for taxable years beginning after June 2, 2020. Additionally, the taxpayer is required to provide an operator's continued certification under § 1.43–3(b)(3) for each project that must be attached to a Form 8933 (or successor forms, or pursuant to instructions and other guidance) and filed not later than the last date prescribed by law (including extensions) for filing the operator's or designated owner's Federal income tax return or Form 1065 for taxable years after the taxable year for which the petroleum engineer's certification is filed but not after the taxable year in which injection activity ceases and all injection wells are plugged and abandoned. The IRS is contemplating making additional changes to the Form 8933 to take these proposed regulations into account.

The collection of information in proposed § 1.45Q–3(d) requires a taxpayer that claims a section 45Q credit for qualified carbon oxide that is captured and then used as a tertiary injectant in a qualified enhanced oil or natural gas recovery project to certify the volume of carbon oxide claimed for purposes of section 45Q. A taxpayer that reported volumes of carbon oxide to the EPA pursuant to subpart RR may self-certify the volume of carbon oxide claimed for purposes of section 45Q. Alternatively, if the taxpayer determined volumes pursuant to CSA/ANSI ISO 27916:19, a taxpayer may prepare documentation as outlined in CSA/ANSI 27916:2019 internally, but such documentation must be provided to a qualified independent engineer or geologist, who then must certify that the documentation provided, including the mass balance calculations as well as information regarding monitoring and containment assurance is accurate and complete. Taxpayers that capture carbon oxide giving rise to the section 45Q credit must file Form 8933 (or successor forms, or pursuant to instructions and other guidance) with a timely filed tax return, including extensions. Taxpayers that dispose of, inject, or utilize qualified carbon oxide must also file Form 8933 (or successor forms, or pursuant to instructions and other guidance) with a timely filed F Federal income tax return or Form 1065, including extensions. The IRS is contemplating making additional changes to the Form 8933 to take these proposed regulations into account.

The collection of information in proposed § 1.45Q–4(c)(1) requires a taxpayer that utilizes qualified carbon oxide to measure the amount of carbon oxide captured and utilized through a combination of direct measurement and life cycle analysis (LCA). The measurement and written LCA report must be performed by or verified by an independent third party. The report must contain documentation consistent with the International Organization for Standardization (ISO) 14044:2006,

''Environmental management—Life cycle assessment—Requirements and Guidelines,'' as well as a statement documenting the qualifications of the third party, including proof of appropriate professional license or foreign equivalent, and an affidavit from the third-party stating that it is independent from the taxpayer. The taxpayer must submit the written LCA report to the IRS and the DOE. The LCA will be subject to a technical review by the DOE, and the IRS, in consultation with the DOE and the EPA, will determine whether to approve the LCA.

For purposes of the Paperwork Reduction Act of 1995 (51087 U.S.C. 3507(d)) (PRA), the reporting burden associated with proposed § 1.45Q–1(e), § 1.45Q–1(h)(3)(iv), § 1.45Q–1(h)(2)(v), § 1.45Q–2(h)(2), § 1.45Q–3(d), and § 1.45Q–4(c)(1) will be reflected in the IRS Paperwork Reduction Act Submission for the Form 8933 (OMB control numbers 1545–0123 and 1545–2132). The IRS is anticipating making revisions to Form 8933 to take these proposed regulations into account. The Treasury Department and the IRS request comments on all aspects of information collection burdens related to the proposed regulations. In addition, when available, drafts of IRS forms are posted for comment at *www.irs.gov/draftforms.*

The current status of the Paperwork Reduction Act submissions related to the section 45Q credit is provided in the following table. The section 45Q provisions are included in aggregated burden estimates for the OMB control numbers listed below which, in the case of 1545–0123, represents a total estimated burden time, including all other related forms and schedules for corporations, of 3.157 billion hours and total estimated monetized costs of $58.148 billion ($2017). The burden estimates provided in the OMB control numbers are aggregate amounts that relate to the entire package of forms associated with the OMB control number, and will in the future include but not isolate the estimated burden of only the section 45Q requirements. These numbers are therefore unrelated to the future calculations needed to assess the burden imposed by the proposed regulations. No burden estimates specific to the proposed regulations are currently available. The Treasury Department has not estimated the burden, including that of any new information collections, related to the requirements under the proposed regulations. Those estimates would capture both changes made to section 45Q by the BBA and those that arise out of discretionary authority exercised in the proposed regulations. The Treasury Department and the IRS request comments on all aspects of information collection burdens related to the proposed regulations.

When available, drafts of IRS forms are posted for comment at *www.irs.gov/draftforms.*

Form	Type of filer	OMB No(s).	Status
Form 8933	Business	1545–2132	Sixty-day notice published in the **Federal Register** on 10/21/19 (84 FR 56283). Public comment period closed on 12/20/19. Thirty-day notice published in the **Federal Register** on 1/31/20 (85 FR 5776). Public comment period closed on 3/2/20. OIRA approval is pending.
Form 8933	Business (NEW Model).	1545–0123	Sixty-day notice published in the **Federal Register** on 9/30/19 (84 FR 51718). Public Comment period closed on 11/29/19. Thirty-day notice published in the **Federal Register** on 12/19/19 (84 FR 69825). Public Comment period closed on 1/21/20. Approved by OIRA on 1/30/20.
	Link: *https://hs-www-federalregister-gov.tickly.io/documents/2019/10/21/2019-22844/proposed-collection-comment-request-for-form-8933.*		

III. Regulatory Flexibility Act

The Regulatory Flexibility Act (5 U.S.C. 601 *et seq.*) (RFA) imposes certain requirements with respect to Federal rules that are subject to the notice and comment requirements of section 553(b) of the Administrative Procedure Act (5 U.S.C. 551 *et seq.*) and that are likely to have a significant economic impact on a substantial number of small entities. Unless an agency determines that a proposal is not likely to have a significant economic impact on a substantial number of small entities, section 603 of the RFA requires the agency to present an initial regulatory flexibility analysis (IRFA) of the proposed rule. The Treasury Department and the IRS have not determined whether the proposed rule, when finalized, will likely have a significant economic impact on a substantial number of small entities. This determination requires further study. However, because there is a possibility of significant economic impact on a substantial number of small entities, an IRFA is provided in these proposed regulations. The Treasury Department and the IRS invite comments on both the number of entities affected and the economic impact on small entities.

Pursuant to section 7805(f), this notice of proposed rulemaking has been submitted to the Chief Counsel of Advocacy of the Small Business Administration for comment on its impact on small business.

1. Need for and Objectives of the Rule

The proposed regulations will provide greater clarity to taxpayers for purposes of claiming the section 45Q credit for the capture and disposal, injection, or utilization of qualified carbon oxide. The proposed rule is expected to encourage taxpayers to invest in carbon capture technologies. Thus, the Treasury Department and the IRS intend and expect that the proposed rule will deliver benefits across the economy that will beneficially impact various industries and reduce emissions of carbon oxides that would otherwise be released into the atmosphere as industrial emission of greenhouse gasses or lead to such release.

2. Affected Small Entities

The Small Business Administration estimates in its 2018 Small Business Profile that 99.9 percent of United States businesses meet its definition of a small business. The applicability of these proposed regulations does not depend on the size of the business, as defined by the Small Business Administration. As described more fully in the preamble to this proposed regulation and in this IRFA, these rules may affect a variety of different businesses across serval different industries.

The section 45Q credit incentivizes three different categories of activities related to captured carbon oxide. First, the section 45Q credit is available to taxpayers who capture carbon oxide and dispose of it in secure geological storage. This would occur if it were injected into a geological formation, such as a deep saline formation, an oil and gas reservoir, or an unminable coal

seam. The taxpayer claiming the credit for carbon oxide that is securely stored can be either the taxpayer who owns the capture equipment, or if an election is made, the taxpayer who disposes of the carbon oxide.

Second, the section 45Q credit is also available for carbon oxide captured and used as a tertiary injectant in a qualified enhanced oil or natural gas recovery project and disposed of in secure geological storage. The taxpayer claiming the credit for carbon oxide that is used as a tertiary injectant in enhanced oil recovery projects can be either the taxpayer who owns the capture equipment, or if an election is made, the taxpayer who uses the carbon oxide as a tertiary injectant in a qualified enhanced oil or natural gas recovery project.

And third, the section 45Q credit is available for carbon oxide ''utilized'' by fixing it through photosynthesis or chemosynthesis, converted to a material or chemical compound in which it is securely stored, or used for any other purpose for which a commercial market exists. The taxpayer claiming the credit for utilization of carbon oxide can be either the taxpayer who owns the carbon capture equipment, or if an election is made, the taxpayer who utilizes the carbon oxide.

Because the potential credit claimants in all three of these scenarios can vary, including potential tax equity investors from the financial services sector as credit claimants, it is difficult to estimate at this time the impact of these proposed regulations, if any, on small businesses.

The Treasury Department and the IRS expect to receive more information on the impact on small businesses through comments on this proposed rule and again when taxpayers start to claim the section 45Q credit using the guidance and procedures provided in these proposed regulations.

3. Impact of the Rule

The proposed regulations will allow taxpayers to plan investments and transactions based on the ability to claim the section 45Q credit. The increased use of the section 45Q credit may lead to increased investment in infrastructure to transport carbon dioxide, and increased development of carbon capture technologies. In addition, the increased use of the section 45Q credit will incentivize the development of technologies for utilization of carbon oxide. The recordkeeping and reporting requirements will increase for taxpayers that claim the section 45Q credit. This includes costs associated with the taxpayer filing the Form 8933, as well as required election statements and maintaining records to substantiate carbon capture of carbon oxide, disposal in secure geological storage, use as a tertiary injectant in a qualified enhanced oil or natural gas recovery project and disposal in secure geological storage, or utilization. Each taxpayer will be required to file a separate Form 8933 for each year that a section 45Q credit is claimed or that an election is made with respect to a section 45Q credit. Although the Treasury Department and the IRS do not have sufficient data to determine precisely the likely extent of the increased costs of compliance, the estimated burden of complying with the recordkeeping and reporting requirements are described in the Paperwork Reduction Act section of the preamble.

4. Alternatives Considered

As described in more detail in the Regulatory Impact Analysis of this preamble, the Treasury Department and the IRS considered alternatives to the proposed regulations. For example, in providing rules related to how to demonstrate secure geological storage in the case of tertiary injection and disposal through secure geological storage, the Treasury Department and the IRS considered whether to (i) require compliance with subpart RR, (ii) allow use of subpart RR or CSA/ANSI ISO 27916:19, or (iii) other alternatives to subpart RR including use of state programs. Commenters to Notice 2019–32, 2019–21 I.R.B. 1187, consistently recommended CSA/ANSI ISO 27916:19 as a potential alternative to subpart RR. The Treasury Department and the IRS, in consultation with the DOE, the EPA and the Interior Department, agreed that, in the case of tertiary injection and disposal through secure geological storage, allowing the use of subpart RR or CSA/ANSI ISO 27916:19 would sufficiently demonstrate secure geological storage for purposes of the statutory requirement, without creating or imposing undue burdens on taxpayers.

5. Duplicative, Overlapping, or Conflicting Federal Rules

The proposed rule would not duplicate, overlap, or conflict with any relevant Federal rules. As discussed above, the proposed rule would merely provide procedures and definitions to allow taxpayers to claim the section 45Q credit. The Treasury Department and the IRS invite input from interested members of the public about identifying and avoiding overlapping, duplicative, or conflicting requirements.

Comments and Requests for a Public Hearing

Before these proposed regulations are adopted as final regulations, consideration will be given to any comments that are submitted timely to the IRS as prescribed in this preamble under the **ADDRESSES** heading. The Treasury Department and the IRS request comments on all aspects of the proposed regulations. Specifically, in section 4 of the Summary of Comments and Explanation of Provisions, the Treasury Department and the IRS request specific comments on how to achieve consistency in boundaries and baselines so that similarly situated taxpayers will be treated consistently. The Treasury Department and the IRS also request specific comments regarding the definition of commercial markets and standards for Lifecycle Analysis. Additionally, in section 5 of the Summary of Comments and Explanation of Provisions, the Treasury Department and the IRS request specific comments on how to apply the recapture provisions to section 45Q credits that are carried forward to future taxable years due to insuffificent income tax liability in the current taxable year.

Any electronic comments submitted, and to the extent practicable any paper comments submitted, will be made available at *www.regulations.gov* or upon request. A public hearing will be scheduled if requested in writing by any person who timely submits electronic or written comments as prescribed in this preamble under the ''DATES'' heading. Requests for a public hearing are also encouraged to be made electronically. If a public hearing is scheduled, notice of the date and time for the public hearing will be published in the **Federal Register**. Announcement 2020–4, 2020–17 IRB 1, provides that until further notice, public hearings conducted by the IRS will be held telephonically. Any telephonic hearing will be made accessible to people with disabilities.

IV. Unfunded Mandates Reform Act

Section 202 of the Unfunded Mandates Reform Act of 1995 requires that agencies assess anticipated costs and benefits and take certain other actions before issuing a final rule that includes any Federal mandate that may result in expenditures in any one year by a state, local, or tribal government, in the aggregate, or by the private sector, of $100 million in 1995 dollars, updated annually for inflation. In 2018, that threshold is approximately $150 million. This rule does not include any Federal mandate that may result in expenditures by state, local, or tribal

governments, or by the private sector in excess of that threshold.

V. Executive Order 13132: Federalism

Executive Order 13132 (entitled Federalism) prohibits an agency (to the extent practicable and permitted by law) from promulgating any regulation that has federalism implications, unless the agency meets the consultation and funding requirements of section 6 of the Executive Order, if the rule either imposes substantial, direct compliance costs on state and local governments, and is not required by statute, or preempts state law. This proposed rule does not have federalism implications and does not impose substantial direct compliance costs on state and local governments or preempt state law within the meaning of the Executive Order.

Drafting Information

The principal author of the proposed regulations is Maggie Stehn of the Office of Associate Chief Counsel (Passthroughs & Special Industries). However, other personnel from the Treasury Department and the IRS participated in the development of the proposed regulations.

List of Subjects

26 CFR Part 1

Income taxes, Reporting and recordkeeping requirements.

Proposed Amendments to the Regulations

Accordingly, 26 CFR part 1 is proposed to be amended as follows:

PART 1—INCOME TAXES

■ **Paragraph 1.** The authority citation for part 1 is amended by adding entries in numerical order to read in part as follows:

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

* * * * *

Section 1.45Q–1 also issued under 26 U.S.C. 45Q.

Section 1.45Q–2 also issued under 26 U.S.C. 45Q(c), (d), and (e).

Section 1.45Q–3 also issued under 26 U.S.C. 45Q(f)(2).

Section 1.45Q–4 also issued under 26 U.S.C. 45Q(f)(5).

Section 1.45Q–5 also issued under 26 U.S.C. 45Q(f)(4).

* * * * *

■ **Par. 2.** Sections 1.45Q–0, 1.45Q–1, 1.45Q–2, 1.45Q–3, 1.45Q–4, and 1.45Q–5 are added to read as follows:

§ 1.45Q–0 Table of Contents.

This section lists the captions contained in §§ 1.45Q–1 through 1.45Q–5.

§ 1.45Q–1 Credit for Carbon Oxide Sequestration.

(a) *In general.* For purposes of section 38 of the Internal Revenue Code (Code), the carbon oxide sequestration credit is determined under section 45Q of the Code and this section. Generally, the amount of the section 45Q credit and the party that is eligible to claim the credit depend on whether the taxpayer captures qualified carbon oxide using carbon capture equipment originally placed in service at a qualified facility before February 9, 2018, or on or after February 9, 2018, and whether the taxpayer disposes of the qualified carbon oxide in secure geological storage without using it as a tertiary injectant in a qualified enhanced oil or natural gas recovery project (disposal), uses it as a tertiary injectant in a qualified enhanced oil or natural gas recovery project and disposes of it in secure geological storage (injection), or utilizes it in a manner described in section 45Q(f)(5) and § 1.45Q–4 (utilization). The section 45Q credit applies only with respect to qualified carbon oxide the capture and disposal, injection, or utilization of which is within the United States (within the meaning of section 638(1) of the Code) or a possession of the United States (within the meaning of section 638(2)).

(b) *Credit amount for carbon capture equipment originally placed in service before February 9, 2018.* For carbon capture equipment originally placed in service at a qualified facility before February 9, 2018, the amount of credit determined under section 45Q(a) and this section is the sum of—

(1) $20 per metric ton of qualified carbon oxide that is—

(i) Captured by the taxpayer at the qualified facility and disposed of by the taxpayer in secure geological storage, and

(ii) Not used by the taxpayer as a tertiary injectant in a qualified enhanced oil or natural gas recovery project or utilized by the taxpayer in a manner described in section 45Q(f)(5) and § 1.45Q–4, and

(2) $10 per metric ton of qualified carbon oxide that is—

(i) Captured by the taxpayer at the qualified facility and used by the taxpayer as a tertiary injectant in a qualified enhanced oil or natural gas recovery project, and disposed of by the taxpayer in secure geological storage, or

(ii) Captured by the taxpayer at the qualified facility and utilized by the taxpayer in a manner described in section 45Q(f)(5) and § 1.45Q–4.

(3) Inflation Adjustment. In the case of any taxable year beginning in a calendar year after 2009, there is substituted for each dollar amount contained in paragraphs (b)(1) and (b)(2) of this section an amount equal to the product of—

(i) Such dollar amount, multiplied by

(ii) The inflation adjustment factor for such calendar year determined under section 43(b)(3)(B) for such calendar year, determined by substituting ''2008'' for ''1990.''

(c) *Credit amount for carbon capture equipment originally placed in service on or after February 9, 2018.* For carbon capture equipment originally placed in service at a qualified facility on or after February 9, 2018, the amount of credit determined under sections 45Q(a)(3) and (4) and this section is the sum of—

(1) The applicable dollar amount (as determined under paragraphs (d)(1) and (d)(2) of this section) per metric ton of qualified carbon oxide that is captured during the 12-year period beginning on the date the equipment was originally placed in service, and is—

(i) Disposed of by the taxpayer in secure geological storage, and

(ii) Not used by the taxpayer as a tertiary injectant in a qualified enhanced oil or natural gas recovery project or utilized by the taxpayer in a manner described in sections 45Q(f)(5) and § 1.45Q–4; and

(2) The applicable dollar amount (as determined under paragraphs (d)(3) and (d)(4) of this section) per metric ton of qualified carbon oxide that is captured during the 12-year period beginning on the date the equipment as originally placed in service and is—

(i) Used by the taxpayer as a tertiary injectant in a qualified enhanced oil or natural gas recovery project and disposed of by the taxpayer in secure geological storage, or

(ii) Utilized by the taxpayer in a manner described in sections 45Q(f)(5) and § 1.45Q–4.

(d) *Applicable dollar amount.* In general, the applicable dollar amount depends on whether section 45Q(a)(3) and paragraph (c)(1) of this section applies or section 45Q(a)(4) and paragraph (c)(2) of this section applies, and whether the taxable year begins in a calendar year after 2016 and before 2027.

(1) *Applicable dollar amount for any taxable year beginning in a calendar year after 2016 and before 2027 for qualified carbon oxide not used as a tertiary injectant or utilized.* For purposes of section 45Q(a)(3) and paragraph (c)(1) of this section, the applicable dollar amount for each taxable year beginning in a calendar year after 2016 and before 2027 is:

Year	Applicable dollar amount
2017	$22.66
2018	25.70
2019	28.74
2020	31.77
2021	34.81
2022	37.85
2023	40.89
2024	43.92
2025	46.96
2026	50.00

(2) *Applicable dollar amount for any taxable year beginning in a calendar year after 2026 for qualified carbon oxide not used as a tertiary injectant or utilized.* For purposes of section 45Q(a)(3) and paragraph (c)(1) of this section, the applicable dollar amount for any taxable year beginning in any calendar year after 2026 is an amount equal to the product of $50 and the inflation adjustment factor for the calendar year determined under section 43(b)(3)(B) for the calendar year, determined by substituting ''2025'' for ''1990.''

(3) *Applicable dollar amount for any taxable year beginning in a calendar year after 2016 and before 2027 for qualified carbon oxide used as a tertiary injectant or utilized.* For purposes of section 45Q(a)(4) and paragraph (c)(2) of this section, the applicable dollar amount for each taxable year beginning in a calendar year after 2016 and before 2027 is:

Year	Applicable dollar amount
2017	$12.83
2018	15.29
2019	17.76
2020	20.22
2021	22.68
2022	25.15
2023	27.61
2024	30.07
2025	32.54
2026	35.00

(4) *Applicable dollar amount for any taxable year beginning in a calendar year after 2026 for qualified carbon oxide used as a tertiary injectant or*

utilized. For purposes of section 45Q(a)(4) and paragraph (c)(2) of this section, the applicable dollar amount for any taxable year beginning in any calendar year after 2026, is an amount equal to the product of $35 and the inflation adjustment factor for such calendar year determined under section 43(b)(3)(B) for such calendar year, determined by substituting ''2025'' for ''1990.''

(e) *Election to apply the $10 and $20 credit amounts in lieu of the applicable dollar amounts.* For purposes of determining the carbon oxide sequestration credit under this section, a taxpayer may elect to have the dollar amounts applicable under section 45Q(a)(1) or (2) and paragraph (b) of this section apply in lieu of the dollar amounts applicable under section 45Q(a)(3) or (4) and paragraph (d) of this section for each metric ton of qualified carbon oxide which is captured by the taxpayer using carbon capture equipment which is originally placed in service at a qualified facility on or after February 9, 2018. The election must be made on a Form 8933, *Carbon Oxide Sequestration Credit* (or successor forms, or pursuant to instructions and other guidance), and applies to all metric tons of qualified carbon oxide captured by the taxpayer at the qualified facility throughout the full 12-year credit period.

(f) *Application of section 45Q for certain carbon capture equipment placed in service before February 9, 2018.* In the case of any carbon capture equipment placed in service before February 9, 2018, the credits under section 45Q(a)(1) and (a)(2) and paragraphs (b)(1) and (b)(2) of this section apply with respect to qualified carbon oxide captured using such equipment before the end of the calendar year in which the Secretary, in consultation with the Administrator of the Environmental Protection Agency (EPA), certifies that, during the period beginning after October 3, 2008, a total of 75,000,000 metric tons of qualified carbon oxide have been taken into account in accordance with section 45Q(a), as in effect on February 9, 2018, and section 45Q(a)(1) and (2). In general, a taxpayer may not claim credits under section 45Q(a)(1) and (a)(2) in taxable years after the year in which the 75,000,000 metric ton limit is reached with respect to carbon capture equipment placed in service before February 9, 2018. However, see § 1.45Q–2(g)(4) regarding the election for applicable facilities to treat certain carbon capture equipment as having been placed in service on February 9, 2018.

(g) *Installation of additional carbon capture equipment.* In general, a facility that placed carbon capture equipment in service before February 9, 2018, is entitled to the credit amounts for property placed in service before February 9, 2018, subject to the limitations under paragraph (f) of this section. The same facility may place additional carbon capture equipment in service on or after February 9, 2018. The additional carbon capture equipment is eligible to qualify for the section 45Q credit amounts for equipment placed in service on or after February 9, 2018.

(1) *Allocation of section 45Q credits for facilities installing additional carbon capture equipment.* In the case of a qualified facility placed in service before February 9, 2018, for which additional carbon capture equipment is placed in service on or after February 9, 2018, the amount of qualified carbon oxide which is captured by the taxpayer is equal to—

(i) For purposes of section 45Q(a)(1)(A) and (2)(A), and paragraphs (b)(1) and (b)(2) of this section, the lesser of the total amount of qualified carbon oxide captured at such facility for the taxable year, or the total amount of the carbon dioxide capture capacity of the carbon capture equipment in service at such facility on February 8, 2018, and

(ii) For purposes of section 45Q(a)(3)(A) and (4)(A), and paragraphs (c)(1) and (c)(2) of this section, an amount (not less than zero) equal to the excess of the total amount of qualified carbon oxide captured at such facility for the taxable year, over the total amount of the carbon dioxide capture capacity of the carbon capture equipment in service at such facility on February 8, 2018.

(2) *Additional carbon capture equipment.* A physical modification or equipment addition that results in an increase in the carbon dioxide capture capacity of existing carbon capture equipment constitutes the installation of additional carbon capture equipment. Merely increasing the amount of carbon dioxide captured by existing carbon capture equipment, even if it operated above the carbon dioxide capture capacity, does not constitute the installation of additional carbon capture equipment.

(3) *New carbon capture equipment.* The cost of a physical modification or equipment addition with a cost that satisfies the 80/20 Rule in § 1.45Q–2(g)(5) constitutes the installation of new carbon capture equipment rather than the installation of additional carbon capture equipment.

(4) *Examples.* The following examples illustrate the rules of this paragraph (g):

(i) *Example 1.* Taxpayer X owns qualifying facility QF. In 2017, X placed in service three units of carbon capture equipment—CC1, CC2, and CC3—to capture carbon dioxide emitted by QF. Each of CC1, CC2, and CC3 are capable of capturing 50,000 metric tons of carbon dioxide. In 2017, X enters into a binding written contract with Y to provide 100,000 metric tons of carbon dioxide annually for Y to dispose of in secure geological storage. X operates CC1 and CC2 to capture carbon dioxide pursuant to the binding written contract with Y, leaving CC3 idle. In 2020, X enters into a binding written contract with Z to provide 50,000 metric tons of carbon dioxide annually for Z to dispose of in secure geological storage. X operates CC3 to capture carbon dioxide pursuant to the binding written contract with Z. CC3 is not additional carbon capture equipment under § 1.45Q–1(g)(2). As a result, any section 45Q credits attributable to the carbon dioxide captured by CC3 and disposed of by Z are calculated under section 45Q(a)(1) and § 1.45Q–1(b)(1), and are subject to the 75,000,000 metric ton limitation described in section 45Q(g) and § 1.45Q–1(f).

(ii) *Example 2.* Assume the same facts as in Example 1, except that in 2019, X makes a physical modification to upgrade CC3 that results in the ability of CC3 to capture 100,000 metric tons of carbon dioxide. The physical modification to upgrade CC3 does not satisfy the 80/20 Rule in § 1.45Q–2(g)(5). In 2020 X enters into a binding written contract with Z to provide 100,000 metric tons of carbon dioxide annually for Z to dispose of in secure geological storage. X operates CC3 to capture carbon dioxide pursuant to the binding written contract with Z. Because the carbon dioxide capture capacity of CC3 was 50,000 metric tons of carbon dioxide before the physical modification and 100,000 metric tons of carbon dioxide after the physical modification, the physical modification to upgrade CC3 is considered the installation of additional carbon capture equipment under § 1.45Q–1(g)(2). As a result, any section 45Q credits attributable to the first 50,000 metric tons of carbon dioxide captured by CC3 and disposed of by Z are calculated under section 45Q(a)(1) and § 1.45Q–1(b)(1), and are subject to the 75,000,000 metric ton limitation described in section 45Q(g) and § 1.45Q–1(f). Any section 45Q credits attributable to additional carbon dioxide captured by CC3 and disposed of by Z in excess of those first 50,000 metric tons are calculated under section 45Q(a)(4) and § 1.45Q–1(c)(2), and are not subject to the 75,000,000 metric ton limitation described in section 45Q(g) and § 1.45Q–1(f).

(iii) *Example 3.* Assume the same facts as in Example 2, except that the physical modification to upgrade CC3 satisfies the 80/20 Rule in § 1.45Q–2(g)(5). The physical modification to upgrade CC3 is considered the installation of new carbon capture equipment under § 1.45Q–1(g)(2) and § 1.45Q–1(g)(3). As a result, any section 45Q credits attributable to carbon dioxide captured by CC3 and disposed of by Z are calculated under section 45Q(a)(4) and

§ 1.45Q–1(c)(2), and are not subject to the 75,000,000 metric ton limitation described in section 45Q(g) and § 1.45Q–1(f).

(h) *Eligibility for the section 45Q credit.* The following rules determine who may claim the section 45Q credit.

(1) *Person to whom the section 45Q credit is attributable.* In general, the person to whom the credit is attributable is the person who may claim the credit. Except as provided in § 1.45Q–1(h)(3), the section 45Q credit is attributable to the following persons—

(i) *Equipment placed in service before February 9, 2018.* In the case of qualified carbon oxide captured using carbon capture equipment that is originally placed in service at a qualified facility before February 9, 2018, the section 45Q credit is attributable to the person that captures and physically or contractually ensures the disposal, injection, or utilization of such qualified carbon oxide.

(ii) *Equipment placed in service on or after February 9, 2018.* In the case of qualified carbon oxide captured using carbon capture equipment that is originally placed in service at a qualified facility on or after February 9, 2018, the section 45Q credit is attributable to the person that owns the carbon capture equipment and physically or contractually ensures the capture and disposal, injection, or utilization of such qualified carbon oxide.

(iii) *Reporting.* The taxpayer described in § 1.45Q–1(h)(1) as eligible to claim the section 45Q credit must claim the credit on a Form 8933 (or successor forms, or pursuant to instructions and other guidance) with the taxpayer's Federal income tax return or Form 1065 for each taxable year for which the taxpayer is eligible. The taxpayer must provide the name and location of the qualified facilities at which the qualified carbon oxide was captured. If the taxpayer is claiming the section 45Q credit on an amended Federal income tax return, an amended Form 1065, or an AAR, as applicable, the taxpayer must state AMENDED RETURN FOR SECTION 45Q CREDIT at the top of the amended Federal income tax return, the amended Form 1065, or the AAR, as applicable. In addition, as provided in Revenue Procedure 2020–23, 2020–18 I.R.B. 749 (see § 601.601(d)(2)(i)(b) and (ii) of this chapter), the exception applies regarding the time to file an amended return by a BBA partnership for the 2018 and 2019 taxable years. The amended Federal income tax return or the amended Form 1065 must be filed, in no event, later than the applicable period of limitations on assessment for the taxable year for which the amended Federal income tax return or Form 1065 is being filed. In the case of a BBA partnership that chooses not to file an amended Form 1065 as permitted under Revenue Procedure 2020–23, the BBA partnership may make a late election by filing an AAR on or before October 15, 2021, but in no event, later than the applicable period of limitations on making adjustments under section 6235 for the reviewed year, as defined in § 301.6241–1(a)(8) of the Procedure and Administration Regulations (26 CFR part 301).

(2) *Contractually ensuring disposal, injection, or utilization of qualified carbon oxide.* A taxpayer is not required to physically carry out the disposal, injection, or utilization of qualified carbon oxide to claim the section 45Q credit if the taxpayer contractually ensures in a binding written contract that the party that physically carries out the disposal, injection, or utilization of the qualified carbon oxide does so in the manner required under section 45Q and these regulations.

(i) *Binding written contract.* A written contract is binding only if it is enforceable under State law against both the taxpayer and the party that physically carries out the disposal, injection, or utilization of the qualified carbon oxide, or a predecessor or successor of either, and does not limit damages to a specified amount.

(ii) *Multiple binding written contracts permitted.* A taxpayer may enter into multiple binding written contracts with multiple parties for the disposal, injection, or utilization of qualified carbon oxide.

(iii) *Contract provisions.* Contracts ensuring the disposal, injection, or utilization of qualified carbon oxide—

(A) Must include commercially reasonable terms and provide for enforcement of the party's obligation to perform the disposal, injection, or utilization of the qualified carbon oxide;

(B) May, but are not required to, include long-term liability provisions, indemnity provisions, penalties for breach of contract, or liquidated damages provisions;

(C) May, but are not required to, include information including how many metric tons of qualified carbon oxide the parties agree to dispose of, inject, or utilize;

(D) May, but are not required to, include minimum quantities that the parties agree to dispose of, inject, or utilize;

(E) Must, in the case of qualified carbon oxide that is intended to be disposed of in secure geological storage and not used as a tertiary injectant in a qualified enhanced oil or natural gas recovery project, obligate the disposing party to comply with §§ 1.45Q–3(b)(1) and 1.45Q–3(c), and, in the case of a recapture event, promptly inform the capturing party of all information that is pertinent to the recapture (*i.e.,* location of leak, quantity of qualified carbon oxide leaked, dollar value of section 45Q credit attributable to leaked qualified carbon oxide) of section 45Q credits as listed in § 1.45Q–5;

(F) Must, for qualified carbon oxide that is intended to be used as a tertiary injectant in a qualified enhanced oil or natural gas recovery, obligate the disposing party to comply with § 1.45Q–3(b)(1) or (2) and § 1.45Q–3(c), and in the case of a recapture event, promptly inform the capturing party of all information that is pertinent to recapture of the section 45Q credit as listed in § 1.45Q–5; and

(G) Must, for qualified carbon oxide that is intended to be utilized in a manner specified in § 1.45Q–4, obligate the utilizing party to comply with § 1.45Q–4.

(iv) *Reporting of contract information.* The existence of each contract and the parties involved must be reported to the IRS annually on a Form 8933 (or successor forms, or pursuant to instructions and other guidance) by each party to the contract, regardless of the party claiming the credit. In addition to any information stated as required on Form 8933 (or successor forms, or pursuant to instructions and other guidance), the report must include the following information—

(A) The name and taxpayer identification number of the taxpayer to whom the credit is attributable;

(B) The name and taxpayer identification number of each party with whom the taxpayer has entered into a contract to ensure the disposal, injection, or utilization of qualified carbon oxide;

(C) The number of metric tons of qualified carbon oxide each contracting party disposes of, injects, or utilizes on behalf of the contracting taxpayer each taxable year for reporting to the IRS; and

(D) For contracts for the disposal of qualified carbon oxide in secure geological storage or the use of qualified carbon oxide as a tertiary injectant in enhanced oil or natural gas recovery, the name of the operator, the field, unit, and reservoir, location by county and state, and identification number assigned to the facility by the EPA's electronic Greenhouse Gas Reporting Tool (e-GGRT ID number) for submission of the facility's 40 CFR part 98 annual reports.

(v) *Relationship with election to allow section 45Q credit.* A taxpayer does not elect to allow all or a portion of the credit to any of the contracting parties merely by contracting with that party to ensure the disposal, injection, or utilization of qualified carbon oxide. Any election to allow all or a portion of the credit to be claimed by another party must be made separately pursuant to § 1.45Q–1(h)(3).

(3) *Election to allow the section 45Q credit to another taxpayer.* The taxpayer described in § 1.45Q–1(h)(1) as eligible to claim section 45Q credits may elect to allow the person that disposes of the qualified carbon oxide, utilizes the qualified carbon oxide, or uses the qualified carbon oxide as a tertiary injectant to claim the credit (credit claimant). The taxpayer that makes the election (electing taxpayer) may not claim any section 45Q credits that are allowable to a credit claimant. An electing taxpayer may elect to allow a credit claimant to claim the full amount or a partial amount of section 45Q credits arising during the taxable year. An electing taxpayer may elect to allow a single credit claimant or multiple credit claimants to claim section 45Q credits in the same taxable year. If an electing taxpayer elects to allow multiple credit claimants to claim section 45Q credits, the maximum amount of section 45Q credits allowable to each credit claimant is proportional to the amount of qualified carbon oxide disposed of, utilized, or used as a tertiary injectant by the credit claimant. A credit claimant may receive allowances of section 45Q credits from multiple electing taxpayers in the same taxable year.

(i) *Example.* Electing Taxpayer, E, captures 100 metric tons of qualified carbon oxide with carbon capture equipment that was placed in service in 2017. E contracts with two companies, A and B, for the disposal of the qualified carbon oxide. The capture and disposal of the qualified carbon oxide makes E eligible for a section 45Q credit at a rate of $10 per metric ton, for a total section 45Q credit of $1,000. E contractually ensures that A will dispose of 30 metric tons of qualified carbon oxide and that B will dispose of 70 metric tons of qualified carbon oxide. E may make a section 45Q(f)(3)(B) election to allow up to $300 of section 45Q credit to A and up to $700 of section 45Q credit to B, equal to the value of the number of metric tons each party has contracted to ensure disposal, multiplied by the credit value of the metric tons disposed of.

(ii) *Time and manner of making election.* The taxpayer described § 1.45Q–1(h)(1) makes a section 45Q(f)(3)(B) election by filing a statement of election containing the information described in § 1.45Q–1(h)(3)(iv) with the taxpayer's Federal income tax return or Form 1065 for each taxable year in which the credit arises. The section 45Q(f)(3)(B) election must be made in accordance with Form 8933 (or successor forms, or pursuant to instructions and other guidance) no later than the time prescribed by law (including extensions) for filing the Federal income tax return or Form 1065 for the year in which the credit arises. The election may not be filed with an amended Federal income tax return, an amended Form 1065, or an AAR, as applicable, after the prescribed date (including extensions) for filing the original Federal income tax return or Form 1065 for the year, with the exception of amended Federal income tax returns, amended Forms 1065, or AARs, as applicable, for any taxable year ending after February 9, 2018, but not for taxable years beginning after the date of issuance of this proposed regulation. In addition, as provided in Revenue Procedure 2020–23, the exception applies regarding the time to file an amended return by a partnership subject to the centralized partnership audit regime enacted as part of the BBA (BBA partnership) for the 2018 and 2019 taxable years. The amended Federal income tax return or the amended Form 1065 must be filed, in no event, later than the applicable period of limitations on assessment for the taxable year for which the amended Federal income tax return or Form 1065 is being filed. In the case of a BBA partnership that chooses not to file an amended Form 1065 as permitted under Revenue Procedure 2020–23, the BBA partnership may make a late election by filing an AAR on or before October 15, 2021, but in no event, later than the applicable period of limitations on making adjustments under section 6235 for the reviewed year, as defined in § 301.6241–1(a)(8) of the Procedure and Administration Regulations (26 CFR part 301).

(iii) *Annual election.* A new section 45Q(f)(3)(B) election must be made annually.

(iv) *Required information.* For the election to be valid, the election statement of the electing taxpayer on Form 8933 (or successor forms, or pursuant to instructions and other guidance) under § 1.45Q–1(h)(3)(ii) must indicate that an election is being made under section 45Q(f)(3)(B). The electing taxpayer must provide each credit claimant with a copy of the electing taxpayer's Form 8933 (or successor forms, or pursuant to instructions and other guidance). The electing taxpayer must, in addition to any information required on Form 8933 (or successor forms, or pursuant to instructions and other guidance), set forth the following information—

(A) The electing taxpayer's name, address, taxpayer identification number, location, and e-GGRT ID number(s) (if available) of each qualified facility where carbon oxide was captured;

(B) The full amount of credit attributable to the taxpayer prior to the election;

(C) The name, address, and taxpayer identification number of each credit claimant, and the location and e-GGRT ID number(s) (if available) of each secure geological storage facility where the qualified carbon oxide is disposed of or injected;

(D) The dollar amount of section 45Q credits the taxpayer is allowing each credit claimant to claim and the corresponding metric tons of qualified carbon oxide; and

(E) The dollar amount of section 45Q credits retained by the electing taxpayer and the corresponding metric tons of qualified carbon oxide.

(v) *Requirements for section 45Q credit claimant.* For a section 45Q(f)(3)(B) election to be valid, the section 45Q credit claimant must include the following information on Form 8933 (or successor forms, or pursuant to instructions and other guidance) with its timely filed Federal income tax return or Form 1065 (including extensions)—

(A) The name, address, taxpayer identification number of the credit claimant;

(B) The name, address, and taxpayer identification number of each taxpayer making an election under section 45Q(f)(3)(B) to allow the credit to the credit claimant;

(C) The location and e-GGRT ID number(s) (if available) of each qualified facility where carbon oxide was captured;

(D) The location and e-GGRT ID number(s) (if available) of each secure geological storage facility where the qualified carbon oxide is disposed of or injected;

(E) The full dollar amount of section 45Q credits attributable to each electing taxpayer prior to the election and the corresponding metric tons of carbon oxide;

(F) The dollar amount of section 45Q credits that each electing taxpayer is allowing the credit claimant to claim and the corresponding metric tons of carbon oxide; and

(G) A copy of the electing taxpayer's Form 8933 (or successor forms, or pursuant to instructions and other guidance).

(i) *Applicability date.* This section applies to taxable years beginning after [date final regulations are published in the **Federal Register**]. Taxpayers may choose to apply this section for taxable years beginning on or after February 9, 2018, provided the taxpayer applies this section and §§ 1.45Q–2, 1.45Q–3, 1.45Q–4, and 1.45Q–5 in their entirety and in a consistent manner.

§ 1.45Q–2 Definitions for Purposes of §§ 1.45Q–1 through 1.45Q–5.

(a) *Qualified carbon oxide.* The term qualified carbon oxide means—

(1) Any carbon dioxide which—

(i) Is captured from an industrial source by carbon capture equipment which is originally placed in service before February 9, 2018,

(ii) Would otherwise be released into the atmosphere as industrial emission of greenhouse gas or lead to such release, and

(iii) Is measured at the source of capture and verified at the point of disposal, injection, or utilization; or

(2) Any carbon dioxide or other carbon oxide which—

(i) Is captured from an industrial source by carbon capture equipment which is originally placed in service on or after February 9, 2018,

(ii) Would otherwise be released into the atmosphere as industrial emission of greenhouse gas or lead to such release, and

(iii) Is measured at the source of capture and verified at the point of disposal, injection, or utilization; or

(3) In the case of a direct air capture facility, any carbon dioxide that is captured directly from the ambient air and is measured at the source of capture and verified at the point of disposal, injection, or utilization.

(b) *Recycled carbon oxide.* The term qualified carbon oxide includes the initial deposit of captured carbon oxide used as a tertiary injectant. Qualified carbon oxide does not include carbon oxide that is recaptured, recycled, and re-injected as part of the enhanced oil or natural gas recovery process.

(c) *Carbon capture equipment.* In general, carbon capture equipment includes all components of property that are used to capture or process carbon oxide until the carbon oxide is transported for disposal, injection, or utilization.

(1) *Use of carbon capture equipment.* Carbon capture equipment is equipment used for the purpose of—

(i) Separating, purifying, drying, and/or capturing carbon oxide that would otherwise be released into the atmosphere from an industrial facility;

(ii) Removing carbon oxide from the atmosphere via direct air capture; or

(iii) Compressing or otherwise increasing the pressure of carbon oxide.

(2) *Carbon capture equipment components.* Carbon capture equipment generally includes components of property necessary to compress, treat, process, liquefy, pump or perform some other physical action to capture qualified carbon oxide. Components of carbon capture equipment include, but are not limited to, absorbers, compressors, conditioners, cooling towers, dehydration equipment, dehydration systems, electrostatic filtration, engines, filters, fixtures, glycol contractors, heat exchangers, liquefaction equipment, lube oil systems, machinery, materials, membranes, meters, monitoring equipment, motors, mounting equipment, pipes, power generators and regenerators, pressure vessels and other vessels, processing equipment, processing plants, processing units, pumps, reboilers, recycling units, scrubbers, separation vessels, solvent pumps, sorbent vessels, specially designed flue gas ducts, support structures, tracking equipment, treating equipment, turbines, water wash equipment, and other carbon oxide related equipment.

(3) *Excluded components.* Components of carbon capture equipment do not include pipelines, branch lines, or land and marine transport vessels used for transporting captured qualified carbon oxide for disposal, injection, or utilization. However, a gathering and distribution system that collects carbon oxide captured from a qualified facility or multiple facilities that constitute a single project (as described in section 8.01 of Notice 2020–12, 2020–11 I.R.B. 495 (see § 601.601(d)(2)(ii) of this chapter)) for the purpose of transporting that carbon oxide away from the qualified facility or single project to a pipeline used to transport carbon oxide from multiple taxpayers or projects is carbon capture equipment.

(d) *Industrial facility.* An *industrial facility* is a facility that produces a carbon oxide stream from a fuel combustion source or fuel cell, a manufacturing process, or a fugitive carbon oxide emission source that, absent capture and disposal, would otherwise be released into the atmosphere as industrial emission of greenhouse gas or lead to such release.

(1) *Exclusion.* An industrial facility does not include a facility that produces carbon dioxide from carbon dioxide production wells at natural carbon dioxide-bearing formations or a naturally occurring subsurface spring. A deposit of natural gas that contains less than 10 percent carbon dioxide by volume is not a natural carbon dioxide-bearing formation. For other deposits, whether a well is producing from a natural carbon dioxide-bearing formation is based on all the facts and circumstances.

(2) *Industrial source.* An *industrial source* is an emission of carbon oxide from an industrial facility.

(3) *Manufacturing process.* A *manufacturing process* is a process involving the manufacture of products, other than carbon oxide, that are intended to be sold at a profit, or are used for a commercial purpose. All facts and circumstances with respect to the process and products are to be taken into account.

(4) *Example.* The following example illustrates the rules of paragraph (a) and (d)(3) of this section:

(i) A natural underground reservoir contains a gas that is comprised of 50 percent carbon dioxide and 50 percent methane by volume. The raw gas is not usable without the application of a separation process to create two gases that are primarily carbon dioxide and methane. Taxpayer B constructs processing equipment that separates the raw gas into qualified carbon oxide and methane. The carbon dioxide is sold to a third party for use in a qualified enhanced oil recovery project. Some of the methane is used as fuel to power the processing equipment. The remainder of the methane is injected into the reservoir. The injection will increase the ultimate recovery of carbon dioxide. The injected methane can be produced later from the reservoir. At the end of the taxable year the taxpayer has not secured a contract to sell methane and does not have any plans to use the methane for a commercial purpose. Because carbon dioxide is the only product manufactured that is intended to be sold at a profit or used for a commercial purpose, the separation process applied to the gases is not a manufacturing process within the meaning of paragraph (d)(3). The carbon dioxide captured by the process is not qualified carbon oxide.

(e) *Electricity generating facility.* An *electricity generating facility* is a facility described in section 45Q(d)(2)(A) or (B) of the Internal Revenue Code (Code) and is subject to depreciation under MACRS Asset Class 49.11(Electric Utility Hydraulic Production Plant), 49.12 (Electric Utility Nuclear Production Plant), 49.13 (Electric Utility Steam Production Plant), or 49.15 (Electric Utility Combustion Turbine Production Plant).

(f) *Direct air capture facility.* A *direct air capture facility* means any facility that uses carbon capture equipment to capture carbon oxide directly from the ambient air. It does not include any facility that captures carbon dioxide that is deliberately released from naturally

occurring subsurface springs or using natural photosynthesis.

(g) *Qualified facility.* A *qualified facility* means any industrial facility, electricity generating facility, or direct air capture facility, the construction of which begins before January 1, 2024, and either at which construction of carbon capture equipment begins before that date, or the original planning and design for which includes installation of carbon capture equipment, and at which carbon capture equipment is placed in service that captures the requisite annual thresholds of carbon oxide described in paragraph (g)(1) of this section. See Notice 2020–12, 2020–11 I.R.B. 495 (see § 601.601(d)(2)(ii) of this chapter), for guidance on the determination of when construction has begun on a qualified facility or on carbon capture equipment.

(1) *Emissions and capture requirements.* The facility must capture—

(i) In the case of a facility, other than a direct air capture facility, which emits not more than 500,000 metric tons of carbon oxide into the atmosphere during the taxable year, at least 25,000 metric tons of qualified carbon oxide during the taxable year which is utilized in a manner consistent with section 45Q(f)(5) and § 1.45Q–4 (Section 45Q(d)(2)(A) Facility);

(ii) In the case of an electricity generating facility which is not a Section 45Q(d)(2)(A) Facility (Section 45Q(d)(2)(B) Facility), not less than 500,000 metric tons of qualified carbon during the taxable year; and

(iii) In the case of a direct air capture facility or other facility that is not a Section 45Q(d)(2)(A) Facility or a Section 45Q(d)(2)(B) Facility, at least 100,000 metric tons of qualified carbon oxide during the taxable year.

(2) *Examples.* The following examples illustrate the rules of paragraph (g) of this section:

(i) *Example 1.* During the taxable year, an ethanol plant emits 200,000 metric tons of carbon dioxide. Equipment located at the facility captures 35,000 metric tons of carbon dioxide, all of which are utilized in a manner consistent with section 45Q(f)(5) and § 1.45Q–4. The ethanol plant is a qualified facility during the taxable year because it met the requirement to capture at least 25,000 metric tons of qualified carbon oxide during the taxable year which were utilized in a manner consistent with section 45Q(f)(5) and § 1.45Q–4.

(ii) *Example 2.* During the taxable year an electricity generating facility emits 600,000 metric tons of carbon dioxide. Equipment located at the facility captures 50,000 metric tons of carbon dioxide, all of which are utilized in a manner consistent with section 45Q(f)(5) and § 1.45Q–4, and 400,000 metric tons of carbon dioxide, all of which are properly disposed of in secure geological storage. The total amount of carbon dioxide captured during the taxable year is 450,000 metric tons. The electricity generating facility is not a qualified facility during the taxable year because it did not meet the requirement to capture not less than 500,000 metric tons of qualified carbon during the taxable year.

(iii) *Example 3.* During the taxable year, a cement manufacturing plant emits 110,000 metric tons of carbon dioxide. Equipment located at the plant captures 10,000 metric tons of carbon dioxide, all of which are utilized in a manner consistent with section 45Q(f)(5) and § 1.45Q–4, and 90,000 metric tons of carbon dioxide, all of which are properly disposed of in secure geological storage. The total amount of carbon dioxide captured during the taxable year is 100,000 metric tons. The cement manufacturing plant is a qualified facility during the taxable year because it met the requirement to capture at least 100,000 metric tons of qualified carbon oxide during the taxable year.

(3) *Annualization of first-year qualified carbon oxide emission and capture amounts*—(i) *In general.* For the year in which carbon capture equipment is placed in service at a qualified facility, annualization of the amount of qualified carbon oxide emitted and captured is permitted to determine if the threshold requirements under paragraph (g)(1) of this section are satisfied. Such annualization may result in a facility being deemed to satisfy the threshold requirements under paragraph (g)(1) of this section for the year and may permit a taxpayer to claim section 45Q credits even though the amount of qualified carbon oxide emitted or captured in its first year is less than the threshold requirements under paragraph (g)(1) of this section.

(ii) *Calculation.* Annualization is only be available for the first year in which the carbon capture equipment is placed in service at the qualified facility. Annualized amounts must be calculated by—

(A) Determining the amount of qualified carbon oxide emitted and captured during the taxable year in which the carbon capture equipment was placed in service at the qualified facility,

(B) Dividing the amount of qualified carbon emitted or captured by the number of days in the tax year beginning with the date on which the carbon capture equipment was placed in service at the qualified facility and ending with the last day of the taxable year; and

(C) Multiplying by 365.

(iii) *Consequences.* If the annualized amounts of qualified carbon oxide emitted and captured as calculated under this formula meet the threshold requirements under paragraph (g)(1) of this section, the threshold requirements under paragraph (g)(1) of this section are deemed satisfied for the taxable year in which the carbon capture equipment was placed in service at the qualified facility. The taxpayer may be eligible for a section 45Q credit for that taxable year but must calculate the credit based on actual amounts of qualified carbon oxide captured and disposed of, injected, or utilized during the taxable year.

(4) *Election for applicable facilities.* In the case of an applicable facility, for any taxable year during which such facility captures not less than 500,000 metric tons of qualified carbon oxide, the person described in section 45Q(f)(3)(A)(ii) and § 1.45Q–1(h)(1), may elect to have such facility, and any carbon capture equipment placed in service at such facility, deemed as having been placed in service on February 9, 2018 (section 45Q(f)(6) election).

(i) *Applicable facility.* An applicable facility means a qualified facility described in section 45Q(f)(6) and § 1.45Q–2(g)(4)(i) that was placed in service before February 9, 2018, for which no taxpayer claimed a section 45Q credit for qualified carbon oxide captured at the facility for any taxable year ending before February 9, 2018.

(ii) *Time and manner of making election.* The taxpayer described § 1.45Q–1(h)(1) makes a section 45Q(f)(6) election by filing a statement of election with the taxpayer's income tax return for each taxable year in which the credit arises. The section 45Q(f)(6) election must be made in accordance with Form 8933 (or successor forms, or pursuant to instructions and other guidance) with the taxpayer's income tax return for the taxable year in which the taxpayer makes the section 45Q(f)(6) election. The statement of election must, in addition to any information required on Form 8933 (or successor forms, or pursuant to instructions and other guidance), set forth the electing taxpayer's name, address, taxpayer identification number, location, and e-GGRT ID number(s) (if available) of the applicable facility.

(iii) *Retroactive credit revocations.* A taxpayer may not file an amended Federal income tax return, an amended Form 1065, or an AAR, as applicable, for any taxable year ending before February 9, 2018, to revoke a prior claim of section 45Q credits.

(5) *Retrofitted qualified facility or carbon capture equipment (80/20 Rule).* A qualified facility or carbon capture equipment may qualify as originally placed in service even if it contains some used components of property,

provided the fair market value of the used components of property is not more than 20 percent of the qualified facility or carbon capture equipment's total value (the cost of the new components of property plus the value of the used components of property) (80/20 Rule). For purposes of the 80/20 Rule, the cost of a new qualified facility or carbon capture equipment includes all properly capitalized costs of the new qualified facility or carbon capture equipment. Solely for purposes of the 80/20 Rule, properly capitalized costs of a new qualified facility or carbon capture equipment may, at the option of the taxpayer, include the cost of new equipment for a pipeline owned and used exclusively by that taxpayer to transport carbon oxides captured from that taxpayer's qualified facility that would otherwise be emitted into the atmosphere.

(h) *Qualified enhanced oil or natural gas recovery project.* The term *qualified enhanced oil or natural gas recovery project* has the same meaning as qualified enhanced oil recovery project under section 43(c)(2) of the Code and § 1.43–2, by substituting crude oil or natural gas for crude oil in section 43(c)(2)(A)(i) and §§ 1.43–2 and 1.43–3.

(1) *Application of §§ 1.43–2 and 1.43–3.* For purposes of applying §§ 1.43–2 and 1.43–3 with respect to a qualified enhanced oil or natural gas recovery project, the term enhanced oil or natural gas recovery is substituted for enhanced oil recovery, and the term oil or natural gas is substituted for oil.

(2) *Required certification.* The qualified enhanced oil or natural gas recovery project must be certified under § 1.43–3. For purposes of a natural gas project—

(i) The petroleum engineer's certification under § 1.43–3(a)(3) and the operator's continued certification of a project under § 1.43–3(b)(3) must include an additional statement that the certification is for purposes of the section 45Q carbon oxide sequestration tax credit;

(ii) The petroleum engineer's certification must be attached to a Form 8933 (or successor forms, or pursuant to instructions and other guidance) and filed not later than the last date prescribed by law (including extensions) for filing the operator's or designated owner's Federal income tax return or Form 1065 for the first taxable year in which qualified carbon oxide is injected into the reservoir; and

(iii) The operator's continued certification of a project must be attached to a Form 8933 (or successor forms, or pursuant to instructions and other guidance) and filed not later than the last date prescribed by law (including extensions) for filing the operator's or designated owner's Federal income tax return or Form 1065 for taxable years after the taxable year for which the petroleum engineer's certification is filed but not after the taxable year in which injection activity ceases and all injection wells are plugged and abandoned.

(3) *Natural gas.* Natural gas has the same meaning as under section 613A(e)(2) of the Code.

(4) *Timely filing of petroleum engineer's certification.* For purposes of this paragraph (h), if a section 45Q credit is claimed on an amended Federal income tax return, an amended Form 1065, or an AAR, as applicable, the petroleum engineer's certification will be treated as filed timely if it is attached to a Form 8933 that is submitted with such amended Federal income tax return, amended Form 1065, or AAR. With respect to a section 45Q credit that is claimed on a timely filed Federal income tax return or Form 1065 for a taxable year ending after February 9, 2018 and beginning before the date of issuance of this proposed regulation, for which the petroleum engineer's certification was not submitted the petroleum engineer's certification will be treated as filed timely if it is attached to an amended Form 8933 for any taxable year ending after February 9, 2018, but not for taxable years beginning after the date of issuance of these proposed regulations.

(5) *Carbon oxide injected in oil reservoir.* Carbon oxide that is injected into an oil reservoir that is not a qualified enhanced oil recovery project under section 43(c)(2) due to circumstances such as the first injection of a tertiary injectant occurring before 1991, or because a petroleum engineer's certification was not timely filed, cannot be treated as qualified carbon oxide, disposed of in secure geological storage, or utilized in a manner described in section 45Q(f)(5). This rule will not apply to an oil reservoir if—

(i) The reservoir permanently ceased oil production;

(ii) The operator has obtained an EPA UIC class VI permit; and

(iii) The operator complies with 40 CFR part 98 subpart RR.

(6) *Tertiary Injectant.* For purposes of section 45Q, a tertiary injectant is qualified carbon oxide that is injected into and stored in a qualified enhanced oil or natural gas recovery project and contributes to the extraction of crude oil or natural gas. The term *tertiary injectant* has the same meaning as used within section 193(b)(1) of the Code.

(i) *Section 45Q credit.* The term *section 45Q credit* means the carbon oxide sequestration credit determined under section 45Q of the Internal Revenue Code and § 1.45Q–1.

(j) *Applicability date.* This section applies to taxable years beginning after [date final regulations are published in the **Federal Register**]. Taxpayers may choose to apply this section for taxable years beginning on or after February 9, 2018, provided the taxpayer applies this section and §§ 1.45Q–1, 1.45Q–3, 1.45Q–4, and 1.45Q–5 in their entirety and in a consistent manner.

§ 1.45Q–3 Secure Geological Storage.

(a) *In general.* To qualify for the section 45Q credit, a taxpayer must either physically or contractually dispose of captured qualified carbon oxide in secure geological storage in the manner provided in § 1.45Q–3(b) or utilize qualified carbon oxide in a manner conforming with section 45Q(f)(5) of the Internal Revenue Code and § 1.45Q–4. Secure geological storage includes, but is not limited to, storage at deep saline formations, oil and gas reservoirs, and unminable coal seams.

(b) *Requirements for secure geological storage.* For purposes of the section 45Q credit, qualified carbon oxide is considered disposed of by the taxpayer in secure geological storage such that the qualified carbon oxide does not escape into the atmosphere if the qualified carbon oxide is—

(1) Stored, and not used as a tertiary injectant in a qualified enhanced oil or natural gas recovery project, in compliance with applicable requirements under 40 CFR part 98 subpart RR; or

(2) Used as a tertiary injectant in a qualified enhanced oil or natural gas recovery project and stored in compliance with applicable requirements under 40 CFR part 98 subpart RR, or the International Organization for Standardization (ISO) standards endorsed by the American National Standards Institute (ANSI) under CSA/ANSI ISO 27916:19, Carbon dioxide capture, transportation and geological storage—Carbon dioxide storage using enhanced oil recovery (CO_2-EOR).

(3) Injected into a well that complies with applicable Underground Injection Control regulations onshore or offshore under submerged lands within the territorial jurisdiction of States.

(c) *Documentation.* Documentation must be filed in accordance with Form 8933 (or successor forms, or pursuant to instructions and other guidance).

(d) *Certification.* For qualified enhanced oil or natural gas recovery

projects in which the taxpayer reported volumes of carbon oxide to the EPA pursuant to 40 CFR part 98 subpart RR, the taxpayer may self-certify the volume of carbon oxide claimed for purposes of section 45Q. For qualified enhanced oil or natural gas recovery projects in which the taxpayer determined volumes pursuant to CSA/ANSI ISO 27916:19, a taxpayer may prepare documentation as outlined in CSA/ANSI 27916:19 internally, but such documentation must be provided to a qualified independent engineer or geologist, who then must certify that the documentation provided, including the mass balance calculations as well as information regarding monitoring and containment assurance, is accurate and complete. Certifications must be made annually. For any leaked amount of qualified carbon oxide (as defined in § 1.45Q–5(c)) that is determined pursuant to CSA/ANSI ISO 27916:19, the certification must also include a statement that the quantity was determined in accordance with sound engineering principles. Taxpayers that capture qualified carbon oxide giving rise to the section 45Q credit must file Form 8933 (or successor forms, or pursuant to instructions and other guidance) with a timely filed Federal income tax return or Form 1065, including extensions or for the purpose of this rule, amendments to Federal income tax returns, Forms 1065, or on AARs, as applicable. Taxpayers that dispose of, inject, or utilize qualified carbon oxide must also file Form 8933 (or successor forms, or pursuant to instructions and other guidance) with a timely filed Federal income tax return or Form 1065, including extensions or for the purpose of this rule, amendments to Federal income tax returns, Forms 1065, or on AARs, as applicable. If the volume of carbon oxide certified and reported is a negative amount, see § 1.45Q–5 for rules regarding recapture.

(e) *Failure to submit complete documentation or certification.* No section 45Q credit is allowed for any taxable year for which the taxpayer (including credit claimants) has failed to timely submit complete documentation and certification that is required by this regulation or Form 8933 (or successor forms, or pursuant to instructions and other guidance). The credit will be allowed only for a taxable year for which complete documentation and certification has been timely submitted. Certifications for each taxable year must be submitted by the due date of the federal income tax return or Form 1065 on which the section 45Q credit is claimed, including extensions. If a section 45Q credit is claimed on an amended Federal income tax return, an amended Form 1065, or an AAR, as applicable, certifications may also be submitted with such amended Federal income tax return, amended Form 1065, or AAR. If a section 45Q credit was claimed on a timely filed Federal income tax return or Form 1065 for a taxable year ending after February 9, 2018, and beginning before the date of issuance of this proposed regulation, for which certifications were not submitted, such certifications may be submitted with an amended Federal income tax return, an amended Form 1065, or an AAR, as applicable, for the taxable year in which the section 45Q credit was claimed.

(f) *Applicability date.* This section applies to taxable years beginning after [date final regulations are published in the **Federal Register**]. Taxpayers may choose to apply this section for taxable years beginning on or after February 9, 2018, provided the taxpayer applies this section and §§ 1.45Q–1, 1.45Q–2, 1.45Q–4, and 1.45Q–5 in their entirety and in a consistent manner.

§ 1.45Q–4 Utilization of Qualified Carbon Oxide.

(a) *In general.* For purposes of this section, utilization of qualified carbon oxide means—

(1) The fixation of qualified carbon oxide through photosynthesis or chemosynthesis, such as through the growing of algae or bacteria,

(2) The chemical conversion of such qualified carbon oxide to a material or chemical compound in which such qualified carbon oxide is securely stored, or

(3) The use of such qualified carbon oxide for any other purpose for which a commercial market exists (with the exception of use as a tertiary injectant in a qualified enhanced oil or natural gas recovery project), as determined by the Secretary of the Treasury or his delegate.

(b) *Measurement.* For purposes of determining the amount of qualified carbon oxide utilized by the taxpayer under § 1.45Q–1(b)(2)(ii) and (c)(2)(ii), such amount is equal to the metric tons of qualified carbon oxide which the taxpayer demonstrates, based upon an analysis of lifecycle greenhouse gas emissions (LCA), were—

(1) Captured and permanently isolated from the atmosphere (isolated), or

(2) Displaced from being emitted into the atmosphere through use of a process described in paragraph (a) of this section (displaced).

(c) *Lifecycle greenhouse gas emissions and lifecycle analysis*—(1) In general. For purposes of paragraph (b) of this section, the term lifecycle greenhouse gas emissions means the aggregate quantity of greenhouse gas emissions (including direct emissions and significant indirect emissions such as significant emissions from land use changes) related to the full product lifecycle, including all stages of product and feedstock production and distribution, from feedstock generation or extraction through the distribution and delivery and use of the finished product to the ultimate consumer, where the mass values for all greenhouse gases are adjusted to account for their relative global warming potential according to Table A–1 of 40 CFR part 98 subpart A.

(2) *Measurement.* The taxpayer measures the amount of carbon oxide captured and utilized through a combination of direct measurement and LCA. The measurement and written LCA report must be performed by or verified by an independent third-party. The report must contain documentation consistent with the International Organization for Standardization (ISO) 14044:2006, ''Environmental management—Life cycle assessment—Requirements and Guidelines,'' as well as a statement documenting the qualifications of the third-party, including proof of appropriate U.S. or foreign professional license, and an affidavit from the third-party stating that it is independent from the taxpayer.

(3) *Approval of the LCA.* The taxpayer must submit the written LCA report required by paragraph (c)(1) of this section to the IRS and the Department of Energy (DOE). The LCA will be subject to a technical review by the DOE, and the IRS, in consultation with the DOE and the Environmental Protection Agency, will determine whether to approve the LCA.

(4) *[Reserved]*

(d)–(e) *[Reserved]*

(f) *Applicability date.* This section applies to taxable years beginning after [date final regulations are published in the **Federal Register**]. Taxpayers may choose to apply this section for taxable years beginning on or after February 9, 2018, provided the taxpayer applies this section and §§ 1.45Q–1, 1.45Q–2, 1.45Q–3, and 1.45Q–5 in their entirety and in a consistent manner.

§ 1.45Q–5 Recapture of Credit.

(a) *Recapture event.* A recapture event occurs when qualified carbon oxide for which a section 45Q credit has been claimed ceases to be captured, disposed of, or used as a tertiary injectant during

the recapture period. Recapture events are determined separately for each project involving capture, disposal, or use of qualified carbon oxide as a tertiary injectant.

(b) *Ceases to be captured, disposed of, or used as a tertiary injectant.* Qualified carbon oxide ceases to be captured, disposed of, or used as a tertiary injectant if the leaked amount of qualified carbon oxide in the taxable year exceeds the amount of qualified carbon oxide disposed of in secure geological storage or used as a tertiary injectant in that same taxable year.

(c) *Leaked amount of qualified carbon oxide.* When a taxpayer, operator, or regulatory agency determines that qualified carbon oxide has leaked to the atmosphere, the taxpayer must quantify the metric tons of qualified carbon oxide that has leaked to the atmosphere pursuant to the requirements of 40 CFR part 98 subpart RR or CSA/ANSI ISO 27916:19. The quantity determined pursuant to CSA/ANSI ISO 27916:19 must be certified by a qualified independent engineer or geologist, including a statement that the quantity was determined in accordance with sound engineering principles. The Internal Revenue Service will consider all available facts, and may consult with the relevant regulatory agency, in verifying the amount of qualified carbon oxide that has leaked to the atmosphere. That amount is the leaked amount of qualified carbon oxide.

(d) *Recaptured qualified carbon oxide.* The quantity of recaptured qualified carbon oxide (in metric tons) is the amount by which the leaked amount of qualified carbon oxide exceeds the amount of qualified carbon oxide disposed of in secure geological storage or used as a tertiary injectant in the taxable year.

(e) *Recapture amount.* The recapture amount is equal to the product of the quantity of recaptured qualified carbon oxide (in metric tons) and the appropriate statutory credit rate.

(f) *Recapture period.* The recapture period begins on the date of first injection of qualified carbon oxide for disposal in secure geological storage or use as a tertiary injectant. The recapture period ends on the earlier of five years after the last taxable year in which the taxpayer claimed a section 45Q credit or the date monitoring ends under the requirements of the standards described in § 1.45Q–3(b)(1) or (b)(2).

(g) *Application of recapture.* (1) *In general.* Any recapture amount must be taken into account in the taxable year in which it is identified and reported. If the leaked amount of qualified carbon oxide does not exceed the amount of qualified carbon oxide disposed of in secure geological storage or used as a tertiary injectant in the taxable year reported, there is no recapture amount and no further adjustments to prior taxable years are needed. The taxpayer must add the recapture amount to the amount of tax due in the taxable year in which the recapture event occurs.

(2) *Calculation.* Recapture amounts are to be calculated on a last-in-first-out basis (LIFO), such that the leaked amount of qualified carbon oxide that exceeds the amount of qualified carbon oxide disposed of in secure geological storage or used as a tertiary injectant in the current taxable year will be deemed attributable first to the prior taxable year, then to taxable year before that, and then up to a maximum of the fifth preceding year.

(3) *Multiple Units.* In the event of a recapture event in which the leaked qualified carbon oxide had been captured from multiple units of carbon capture equipment that were not under common ownership, the recapture amount must be allocated on a pro rata basis among the multiple units of carbon capture equipment. Each taxpayer that claimed a section 45Q credit with respect to one or more of such units of carbon capture equipment is responsible for adding the recapture amount to their amount of tax due in the taxable year in which the recapture event occurs.

(4) *Multiple Taxpayers.* In the event of a recapture event where the leaked amount of qualified carbon oxide is deemed attributable to qualified carbon oxide with respect to which multiple taxpayers claimed section 45Q credit amounts (for example, if ownership of the carbon capture equipment was transferred, or if a taxpayer made an election under section 45Q(f)(3)(B) of the Internal Revenue Code to allow one or more credit claimants to claim a portion of the section 45Q credit), the recapture amount must be allocated on a pro rata basis among the taxpayers that claimed the section 45Q credits with respect to the qualified carbon oxide that the leaked qualified carbon oxide is deemed attributable to.

(5) *Reporting.* If a recapture event occurs during a project's recapture period, any taxpayer that claimed a section 45Q credit for that project must report the following information on a Form 8933 (or successor forms, or pursuant to instructions and other guidance) filed with that taxpayer's Federal income tax return or Form 1065 for the taxable year for which the recapture event occurred—

(i) The recapture amount (as defined in § 1.45Q–5(e));

(ii) The quantity of leaked qualified carbon oxide (in metric tons) (as defined in § 1.45Q–5(c));

(iii) The statutory credit rate at which the section 45Q credits were originally calculated; and

(iv) A statement that describes how the taxpayer became aware of the recapture event, how the leaked amount was determined, and the identity and involvement of any regulatory agencies.

(6) *Examples.* The following examples illustrate the principles of this paragraph (g):

(i) *Example 1.* (A) A owns direct air capture Facility X. No other taxpayer has owned Facility X, and A has never allowed another taxpayer to claim any section 45Q credits with respect to qualified carbon oxide captured by Facility X. Facility X captured 100,000 metric tons of carbon dioxide in each of 2021, 2022, and 2023. All captured carbon dioxide was sold to B for use a tertiary injectant in a qualified enhanced oil recovery project. B provided contractual assurance that the carbon dioxide would be sequestered in secure geological storage. A claimed section 45Q credit amounts of $2,268,000 in 2021, $2,515,000 in 2022, and $2,761,000 in 2023 using the statutory rates in § 1.45Q–1(d)(3). In 2024, A captured and sold another 100,000 metric tons of carbon dioxide to B, which B used as a tertiary injectant in a qualified enhanced oil recovery project. In late 2024, B determined that 10,000 metric tons of carbon dioxide injected during 2021 had leaked from the containment area of the reservoir and will eventually migrate to the atmosphere.

(B) Because the leakage determined in 2024 (10,000 metric tons) did not exceed the amount stored in 2024 (100,000 metric tons), a recapture event did not occur in 2024. A's section 45Q credit for 2024 is $2,706,300 (net 90,000 metric tons of qualified carbon oxide captured and used as a tertiary injectant multiplied by the statutory credit rate for 2024 of $30.07).

(ii) *Example 2.* (A) Assume same facts as in Example 1. Additionally, in 2025, B determines that 190,000 metric tons of carbon dioxide injected in 2021 and 2022 have leaked and will eventually migrate to the atmosphere. No injection of carbon dioxide takes place in 2025.

(B) Because the leakage determined in 2025 (190,000 metric tons) exceeds the amount stored in 2025 (0 metric tons), a recapture event occurred in 2025. A's credit for 2025 is $0 because the net amount of carbon dioxide captured and used as a tertiary injectant in 2025 was 0 metric tons. The 2025 recapture amount is calculated by multiplying the 190,000 metric tons of recaptured qualified carbon oxide by the appropriate statutory credit rate using the LIFO method. The first 90,000 metric tons of recaptured qualified carbon oxide is deemed attributable to 2024, and is recaptured at the 2024 statutory rate of $30.07 per metric ton. The remaining 100,000 metric tons of recaptured qualified carbon oxide are deemed attributable to 2023. The credits attributable to 2023 are recaptured at the

2023 statutory rate of $27.61 per metric ton. Thus, the total recapture amount is $5,467,300, and is added to A's tax due for 2025.

(iii) *Example 3.* (A) Assume the same facts as in Example 2, except that A sells Facility X to C on January 1, 2024. C sells 100,000 metric tons of carbon dioxide captured by Facility X to B for use as a tertiary injectant in a qualified enhanced oil recovery project. Thus, C claims a section 45Q credit in 2024 of $2,706,300 (net 90,000 metric tons of qualified carbon oxide captured and used as a tertiary injectant multiplied by the statutory credit rate for 2024 of $30.07).

(B) The total recapture amount in 2025 is the same $5,467,300 as in Example 2, but is allocated between A and C. The first 90,000 metric tons of recaptured qualified carbon oxide are deemed attributable to 2024. The credits that are attributable to 2024 are recaptured at the 2024 statutory rate of $30.07 per ton (for a recapture amount of $2,706,300). Because C claimed that amount of section 45Q credit in 2024, a recapture amount of $2,706,300 is added to C's tax due for 2025. The remaining 100,000 metric tons of recaptured qualified carbon oxide are deemed attributable to 2023. The credits that are attributable to 2023 are recaptured at the 2023 statutory rate of $27.61 per ton (for a recapture amount of $2,761,000). Because A claimed that amount of section 45Q credit in 2023, a recapture amount of $2,761,000 is added to A's tax due for 2025.

(iv) *Example 4.* (A) Assume the same facts as in Example 2, except that in 2023 A made a section 45Q(f)(3)(B) election to allow B to claim one-half of the section 45Q credit for 2023. A and B each claimed $1,380,500 of section 45Q credit in 2023 (50,000 metric tons each multiplied by the 2023 statutory rate of $27.61).

(B) The total recapture amount in 2025 is the same $5,467,300 as in Example 2, but is allocated among A and B. The first 90,000 metric tons of recaptured qualified carbon oxide is deemed attributable to 2024. The section 45Q credit amounts attributable to 2024 are recaptured at the 2024 statutory rate of $30.07 per ton (for a recapture amount of $2,706,300). Because A claimed that amount of section 45Q credit in 2024, $2,706,300 is added to A's tax due for 2025. The remaining 100,000 metric tons of recaptured qualified carbon oxide is deemed attributable to 2023. The section 45Q credit amounts attributable to 2023 are recaptured at the 2023 statutory rate of $27.61 per ton (for a recapture amount of $2,761,000). Because A and B each claimed half of that amount ($1,380,500) of section 45Q credit in 2023, $1,380,500 is added to both A's and B's tax due for 2025. Thus, a recapture amount of $4,086,800 is added to A's tax due for 2025, and a recapture amount of $1,380,500 is added to B's tax due for 2025.

(v) *Example 5.* (A) Assume the same facts as in Example 2, except that the 100,000 metric tons of carbon dioxide sold to B in 2021, 2022, 2023, and 2024 for use as a tertiary injectant in a qualified enhanced oil recovery project were captured equally (50,000 metric tons per year) from qualified facilities owned by J and K. Neither J nor K made a section 45Q(f)(3)(B) election to allow B to claim the credit.

(B) Because the leakage determined in 2024 (10,000 metric tons) did not exceed the amount used as a tertiary injectant in 2024 (100,000 metric tons) a recapture event did not occur in 2024. The total amount of section 45Q credit for 2024 is $2,706,300 (net 90,000 metric tons of qualified carbon oxide captured and used as a tertiary injectant multiplied by the statutory credit rate for 2024 of $30.07). J and K may each claim half of this amount of section 45Q credit ($1,353,150) in 2024.

(C) The total recapture amount in 2025 is the same $5,467,300 as in Example 2, but is allocated between J and K. The section 45Q credit amounts relating to the first 90,000 metric tons of recaptured qualified carbon oxide are deemed attributable to 2024 and are recaptured at the 2024 statutory rate of $30.07 per ton (for a recapture amount of $2,706,300). Because J and K each claimed half of that amount ($1,353,150) of section 45Q credit in 2024, $1,353,150 is added to both J's and K's tax due for 2025. The section 45Q credit amounts relating to the remaining 100,000 metric tons of recaptured qualified carbon oxide are deemed attributable to 2023 and are recaptured at the 2023 statutory rate of $27.61 per ton (for a recapture amount of $2,761,000). Because J and K each claimed half of that amount ($1,380,500) of section 45Q credit in 2023, an additional $1,380,500 is added to both J's and Ks tax due for 2025. Thus, a total recapture amount of $2,733,650 is added to both J's and K's tax due for 2025.

(vi) *Example 6.* (A) M owns Industrial Facility Z. No other taxpayer has ever owned Z, and M has never allowed another taxpayer to claim any section 45Q credits with respect to qualified carbon oxide captured from Z. M captured 1,000,000 metric tons of carbon dioxide annually in each of 2017, 2018, 2019, 2020, 2021, 2022, 2023, 2024, and 2025. All captured carbon dioxide was sold to N for use a tertiary injectant in a qualified enhanced oil recovery project. N provided contractual assurance that the carbon dioxide would be sequestered in secure geological storage. M claimed section 45Q credit amounts of $12,830,000 in 2017, $15,209,000 in 2018, $17,760,000 in 2019, $20,220,000 in 2020, $22,680,000 in 2021, $25,150,000 in 2022, $27,610,000 in 2023, $30,070,000 in 2024, and $32,540,000 in 2025 using the statutory rates in § 1.45Q–1(d)(3). No injection of carbon oxides takes place in 2026. In 2026, N determined that 6,200,000 metric tons of carbon dioxide previously injected had leaked from the containment area of the reservoir and will eventually migrate to the atmosphere.

(B) Because the leakage determined in 2025 (6,200,000 metric tons) exceed the amount stored in 2026 (0 metric tons) a recapture event occurred in 2026. A's credit for 2026 is $0 because the net amount of carbon dioxide captured and used as a tertiary injectant in 2026 was 0 metric tons. The 2026 recapture amount is calculated by multiplying the 6,200,000 metric tons of recaptured qualified carbon oxide by the appropriate statutory credit rate using the LIFO method. The first 1,000,000 metric tons of recaptured qualified carbon oxide is deemed attributable to 2025, and is recaptured at the 2025 statutory rate of $32.54 per metric ton. The next 1,000,000 metric tons of recaptured qualified carbon oxide is deemed attributable to 2024, and is recaptured at the 2024 statutory rate of $30.07 per metric ton. The next 1,000,000 metric tons of recaptured qualified carbon oxide is deemed attributable to 2024, and is recaptured at the 2023 statutory rate of $27.16 per metric ton. The next 1,000,000 metric tons of recaptured qualified carbon oxide is deemed attributable to 2022, and is recaptured at the 2022 statutory rate of $25.15 per metric ton. The next 1,000,000 metric tons of recaptured qualified carbon oxide is deemed attributable to 2021, and is recaptured at the 2021 statutory rate of $22.68 per metric ton. The remaining 1,200,000 metric tons are not subject to recapture because of the five-year lookback limit in § 1.45Q–1(g)(2). Thus, the total recapture amount is $138,050,000, and is added to A's tax due for 2026.

(h) *Recapture in the event of intentional removal from storage.* If qualified carbon oxide for which a credit has been claimed is deliberately removed from a secure geological storage site, then a recapture event would occur in the year in which the qualified carbon oxide is removed from the storage site pursuant to § 1.45Q–5(a).

(i) *Limited exceptions.* A recapture event is not triggered in the event of a loss of containment of qualified carbon oxide resulting from actions not related to the selection, operation, or maintenance of the storage facility, such as volcanic activity or terrorist attack.

(j) *Applicability date.* This section applies to taxable years beginning after [date final regulations are published in the **Federal Register**]. Taxpayers may choose to apply this section for taxable years beginning on or after February 9, 2018, provided the taxpayer applies this section and sections 1.45Q–1, 1.45Q–2, 1.45Q–3, and 1.45Q–4 in their entirety and in a consistent manner.

Sunita Lough,

Deputy Commissioner for Services and Enforcement.

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Part V

The President

Executive Order 13925—Preventing Online Censorship

Federal Register
Vol. 85, No. 106
Tuesday, June 2, 2020

Presidential Documents

Title 3—

The President

Executive Order 13925 of May 28, 2020

Preventing Online Censorship

By the authority vested in me as President by the Constitution and the laws of the United States of America, it is hereby ordered as follows:

Section 1. *Policy.* Free speech is the bedrock of American democracy. Our Founding Fathers protected this sacred right with the First Amendment to the Constitution. The freedom to express and debate ideas is the foundation for all of our rights as a free people.

In a country that has long cherished the freedom of expression, we cannot allow a limited number of online platforms to hand pick the speech that Americans may access and convey on the internet. This practice is fundamentally un-American and anti-democratic. When large, powerful social media companies censor opinions with which they disagree, they exercise a dangerous power. They cease functioning as passive bulletin boards, and ought to be viewed and treated as content creators.

The growth of online platforms in recent years raises important questions about applying the ideals of the First Amendment to modern communications technology. Today, many Americans follow the news, stay in touch with friends and family, and share their views on current events through social media and other online platforms. As a result, these platforms function in many ways as a 21st century equivalent of the public square.

Twitter, Facebook, Instagram, and YouTube wield immense, if not unprecedented, power to shape the interpretation of public events; to censor, delete, or disappear information; and to control what people see or do not see.

As President, I have made clear my commitment to free and open debate on the internet. Such debate is just as important online as it is in our universities, our town halls, and our homes. It is essential to sustaining our democracy.

Online platforms are engaging in selective censorship that is harming our national discourse. Tens of thousands of Americans have reported, among other troubling behaviors, online platforms ''flagging'' content as inappropriate, even though it does not violate any stated terms of service; making unannounced and unexplained changes to company policies that have the effect of disfavoring certain viewpoints; and deleting content and entire accounts with no warning, no rationale, and no recourse.

Twitter now selectively decides to place a warning label on certain tweets in a manner that clearly reflects political bias. As has been reported, Twitter seems never to have placed such a label on another politician's tweet. As recently as last week, Representative Adam Schiff was continuing to mislead his followers by peddling the long-disproved Russian Collusion Hoax, and Twitter did not flag those tweets. Unsurprisingly, its officer in charge of so-called ''Site Integrity'' has flaunted his political bias in his own tweets.

At the same time online platforms are invoking inconsistent, irrational, and groundless justifications to censor or otherwise restrict Americans' speech here at home, several online platforms are profiting from and promoting the aggression and disinformation spread by foreign governments like China. One United States company, for example, created a search engine for the Chinese Communist Party that would have blacklisted searches for ''human rights,'' hid data unfavorable to the Chinese Communist Party,

and tracked users determined appropriate for surveillance. It also established research partnerships in China that provide direct benefits to the Chinese military. Other companies have accepted advertisements paid for by the Chinese government that spread false information about China's mass imprisonment of religious minorities, thereby enabling these abuses of human rights. They have also amplified China's propaganda abroad, including by allowing Chinese government officials to use their platforms to spread misinformation regarding the origins of the COVID–19 pandemic, and to undermine pro-democracy protests in Hong Kong.

As a Nation, we must foster and protect diverse viewpoints in today's digital communications environment where all Americans can and should have a voice. We must seek transparency and accountability from online platforms, and encourage standards and tools to protect and preserve the integrity and openness of American discourse and freedom of expression.

Sec. 2. *Protections Against Online Censorship.* (a) It is the policy of the United States to foster clear ground rules promoting free and open debate on the internet. Prominent among the ground rules governing that debate is the immunity from liability created by section 230(c) of the Communications Decency Act (section 230(c)). 47 U.S.C. 230(c). It is the policy of the United States that the scope of that immunity should be clarified: the immunity should not extend beyond its text and purpose to provide protection for those who purport to provide users a forum for free and open speech, but in reality use their power over a vital means of communication to engage in deceptive or pretextual actions stifling free and open debate by censoring certain viewpoints.

Section 230(c) was designed to address early court decisions holding that, if an online platform restricted access to some content posted by others, it would thereby become a ''publisher'' of all the content posted on its site for purposes of torts such as defamation. As the title of section 230(c) makes clear, the provision provides limited liability ''protection'' to a provider of an interactive computer service (such as an online platform) that engages in '' 'Good Samaritan' blocking'' of harmful content. In particular, the Congress sought to provide protections for online platforms that attempted to protect minors from harmful content and intended to ensure that such providers would not be discouraged from taking down harmful material. The provision was also intended to further the express vision of the Congress that the internet is a ''forum for a true diversity of political discourse.'' 47 U.S.C. 230(a)(3). The limited protections provided by the statute should be construed with these purposes in mind.

In particular, subparagraph (c)(2) expressly addresses protections from ''civil liability'' and specifies that an interactive computer service provider may not be made liable ''on account of'' its decision in ''good faith'' to restrict access to content that it considers to be ''obscene, lewd, lascivious, filthy, excessively violent, harassing or otherwise objectionable.'' It is the policy of the United States to ensure that, to the maximum extent permissible under the law, this provision is not distorted to provide liability protection for online platforms that—far from acting in ''good faith'' to remove objectionable content—instead engage in deceptive or pretextual actions (often contrary to their stated terms of service) to stifle viewpoints with which they disagree. Section 230 was not intended to allow a handful of companies to grow into titans controlling vital avenues for our national discourse under the guise of promoting open forums for debate, and then to provide those behemoths blanket immunity when they use their power to censor content and silence viewpoints that they dislike. When an interactive computer service provider removes or restricts access to content and its actions do not meet the criteria of subparagraph (c)(2)(A), it is engaged in editorial conduct. It is the policy of the United States that such a provider should properly lose the limited liability shield of subparagraph (c)(2)(A) and be exposed to liability like any traditional editor and publisher that is not an online provider.

(b) To advance the policy described in subsection (a) of this section, all executive departments and agencies should ensure that their application of section 230(c) properly reflects the narrow purpose of the section and take all appropriate actions in this regard. In addition, within 60 days of the date of this order, the Secretary of Commerce (Secretary), in consultation with the Attorney General, and acting through the National Telecommunications and Information Administration (NTIA), shall file a petition for rulemaking with the Federal Communications Commission (FCC) requesting that the FCC expeditiously propose regulations to clarify:

(i) the interaction between subparagraphs (c)(1) and (c)(2) of section 230, in particular to clarify and determine the circumstances under which a provider of an interactive computer service that restricts access to content in a manner not specifically protected by subparagraph (c)(2)(A) may also not be able to claim protection under subparagraph (c)(1), which merely states that a provider shall not be treated as a publisher or speaker for making third-party content available and does not address the provider's responsibility for its own editorial decisions;

(ii) the conditions under which an action restricting access to or availability of material is not ''taken in good faith'' within the meaning of subparagraph (c)(2)(A) of section 230, particularly whether actions can be ''taken in good faith'' if they are:

(A) deceptive, pretextual, or inconsistent with a provider's terms of service; or

(B) taken after failing to provide adequate notice, reasoned explanation, or a meaningful opportunity to be heard; and

(iii) any other proposed regulations that the NTIA concludes may be appropriate to advance the policy described in subsection (a) of this section.

Sec. 3. *Protecting Federal Taxpayer Dollars from Financing Online Platforms That Restrict Free Speech.* (a) The head of each executive department and agency (agency) shall review its agency's Federal spending on advertising and marketing paid to online platforms. Such review shall include the amount of money spent, the online platforms that receive Federal dollars, and the statutory authorities available to restrict their receipt of advertising dollars.

(b) Within 30 days of the date of this order, the head of each agency shall report its findings to the Director of the Office of Management and Budget.

(c) The Department of Justice shall review the viewpoint-based speech restrictions imposed by each online platform identified in the report described in subsection (b) of this section and assess whether any online platforms are problematic vehicles for government speech due to viewpoint discrimination, deception to consumers, or other bad practices.

Sec. 4. *Federal Review of Unfair or Deceptive Acts or Practices.* (a) It is the policy of the United States that large online platforms, such as Twitter and Facebook, as the critical means of promoting the free flow of speech and ideas today, should not restrict protected speech. The Supreme Court has noted that social media sites, as the modern public square, ''can provide perhaps the most powerful mechanisms available to a private citizen to make his or her voice heard.'' *Packingham* v. *North Carolina,* 137 S. Ct. 1730, 1737 (2017). Communication through these channels has become important for meaningful participation in American democracy, including to petition elected leaders. These sites are providing an important forum to the public for others to engage in free expression and debate. *Cf. PruneYard Shopping Center* v. *Robins,* 447 U.S. 74, 85–89 (1980).

(b) In May of 2019, the White House launched a Tech Bias Reporting tool to allow Americans to report incidents of online censorship. In just weeks, the White House received over 16,000 complaints of online platforms censoring or otherwise taking action against users based on their political

viewpoints. The White House will submit such complaints received to the Department of Justice and the Federal Trade Commission (FTC).

(c) The FTC shall consider taking action, as appropriate and consistent with applicable law, to prohibit unfair or deceptive acts or practices in or affecting commerce, pursuant to section 45 of title 15, United States Code. Such unfair or deceptive acts or practice may include practices by entities covered by section 230 that restrict speech in ways that do not align with those entities' public representations about those practices.

(d) For large online platforms that are vast arenas for public debate, including the social media platform Twitter, the FTC shall also, consistent with its legal authority, consider whether complaints allege violations of law that implicate the policies set forth in section 4(a) of this order. The FTC shall consider developing a report describing such complaints and making the report publicly available, consistent with applicable law.

Sec. 5. *State Review of Unfair or Deceptive Acts or Practices and Anti-Discrimination Laws.* (a) The Attorney General shall establish a working group regarding the potential enforcement of State statutes that prohibit online platforms from engaging in unfair or deceptive acts or practices. The working group shall also develop model legislation for consideration by legislatures in States where existing statutes do not protect Americans from such unfair and deceptive acts and practices. The working group shall invite State Attorneys General for discussion and consultation, as appropriate and consistent with applicable law.

(b) Complaints described in section 4(b) of this order will be shared with the working group, consistent with applicable law. The working group shall also collect publicly available information regarding the following:

(i) increased scrutiny of users based on the other users they choose to follow, or their interactions with other users;

(ii) algorithms to suppress content or users based on indications of political alignment or viewpoint;

(iii) differential policies allowing for otherwise impermissible behavior, when committed by accounts associated with the Chinese Communist Party or other anti-democratic associations or governments;

(iv) reliance on third-party entities, including contractors, media organizations, and individuals, with indicia of bias to review content; and

(v) acts that limit the ability of users with particular viewpoints to earn money on the platform compared with other users similarly situated.

Sec. 6. *Legislation.* The Attorney General shall develop a proposal for Federal legislation that would be useful to promote the policy objectives of this order.

Sec. 7. *Definition.* For purposes of this order, the term ''online platform'' means any website or application that allows users to create and share content or engage in social networking, or any general search engine.

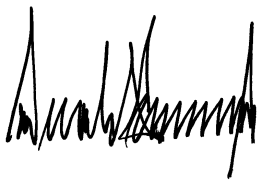
Sec. 8. *General Provisions.* (a) Nothing in this order shall be construed to impair or otherwise affect:

(i) the authority granted by law to an executive department or agency, or the head thereof; or

(ii) the functions of the Director of the Office of Management and Budget relating to budgetary, administrative, or legislative proposals.

(b) This order shall be implemented consistent with applicable law and subject to the availability of appropriations.

(c) This order is not intended to, and does not, create any right or benefit, substantive or procedural, enforceable at law or in equity by any party against the United States, its departments, agencies, or entities, its officers, employees, or agents, or any other person.



THE WHITE HOUSE,
May 28, 2020.

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LIST OF PUBLIC LAWS

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