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

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DEPARTMENT OF AGRICULTURE

Agricultural Marketing Service

7 CFR Parts 1221 and 1280

[Doc. No. AMS-LPS-17-0052]

Referendum Procedures Under the Sorghum Promotion, Research, and Information Order and the Lamb Promotion, Research, and Information Order; Removal of Obsolete References

AGENCY: Agricultural Marketing Service, USDA.

ACTION: Direct final rule; request for comments.

SUMMARY: This direct final rule will make technical amendments to the Sorghum Promotion, Research, and Information Order (Sorghum Order) and the Lamb Promotion, Research, and Information Order (Lamb Order) to remove obsolete and unnecessary provisions and to make conforming changes affected by the amendatory language revisions.

DATES: This rule is effective October 23, 2018 without further action, unless adverse comment is received by August 24, 2018. If adverse comment is received, the Agricultural Marketing Service (AMS) will publish a timely withdrawal of the rule in the **Federal Register**.

ADDRESSES: Comments should be submitted electronically at *www.regulations.gov*. Comments received will be posted without change, including any personal information provided. All comments should reference the docket number AMS–LPS– 17–0052, the date of submission, and the page number of this issue of the **Federal Register**. Comments may also be submitted to: Kenneth R. Payne, Director, Research and Promotion Division; Livestock and Poultry Program, AMS, U.S. Department of Agriculture (USDA); Room 2608–S, STOP 0251, 1400 Independence Avenue SW, Washington, DC 20250–0251; or fax to (202) 720–1125. Comments will be made available for public inspection at Room 2608–S of the above address during regular business hours or electronically at *www.regulations.gov*.

FOR FURTHER INFORMATION CONTACT: Kenneth R. Payne, Director, Research and Promotion Division, by telephone at (202) 720–1118, by fax at (202) 720– 1125, or by email at *kenneth.payne@ ams.usda.gov*.

SUPPLEMENTARY INFORMATION:

Executive Orders 12866 and 13771, and Regulatory Flexibility Act

This direct final rule falls within a category of regulatory actions that the Office of Management and Budget (OMB) exempted from Executive Order (E.O.) 12866 review. Additionally, because this rule does not meet the definition of a significant regulatory action it does not trigger the requirement contained in E.O. 13771. See OMB's Memorandum titled "Interim Guidance Implementing Section 2 of the Executive Order of January 30, 2017, titled 'Reducing Regulation and Controlling Regulatory Costs'" (February 2, 2017).

Pursuant to the requirements set forth in the Regulatory Flexibility Act (RFA) (5 U.S.C. 601 *et seq.*), the Administrator of AMS has considered the economic effect of this direct final rule on small entities and has determined that this action does not have a significant economic impact on a substantial number of small business entities. The purpose of RFA is to fit regulatory actions to the scale of businesses subject to such actions in order that small businesses will not be unduly burdened.

USDA's National Agricultural Statistics Service reported in the 2012 Census of Agriculture that there are 31,316 sheep farms in the U.S. and 22,908 farms where grain sorghum is grown. The majority of producers' subject to the Sorghum Order, 7 CFR part 1221, and Lamb Order, 7 CFR part 1280, are small businesses under the criteria established by the Small Business Administration (SBA) (13 CFR 121.201). SBA defines small agricultural producers as those having annual receipts of less than \$750,000.

This direct final rule imposes no new burden on the sorghum and lamb industries. It merely reduces the size of the Sorghum and Lamb Orders by removing sections that relate to now obsolete referendum activities. There are no new reporting, recordkeeping, or other compliance requirements as a result of this rule. Accordingly, the Administrator of AMS has determined that this direct final rule does not have a significant economic impact on a substantial number of small entities.

AMS is committed to complying with the E–Government Act of 2002 to promote the use of the internet and other information technologies to provide increased opportunities for citizen access to government information and services, and for other purposes. Accordingly, AMS developed options for companies requesting service to do so electronically.

USDA has not identified any relevant Federal rules that duplicate, overlap, or conflict with this direct final rule.

Executive Order 13175

This direct final rule has been reviewed in accordance with the requirements of E.O. 13175, Consultation and Coordination with Indian Tribal Governments. The review reveals that this action does not have substantial and direct effects on Tribal Governments and does not have significant Tribal implications.

Executive Order 12988

This direct final rule has been reviewed under E.O. 12988, Civil Justice Reform. It is not intended to have retroactive effect. The Act prohibits States or political subdivisions of a State from imposing any requirement that is in addition to, or inconsistent with, any requirement of the Act. There are no civil justice implications associated with this direct final rule.

Paperwork Reduction Act

This direct final rule also contains no new information collection requirements; therefore, no analysis or approval under the Paperwork Reduction Act (44 U.S.C. 3501–3520) is required.

Background and Technical Amendments

National agricultural commodity research and promotion programs—also called R&P programs or checkoff programs (checkoff programs)—are designed to maintain and expand existing markets and develop new markets both domestically and internationally. They are funded through assessments paid by persons subject to the assessment. Checkoff programs are administered by national boards created for that purpose and oversight is provided by USDA.

Some checkoff programs are authorized by their own commodityspecific Federal statutes. Others, like the sorghum and lamb checkoff programs addressed by this direct final rule, are authorized by the Commodity Promotion, Research, and Information Act of 1996, 7 U.S.C. 7401 *et seq.* (Generic Act).

The Sorghum and Lamb Orders authorize the collection of assessments from, respectively, sorghum producers and importers, and lamb producers, feeders, seedstock producers, first handlers, and exporters. Under both Orders, payers of assessments are entitled to vote in referenda on the continuation, suspension, or termination of their checkoff programs.

The Generic Act provides that two referenda must be conducted in each checkoff program created pursuant to its authority. The first referendum must be conducted either before a checkoff program goes into effect (to ascertain whether the Order is favored by the persons to be covered by it) or, alternatively, within 3 years after assessments begin (to determine whether a majority favors the continuation, suspension, or termination of the program). The second referendum must be conducted within 7 years after assessments begin to determine whether a majority favors the continuation, suspension, or termination of the program. All persons subject to assessments are allowed to vote in referenda.

The Sorghum and Lamb Orders each incorporate provisions for two required referenda, the first within 3 years and the second within 7 years after assessments begin. Both Orders contain provisions for assessment payers to obtain refunds of assessments and for both boards to maintain escrow accounts ahead of these referenda. All of those referenda, two for sorghum and two for lamb, were conducted within the time frames defined by the Orders. In each of the four referenda, a large majority approved the relevant program's continuance. Those referenda will not be repeated. Thus, AMS is removing the sections and paragraphs of the Sorghum and Lamb Orders that relate to refunds and escrow accounts because they are obsolete.

In the Sorghum Order, §§ 1221.112(g), 1221.112(h), 1221.118, 1221.119, and 1221.120, which provided for escrow

accounts and refunds in connection with required referenda, will be removed. In § 1221.112, paragraphs (i) through (m) will be redesignated as (g) through (k), respectively. A conforming change will be made to § 1221.128(a) to correct a reference.

In the Lamb Order, §§ 1280.214, 1280.215, 1280.216, and 1280.403, which provided for escrow accounts and refunds in connection with required referenda, will be removed.

AMS is issuing this direct final rule without a preceding proposed rule because this action is a routine, noncontroversial regulatory change that AMS believes will not generate adverse comment. The rule is conditional on the non-receipt of adverse comments. If adverse comment is received, AMS will withdraw the rule before the effective date.

List of Subjects

7 CFR Part 1221

Administrative practice and procedure, Advertising, Agricultural research, Reporting and recordkeeping requirements, Sorghum.

7 CFR Part 1280

Administrative practice and procedure, Advertising, Agricultural research, Meat and meat products, Reporting and recordkeeping requirements.

For reasons set forth in the preamble, AMS is amending 7 CFR parts 1221 and 1280 as follows:

PART 1221—SORGHUM PROMOTION, RESEARCH, AND INFORMATION ORDER

■ 1. The authority citation for part 1221 continues to read as follows:

Authority: 7 U.S.C. 7411–7425 and 7 U.S.C. 7401.

§1221.112 [Amended]

■ 2. In § 1221.112 remove paragraphs (g) and (h) and redesignate paragraphs (i) through (m) as paragraphs (g) through (k), respectively.

§§ 1221.118, 1221.119, and 1221.120 [Removed]

■ 3. Remove §§ 1221.118, 1221.119, and 1221.120.

■ 4. Revise § 1221.128(a) to read as follows:

§1221.128 Qualification.

(a) Organizations receiving qualification from the Secretary will be entitled to submit requests for funding to the Board pursuant to § 1221.112(h). Only one sorghum producer organization per State may be qualified.

PART 1280—LAMB PROMOTION, RESEARCH, AND INFORMATION ORDER

■ 5. The authority citation for part 1280 continues to read as follows:

Authority: 7 U.S.C. 7411–7425 and 7 U.S.C. 7401.

§§ 1280.214, 1280.215, 1280.216, and 1280.403 [Removed]

■ 6. Remove §§ 1280.214, 1280.215, 1280.216, and 1280.403.

Dated: July 20, 2018.

Bruce Summers,

Administrator, Agricultural Marketing Service. [FR Doc. 2018–15893 Filed 7–24–18; 8:45 am]

BILLING CODE 3410-02-P

DEPARTMENT OF ENERGY

10 CFR Part 590

[FE Docket No. 17-86-R]

RIN 1901-AB43

Small-Scale Natural Gas Exports

AGENCY: Office of Fossil Energy, Department of Energy. **ACTION:** Final rule.

SUMMARY: The Department of Energy (DOE or the Department) is revising its regulations to provide that DOE will issue an export authorization upon receipt of any complete application that seeks to export natural gas, including liquefied natural gas (LNG), to countries with which the United States has not entered into a free trade agreement (FTA) requiring national treatment for trade in natural gas and with which trade is not prohibited by U.S. law or policy (non-FTA countries), provided that the application satisfies the following two criteria: The application proposes to export natural gas in a volume up to and including 51.75 billion cubic feet (Bcf) per year (Bcf/yr) (equivalent to 0.14 Bcf per day (Bcf/d)), and DOE's approval of the application does not require an environmental impact statement (EIS) or an environmental assessment (EA) under the National Environmental Policy Act of 1969 (NEPA). Applications that satisfy these criteria are requesting authorization for "small-scale natural gas exports," and DOE deems such exports to be consistent with the public interest under the Natural Gas Act (NGA). DOE's regulations regarding

notice of applications and procedures conducted on applications do not apply to applications that satisfy these criteria. This regulation is intended to expedite DOE's processing of these applications and reduce administrative burdens for the small-scale natural gas export market.

DATES: This final rule is effective August 24.2018.

FOR FURTHER INFORMATION CONTACT:

Amy Sweeney, U.S. Department of Energy (FE-34), Office of Regulation and International Engagement, Office of Fossil Energy Forrestal Building, Room 3E-042, 1000 Independence Avenue SW, Washington, DC 20585; (202) 586-2627; or Cassandra Bernstein or Ronald (R.J.) Colwell, U.S. Department of Energy (GC-76), Office of the Assistant General Counsel for Electricity and Fossil Energy, Forrestal Building, Room 6D-033, 1000 Independence Ave. SW. Washington, DC 20585; (202) 586-9793 or (202) 586-8499.

SUPPLEMENTARY INFORMATION:

Acronyms and Abbreviations. A number of acronyms and abbreviations are used in this final rule and set forth below for reference.

- AEO Annual Energy Outlook
- Administrative Procedure Act APA
- Bcf/d Billion Cubic Feet per Day
- Bcf/yr Billion Cubic Feet per Year
- CNG Compressed Natural Gas
- DOE Department of Energy
- EA Environmental Assessment
- EIA U.S. Energy Information
- Administration
- EIS Environmental Impact Statement FE
- Office of Fossil Energy, U.S. Department of Energy FERC Federal Energy Regulatory
- Commission
- FTA Free Trade Agreement
- ISO ISO IMO7/TVAC-ASME LNG
- LNG Liquefied Natural Gas
- Million Metric Tons per Annum mtpa NEPA National Environmental Policy Act of 1969
- NGA Natural Gas Act of 1938
- I. Background
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- F. Unfunded Mandates Reform Act of 1995 G. Treasury and General Government Appropriations Act, 1999
- H. Executive Order 13132
- I. Executive Order 12988
- I. Treasury and General Government Appropriations Act, 2001
- K. Executive Order 13211
- L. Congressional Notification
- IV. Approval of the Office of the Secretary

I. Background

The Department of Energy is responsible for authorizing exports of domestically produced natural gas to foreign nations pursuant to section 3 of the NGA, 15 U.S.C. 717b. For applications to export natural gas to non-FTA countries under NGA section 3(a), 15 U.S.C. 717b(a),¹ DOE has consistently interpreted section 3 of the NGA as creating a rebuttable presumption that a proposed export of natural gas is in the public interest.² Accordingly, DOE will conduct an informal adjudication and grant a non-FTA application unless DOE finds that the proposed exportation will not be consistent with the public interest.³ Before reaching a final decision, DOE must also comply with NEPA, 42 U.S.C. 4321 et seq.

In this final rule, DOE revises its regulations to expedite the application and approval process for "small-scale" exports of natural gas to non-FTA countries, pursuant to section 3(a) of the NGA. This emerging market involves exports of small volumes of natural gas from the United States to countries primarily in, but not limited to, the Caribbean, Central America, and South America. The small-scale export market has developed as a solution to the practical and economic constraints limiting large-scale natural gas exports to these countries. In contrast to largescale natural gas exports, small-scale exports typically originate from existing facilities in the United States, are transported shorter distances, and rely

² See Sierra Club v. U.S. Dep't of Energy, 867 F.3d 189, 203 (D.C. Cir. 2017) ("We have construed [NGA section 3(a)] as containing a 'general presumption favoring [export] authorization.' (quoting W. Va. Pub. Serv. Comm'n v. U.S. Dep't of Energy, 681 F.2d 847, 856 (D.C. Cir. 1982)).

³ See id. ("there must be 'an affirmative showing of inconsistency with the public interest' to deny the application'' under NGA section 3(a)) (quoting Panhandle Producers & Royalty Owners Ass'n v. Econ. Regulatory Admin., 822 F.2d 1105, 1111 (D.C. Cir. 1987)).

on a variety of transportation modes, such as approved ISO IMO7/TVAC-ASME LNG (ISO) containers loaded onto container ships and barges. DOE believes that facilitating small-scale natural gas exports will allow for greater diversity and competition in the natural gas market, consistent with the public interest under NGA section 3(a).

For each small-scale export application submitted to DOE, DOE will first determine if the application is complete under DOE's regulations. If the application is complete, DOE will post the application on DOE's website, consistent with DOE practice. This final rule establishes that, upon receipt of any complete application to export natural gas (including LNG) to non-FTA countries, DOE will grant the application provided that it satisfies the following two criteria: (1) The application proposes to export natural gas in a volume up to and including 51.75 Bcf/yr⁴ (10 CFR 590.102(p)(1)); and (2) DOE's approval of the application does not require an EIS or EA under NEPA (10 CFR 590.102(p)(2))-that is, the application is eligible for a categorical exclusion under DOE's NEPA regulations.

Any non-FTA application that satisfies these two criteria will qualify as a "small-scale natural gas export" as that term is defined under this final rule (10 CFR 590.102(p)), and will be deemed to be consistent with the public interest under NGA section 3(a) (10 CFR 590.208(a)). DOE will issue an export authorization granting the application on an expedited basis. Specifically, DOE will not provide notice of each individual application nor apply other procedures typically conducted for non-FTA export applications under DOE's regulations, 10 CFR 590.205 and 10 CFR part 590, subpart C (10 CFR 590.303-10 CFR 590.317).

On September 1, 2017, DOE published the notice of proposed rulemaking (NOPR or proposed rule) to revise its regulations to provide for this expedited approval of small-scale export applications (82 FR 41570; Sept. 1, 2017). Publication of the NOPR began a 45-day public comment period that ended on October 16, 2017. DOE received approximately 85 unique

¹This final rule does not apply to exports to FTA countries under section 3(c) of the NGA, 15 U.S.C. 717b(c). This final rule also does not affect existing DOE authorizations or DOE's evaluation of any non-FTA application that does not meet the criteria for small-scale natural gas exports.

⁴ In this final rule, DOE is changing the volume criterion from a daily limitation of "up to and including 0.14 Bcf/d," as stated in the proposed rule, to an annualized limitation of "up to and including 51.75 Bcf/yr." This change does not affect the total volume, as 0.14 Bcf/d and 51.75 Bcf/yr represent the same amount of natural gas express in different terms. DOE has determined that expressing the volume criterion in an annualized figure is both more consistent with industry practice and more practicable for DOE's administration of the small-scale export program.

comments on the NOPR from a variety of sources, including natural gas industry groups, environmental organizations, and individuals. The NOPR and comments received on the NOPR can be accessed through DOE's website at https://www.energy.gov/fe/ articles/notice-proposed-rulemakingregarding-small-scale-lng-exports.

For additional background information on this final rule, please see the proposed rule. In the proposed rule, DOE provides information on DOE's practice of issuing non-FTA export authorizations and the various studies DOE has commissioned to evaluate the reasonably foreseeable economic and environmental impacts of natural gas exports—including those that would qualify as small-scale exports under this final rule.

II. Discussion of Final Rule and Response to Comments

DOE has evaluated the comments received during the public comment period. In this section, DOE discusses the relevant, significant comments received on the proposed rule and provides DOE's responses to those comments. Some commenters raised a variety of other concerns that are outside the scope of the rule-including criticizing individual LNG export projects currently in operation or pending before DOE and questioning the scope of the Federal Energy Regulatory Commission's (FERC) jurisdiction over certain types of LNG export facilities under NGA section 3. DOE does not address these comments in the final rule.

A. Public Interest Determination

1. General

In issuing this final rule, DOE has determined that small-scale natural gas exports are consistent with the public interest under NGA section 3(a). In reaching this conclusion, DOE has considered its obligations under NGA section 3(a), the public comments received on the proposed rule, and a wide range of information bearing on the public interest, including (but not limited to) information on economic impacts, international impacts, security of domestic natural gas supply, and environmental impacts associated with these exports (82 FR 41573-41574; Sept. 1, 2017).

Additionally, DOE has considered the 29 final non-FTA export authorizations issued to date,⁵ as well as authoritative

projections for natural gas supply, demand, and prices set forth in the U.S. Energy Information Administration's (EIA) Annual Energy Outlook 2017 (AEO 2017)⁶ (discussed in the proposed rule) and Annual Energy Outlook 2018 (AEO 2018).⁷ With respect to the regulatory criteria established by this rulemaking, DOE considered industry sources in establishing the volume limitation, as well as its obligations under NEPA in establishing the NEPA criterion.

In sum, DOE has thoroughly analyzed the many factors affecting the export of U.S. natural gas, as well as the unique characteristics and minimal adverse impacts of the emerging small-scale natural gas market. On this basis (and as discussed in the proposed rule), DOE has determined that the final rule is in accordance with section 3 of the NGA, DOE's interpretation of the public interest standard set forth in NGA section 3(a), and DOE's long-standing policy of minimizing federal control and involvement in energy markets and promoting a balanced and mixed energy resource system. Based on this evidence, 10 CFR 590.208 of the final rule establishes that small-scale natural gas exports, as defined in 10 CFR 590.102(p), are deemed to be consistent with the public interest under NGA section 3(a).

Many commenters expressed overall support for DOE's authorization of LNG exports and, specifically, for DOE's efforts to expedite the approval of applications for small-scale natural gas exports to non-FTA countries. Several commenters agreed that small-scale natural gas exports are an important emerging market that DOE should facilitate through a streamlined approval process for qualifying applicants. They commented that smallscale exports will provide a variety of benefits both to the United States and to the anticipated importing countries primarily located in the Caribbean,

⁶ U.S. Energy Info. Admin., *Annual Energy Outlook* 2017 (Jan. 2017), *available at: https://www.eia.gov/outlooks/archive/aeo17/.*

⁷ U.S. Energy Info. Admin., Annual Energy Outlook 2018 (Feb. 2018), available at: http:// www.eia.gov/outlooks/aeo.

Central America, and South America. Benefits identified for the United States include stimulating the natural gas market, generating economic growth, strengthening the global natural gas market, and enhancing U.S. national security interests abroad. Benefits identified for the importing countries include expanding natural gas markets and providing access to cleaner and more reliable sources of energy Commenters also expressed support for DOE's regulatory definition of "smallscale natural gas export," such that qualifying applications are deemed consistent with the public interest; as well as DOE's efforts to reduce regulatory burdens for these applicants. DOE generally agrees with these comments and recognizes the variety of important benefits that are expected to occur under the final rule.

2. Scope of Rule

Some commenters remarked that this rulemaking is an important step, yet encouraged DOE to liberalize *all* natural gas exports—not just qualifying smallscale natural gas exports—to ensure that the benefits of natural gas exports can be fully realized.

Based on findings from The Macroeconomic Impact of Increasing U.S. LNG Exports (2015 LNG Export Study),⁸ DOE agrees that higher natural gas exports are associated with marginally higher macroeconomic benefits to the United States (82 FR 41572).⁹ This rulemaking focuses only on small-scale natural gas exports to non-FTA countries, in light of the unique characteristics and minimal adverse impacts associated with that market. Insofar as the commenters are suggesting that DOE undertake additional deregulatory efforts under NGA section 3(a), DOE welcomes suggestions, data, and information on this topic through its regulatory reform email inbox at Regulatory.Review@ hq.doe.gov.

3. Public Interest Standard

Several commenters disagreed with various aspects of DOE's public interest analysis generally. For example, some commenters disagreed with DOE's position that NGA section 3(a) creates a

⁵ As of the date of the proposed rule, DOE had issued 28 final authorizations to export LNG or compressed natural gas (CNG) to non-FTA countries (82 FR 41572). After the proposed rule was

published, DOE issued an additional non-FTA export authorization. See Eagle LNG Partners Jacksonville II LLC, DOE/FE Order No. 4078, FE Docket No. 17–79–LNG, Opinion and Order Granting Long-Term, Multi-Contract Authorization to Export Liquefied Natural Gas in ISO Containers Loaded at the Eagle Maxville Facility in Jacksonville, Florida, and Exported by Vessel to Free Trade Agreement and Non-Free Trade Agreement Nations (Sept. 15, 2017). Thus, to date, DOE has issued 29 final export authorizations to non-FTA countries, bringing the cumulative total of approved non-FTA exports of LNG and CNG to 21.35 Bcf/d of natural gas, or 7.79 trillion cubic feet per year. See id. at 34–37.

⁸Center for Energy Studies at Rice University Baker Institute and Oxford Economics, *The Macroeconomic Impact of Increasing U.S. LNG Exports* (Oct. 29, 2015), available at: http:// energy.gov/sites/prod/files/2015/12/f27/20151113_ macro_impact_of_Ing_exports_0.pdf [hereinafter 2015 LNG Export Study].

⁹ On June 12, 2018, DOE published a notice of availability of the 2018 LNG Export Study and request for comments. *See* U.S. Dep't of Energy, Study on Macroeconomic Outcomes of LNG Exports, 83 FR 27314 (June 12, 2018).

rebuttable presumption that natural gas exports are consistent with the public interest. Some stated that Congress, not DOE, must define "public interest" under section 3(a), whereas other commenters criticized DOE for not providing a regulatory definition of the public interest. Another commenter suggested that applications to export natural gas should be subjected to the same standard, regardless of whether the natural gas is being exported to FTA or non-FTA countries.

As an initial matter, section 3 of the NGA (as amended by section 201 of the Energy Policy Act of 1992 (Pub. L. 102–486)) distinguishes between exports to non-FTA countries under section 3(a) and FTA countries under section 3(c).¹⁰ These provisions establish different standards of review for proposed exports to FTA and non-FTA countries, and DOE has comported with the appropriate standard of review for the future non-FTA exports at issue in this rulemaking.¹¹

In every non-FTA authorization to date,¹² as well as in the proposed rule (82 FR 41571-41572; Sept. 1, 2017), DOE has explained its interpretation of the public interest analysis under NGA section 3(a). The commenters' concerns reflect a lack of familiarity with both the statute and DOE's long-standing practice in evaluating non-FTA applications—a practice that was upheld by the U.S. Court of Appeals for the District of Columbia Circuit in a series of cases decided in 2017.13 Indeed, the D.C. Circuit has consistently affirmed DOE's interpretation that NGA section 3(a) creates a rebuttable presumption favoring authorization of applications to import or export natural gas.¹⁴

Although section 3(a) establishes a broad public interest standard and a

¹⁴ See Sierra Club, 867 F.3d at 203; see also, e.g., W. Va. Pub. Serv. Comm'n v. U.S. Dep't of Energy, 681 F.2d 847 (D.C. Cir. 1982); Panhandle Producers and Royalty Owners Ass'n v. Economic Regulatory Admin., 822 F.2d 1105 (D.C. Cir. 1987); Panhandle Producers and Royalty Owners Ass'n v. Economic Regulatory Admin., 847 F.2d 1168 (1988). presumption favoring export authorizations, Congress has not defined the phrase "public interest" or identified specific criteria that must be considered in issuing a non-FTA authorization under that statute. As a result, DOE has identified a range of factors, described above, that it considers when determining whether a proposed export of natural gas is consistent with the public interest. The D.C. Circuit has upheld DOE's non-FTA export authorizations granted on the basis of this public interest evaluation.¹⁵

In this rulemaking, DOE has followed its established approach in interpreting NGA section 3(a) to determine that qualifying small-scale natural gas exports are consistent with the public interest after considering all relevant factors (82 FR 41573). There is nothing fundamentally unique about small-scale exports that would alter DOE's analysis of the public interest in this context.

4. Domestic Supply of Natural Gas

Numerous commenters disagreed as to whether the United States has sufficient natural gas supplies to support the expedited approval of small-scale exports under this rule. Some commenters asserted that the United States has sufficient natural gas supplies to meet both increased natural gas exports and increased domestic natural gas demand, as DOE set forth in the proposed rule (82 FR 41573–41574). Other commenters asserted that the United States does not have sufficient natural gas supplies to meet current demand, much less increased demand associated with this rulemaking. One commenter, for example, argued that approvals for natural gas exports to FTA and non-FTA countries combined already exceed 71% of domestic demand, thereby calling into question the sufficiency of U.S. natural gas supplies.

First, DOE notes that the volumes authorized for export to FTA and non-FTA countries are not additive to one another. The 71% figure cited by the commenter for "combined LNG exports" fails to acknowledge this fact, which is reflected in DOE's orders. Rather, each authorization grants authority to export the entire volume of a facility to FTA or non-FTA countries, respectively, to provide the authorization holder with maximal flexibility in determining its export destinations.

Next, to date DOE has issued 29 final non-FTA authorizations in a cumulative volume of exports totaling 21.35 Bcf/d of natural gas.¹⁶ By comparison, approximately 3.5 Bcf/d of capacity has been built and is being utilized, and approximately 7.5 Bcf/d of additional capacity is under construction.¹⁷ Industry outlooks, including Reference cases in the last several years of EIA's Annual Energy Outlook, do not foresee long-term LNG exports from the United States exceeding the volume currently authorized for export from non-FTA countries.

By DOE's standard measures of supply, there are adequate natural gas resources to meet demand associated with the final rule. EIA's most recent natural gas estimates of future production, price, and other domestic industry fundamentals set forth in AEO 2017 and AEO 2018 support this conclusion. For example, the AEO 2017 Reference case projection of lower-48 states dry natural gas production in 2035 increased significantly (by 27.9 Bcf/d) as compared with AEO 2011, while the AEO 2018 Reference case projection of that figure was higher still, an increase of 33.8 Bcf/d over AEO 2011. Projections of domestic natural gas consumption in 2035 also increased in both AEO 2017 and AEO 2018, as compared to AEO 2011 (by 11.3 Bcf/d in AEO 2017 and by 13.3 Bcf/d in AEO 2018). Even with higher production and consumption, the 2035 projected natural gas market price in the Reference case declined from \$8.04/MMBtu (2017\$) in AEO 2011 to \$5.20/MMBtu (2017\$) in AEO 2017 and to \$4.26/MMBtu (2017\$) in AEO 2018. The implication of the latest EIA projections in AEO 2017 and AEO 2018 is that a significantly greater quantity of natural gas is projected to be available at a lower cost than was estimated seven years ago.

¹⁰ See supra note 1.

¹¹ See id.

¹² See, e.g., Eagle LNG Partners Jacksonville II LLC, DOE/FE Order No. 4078, at 8–10, *supra* note 5.

¹³ See Sierra Club v. U.S. Dep't of Energy, 867 F.3d 189 (D.C. Cir. 2017) (denying petition for review challenging non-FTA export authorization); Sierra Club v. U.S. Dep't of Energy, Nos. 16–1186, 16–1252, 16–1253, 703 Fed. Appx. 1 (D.C. Cir. Nov. 1, 2017) (denying petitions for review challenging three non-FTA export authorizations).

¹⁵ See supra note 13.

¹⁶ See Eagle LNG Partners Jacksonville II LLC, DOE/FE Order No. 4078, at 34–37, supra note 5.

¹⁷ See, e.g., U.S. Energy Info. Admin., Existing and Under Construction Large Scale U.S. Liquefaction Facilities (June 18, 2018), available at: https://www.eia.gov/naturalgas/U.S.liquefaction capacity.xlsx (also see Contents tab): Cheniere Energy, Inc., "Cheniere Makes Positive Final Investment Decision on Train 3 at the Corpus Christi Liquefaction Project" (May 22, 2018), available at: http://phx.corporate-ir.net/ phoenix.zhtml?c=101667&p=irol-news Article&ID=2350302.

Proved reserves of natural gas—*i.e.*, volumes of oil and natural gas that geologic and engineering data demonstrate with reasonable certainty to be recoverable in future years from known reservoirs—also have been increasing. From 2000 to 2015, proved reserves have increased 73% to 307,730 Bcf, while production has increased only 41% during the same period, demonstrating the growing supply of natural gas available under existing economic and operating conditions.¹⁸

EIA's estimates of technically recoverable reserves point to the availability of domestic natural gas for decades to come. These reserves are resources in accumulations (both proved and unproved) that are producible using current recovery technology but without reference to economic profitability. EIA's estimates of lower-48 natural gas technically recoverable reserves total 1,796 Tcf in AEO 2017.¹⁹

Next, the 2014 and 2015 Studies concluded that, for the period of the analysis (through 2040), the United States is projected to have ample supplies of natural gas resources that can meet domestic needs for natural gas and the LNG export market. Further, most projections of domestic natural gas resources extend beyond 20 to 40 years. Although not all technically recoverable resources are currently economical to produce, it is instructive to note that EIA's recent estimate of technically recoverable resources as of January 1, 2015, equates to nearly 66 years of natural gas supply at the 2015 domestic consumption level of 27.24 Tcf.²⁰

Based upon this record evidence and the discussion in the proposed rule, DOE finds that the small-scale exports will not adversely affect the availability of natural gas supplies to domestic consumers, such as would negate the

¹⁹ See U.S. Energy Info. Admin., Assumptions to the Annual Energy Outlook 2017 (July 2017), Table 9.2. Technically recoverable U.S. dry natural gas resources as of January 1, 2015, at 133, available at: https://www.eia.gov/outlooks/aeo/assumptions/ pdf/oilgas.pdf (2017).pdf, and Assumptions to the Annual Energy Outlook 2010 (Apr. 2010), Table 9.2. Technically recoverable U.S. natural gas resources as of January 1, 2008, at 111, available at: http:// www.eia.gov/oiaf/aeo/assumption/pdf/ 0554(2010).pdf.

²⁰ See U.S. Energy Info. Admin., Natural Gas Consumption by End Use (Feb. 12, 2018), available at: http://www.eia.gov/dnav/ng/ng_cons_sum_dcu_ nus_a.htm. net economic benefits to the United States.

5. Cumulative Impacts

Several commenters asserted that DOE must account for cumulative impacts in various ways as part of its public interest determination for this final rule. Some commenters urged DOE to provide a "cap" or other language in the final rule to halt automatic approval of small-scale exports if the cumulative volume of exports exceeds the scope of existing cumulative impact analyses (which the commenters acknowledge is 28 Bcf/d of exports based on the 2015 LNG Export Study, 82 FR 41572), or if other circumstances arise that would render these exports inconsistent with the public interest. Commenters suggested, for example, that DOE should cease approval of small-scale export applications if the United States loses its competitive price advantage in exporting LNG, or if exporting natural gas above a certain volume would have negative economic impacts or threaten the security of domestic natural gas supplies. Other commenters expressed concern that U.S. natural gas production could not meet "unlimited" LNG exports as might occur under the proposed rule, and therefore urged DOE to implement a "safety net" in the rule allowing DOE to halt approvals of smallscale applications.

DOE declines to adopt a mechanism in the final rule that would automatically halt approvals of smallscale applications if the cumulative volume of approvals exceeds the scope of DOE's cumulative impact analyses to date. The 2015 Study considered export volumes ranging from 12 to 20 Bcf/d of natural gas, as well as a high resource recovery case examining export volumes up to 28 Bcf/d of natural gas. By comparison, to date DOE has issued final non-FTA authorizations in a cumulative volume of exports totaling 21.35 Bcf/d of natural gas²¹—well below the 28 Bcf/d case considered in the 2015 Study. DOE already assesses the cumulative impacts of each succeeding request for export authorization on the public interest with due regard to the effect on domestic natural gas supply and demand fundamentals. DOE will continue to do so for non-small-scale export applications (i.e., applications requesting an export volume greater than 51.75 Bcf/vr), which constitute both 99% of the non-FTA LNG export volumes authorized to date and 99% of the LNG export volumes requested in

²¹ See Eagle LNG Partners Jacksonville II LLC, DOE/FE Order No. 4078, at 34–37, supra note 5.

non-FTA applications currently pending before DOE.²²

For this final rule, DOE has determined that domestic supplies of natural gas will be adequate to supply small-scale exports of natural gas while meeting domestic demand. In so doing, DOE considered the economic impacts of higher natural gas prices, potential increases in natural gas price volatility, and the security of domestic natural gas supplies, among other factors. DOE also explained that the prospect of "unlimited" exports of U.S. natural gas is not realistic, as discussed in the 2015 LNG Export Study.23 The authors of the 2015 Study had to include several assumptions about the global natural gas market for U.S. LNG exports to exceed 12 Bcf/d, and include far less likely assumptions to reach the high resource recovery case of 28 Bcf/d of exports. Further, as DOE has observed in prior orders, receiving a non-FTA authorization from DOE does not guarantee that a particular facility will be financed and built; nor does it guarantee that, if built, market conditions would continue to favor exports once the facility is operational.²⁴ For more information on DOE's LNG export studies and DOE's conclusions regarding these public interest factors, please see the proposed rule (82 FR 41571-41574; Sept. 1, 2017).

As to the commenter's concern that the global natural gas market for U.S. LNG exports could change in the future, DOE notes that the 2015 LNG Export Study included several assumptions about the global market for the time period covering 2015 to 2040. Nonetheless, DOE's long-standing policy is to minimize federal control and involvement in energy markets (82 FR 41571, 41574), such that even a change in the competitive status of U.S. LNG globally would not affect DOE's

²³ The 2015 LNG Export Study included scenarios in which LNG exports were unconstrained. These scenarios indicated that, should the U.S. resource base be less robust and more expensive than anticipated, U.S. LNG exports would be less competitive in the world market, thereby resulting in lower export levels from the United States. Further, in all of the unconstrained scenarios, the supply and price response to LNG exports did not negate the net economic benefit to the economy from the exports.

²⁴ See, e.g., Golden Pass Products LLC, DOE/FE Order No. 3978, FE Docket No. 12–156–LNG, Opinion and Order Granting Long-Term, Multi-Contract Authorization to Export Liquefied Natural Gas by Vessel from the Golden Pass LNG Terminal Located in Jefferson County, Texas, to Non-Free Trade Agreement, at 148 (Apr. 25, 2017).

¹⁸ U.S. Energy Info. Admin., U.S. Dry Natural Gas Proved Reserves (Feb. 12, 2018), available at: http:// www.eia.gov/dnav/ng/ng_enr_dry_dcu_nus_a.htm; U.S. Energy Info. Admin., U.S. Dry Natural Gas Production (Feb. 12, 2018), available at: https:// www.eia.gov/dnav/ng/hist/n9070us2a.htm (additional calculations conducted to produce percentage change and R/P ratios).

²² U.S. Dep't of Energy, Office of Fossil Energy, Summary of LNG Export Applications of the Lower 48 States Annual Energy Outlook 2017 (Feb. 14, 2018), available at: https://energy.gov/fe/ downloads/summary-Ing-export-applications-lower-48-states.

approval of small-scale natural gas exports as set forth in this final rule.

Next, commenters stated that the proposed rule is deficient because DOE has neither: (i) Attempted to predict the potential cumulative size of the U.S. small-scale export market, nor (ii) identified the potential LNG demand in the importing Caribbean, Central American, and South American countries that are the target of this rule.

DOE explained in the proposed rule that foreign demand for imports of U.S. natural gas has increased as many countries, such as those in the Caribbean, Central America, and South America, seek to import cleaner sources of energy. Based on the record evidence and the small volumes at issue in this rulemaking, DOE has determined that domestic supplies of natural gas will be adequate both to meet domestic needs and to supply small-scale exports of natural gas (82 FR 41572-41574). We therefore disagree with the comment that DOE was required to consider projections of the potential cumulative size of the U.S. small-scale market and/ or the market demand of the importing regions among the many factors evaluated as part of its public interest determination.

6. Economic Impacts

Several commenters agreed with DOE's position that small-scale natural gas exports will not lead to a detectable impact on domestic natural gas prices (82 FR 41574), whereas other commenters disputed this position. The dissenting commenters expressed concern that this rulemaking will increase exports of U.S. natural gas (including LNG), leading to increases in natural gas prices. They further argued that even very small increases in natural gas prices are likely to lead to the loss of employment in energy-intensive industries. In sum, they asserted that, if there are any economic or job-creation impacts associated with this final rule, these impacts are likely to be negative.

First, as discussed in the proposed rule, the 2014 and 2015 LNG Export Studies²⁵ projected the economic impacts of LNG exports in a range of scenarios, including scenarios that exceeded the current amount of LNG exports authorized in the final non-FTA export authorizations to date. The 2015 LNG Export Study concluded that LNG exports at these levels (in excess of 12 Bcf/d of natural gas) would result in higher U.S. natural gas prices, but that these price changes would remain in a relatively narrow range across the scenarios studied. However, even with these estimated price increases, the 2015 LNG Export Study found that the United States would experience net economic benefits from increased LNG exports in all cases studied.²⁶

Next, for the proposed rule, DOE reviewed EIA's AEO 2017. The Reference case of this projection includes the effects of the Clean Power Plan (CPP) final rule,27 which was intended to reduce carbon emissions from the power sector. DOE assessed AEO 2017 to evaluate any differences from AEO 2014, which formed the basis for the 2014 LNG Export Study.²⁸ Comparing key results from 2040 (the end of the projection period in Reference case projections from AEO 2014) shows that the latest Reference case Outlook foresees lower-48 market conditions that would be even more

supportive of LNG exports, including higher production and demand coupled with notably lower prices. Results from EIA's AEO 2017 no-CPP case, which is the same as the Reference case but does not include the CPP, are also more supportive of LNG exports on the basis of higher production with lower prices relative to AEO 2014.

For the year 2040, the AEO 2017 Reference case anticipates 3% more natural gas production in the lower-48 than AEO 2014. It also projects an average Henry Hub natural gas price that is lower than AEO 2014 by 38% in 2017\$. In the AEO 2017 no-CPP case, for the year 2040, lower-48 production is 2% higher than in AEO 2014, with the price differential being approximately the same. Both higher production and lower prices in both AEO 2017 cases illustrate a market environment supportive of LNG exports.

On February 6, 2018, EIA issued AEO 2018. For this final rule, DOE has considered AEO 2018 to determine whether EIA's most recent projections present any material difference in terms of price impacts. AEO 2018, which does not include the CPP in its Reference case, is even more supportive of exports than AEO 2017 and AEO 2014, showing Henry Hub prices of \$4.50 in 2040, which is 46% lower than AEO 2014 and 13% lower than AEO 2017 in 2017\$. Production levels are also increased in 2040 in AEO 2018 over AEO 2014 and AEO 2017—with AEO 2018 showing lower-48 dry production at 109.1 Bcf/d over lower-48 production levels of 99.7 and 102.5 in AEO 2014 and 2017, respectively, as shown in the table below.

	AEO 2014 reference case	AEO 2017 reference case	AEO 2017 reference case without clean power plan	AEO 2018 reference case
Henry Hub Prices in 2040 (in 2017\$)	\$8.27	\$5.18	\$5.01	\$4.50
Lower-48 Production (Bcf/d) in 2040	99.7	102.5	101.6	109.1

In sum, the conclusion of the 2015 LNG Export Study is that the United States will experience net economic benefits from issuance of authorizations to export domestically produced LNG. The 2015 LNG Export Study projected that an increase in U.S. natural gas exports will generate small declines in output at the margin for some energy-

²⁵ U.S. Energy Info. Admin., *Effect of Increased Levels of Liquefied Natural Gas Exports on U.S. Energy Markets* (Oct. 2014), *available at: https://www.eia.gov/analysis/requests/fe/pdf/lng.pdf* [hereinafter 2014 LNG Export Study]; 2015 LNG Export Study, *supra* note 8; *see also* 82 FR 41571–41572 (Sept. 1, 2017).

²⁶ See 2015 LNG Export Study, supra note 8, at 82.

²⁷ U.S. Envtl. Prot. Agency, Carbon Pollution Emission Guidelines for Existing Stationary Sources: Electric Utility Generating Units; Final

Rule, 80 FR 64662 (Oct. 23, 2015). On February 9, 2016, the U.S. Supreme Court issued a stay of the effectiveness of the CPP final rule pending review by the U.S. Court of Appeals for the District of Columbia Circuit in consolidated cases challenging the rule. See *Chamber of Commerce, et al. v. EPA, et al.*, No. 15A787, Order in Pending Cases (U.S. Feb. 9, 2016). The litigation over the CPP final rule pending in the D.C. Circuit has been held in abeyance as the U.S. Environmental Protection Agency (EPA) reviews the rule. *See West Virginia, et al. v. EPA, et al.*, Case Nos. 15–1363 *et al.*, EPA Status Report, at 3 (D.C. Cir. June 1, 2018). On

October 10, 2017, EPA issued a notice proposing to repeal the CPP final rule. U.S. Envtl. Prot. Agency, Repeal of Carbon Pollution Emission Guidelines for Existing Stationary Sources: Electric Utility Generating Units; Proposed Rule, 82 FR 48035 (Oct. 16, 2017). That rulemaking is on-going, and EPA has asked for the consolidated cases to remain in abeyance pending the conclusion of the rulemaking. *See* EPA Status Report at 4–5.

²⁸ See 2014 LNG Export Study, *supra* note 25 (discussed in the proposed rule at 82 FR 41571– 41572; Sept. 1, 2017).

intensive, trade-exposed industries, but that negative impacts in energyintensive sectors will be offset by positive impacts (82 FR 41572; Sept 1, 2017).

DOE has reviewed both the evidence in the record and relevant precedent, and has not found evidence to support the commenters' claims of negative economic impact. Nor have those commenters presented sufficient evidence to support their assertions of economic harm.²⁹ On this basis, DOE concludes that small-scale natural gas exports are expected to generate positive economic benefits in the United States through direct and indirect job creation, increased economic activity, tax revenues, and improved U.S. balance of trade.

7. Environmental Issues

In reviewing the potential environmental impacts of the proposed rulemaking, DOE has considered both its obligations under NEPA (discussed in Section II.B.2) and its obligation under NGA section 3(a) to ensure that the proposal is not inconsistent with the public interest.

In the context of NGA section 3(a), several commenters contended that this rulemaking is inconsistent with the public interest on environmental grounds. According to these commenters, expediting the approval of small-scale natural gas exports will lead to increased natural gas production and transmission which, in turn, will result in negative environmental impacts. They cite, for example, the possibility of accelerated climate change and increased greenhouse gas emissions, both in the United States and in the importing countries, as a result of these increased small-scale exports. These commenters contend that, rather than facilitating small-scale exports, DOE should closely scrutinize or ban natural gas exports to non-FTA countries altogether.

As discussed in Section II.B.2 and in the proposed rule, qualifying

applications for small-scale exports must not require an environmental impact statement (EIS) or an environmental assessment (EA) under NEPA. That is, the application must be eligible for a categorical exclusion. Further, DOE has determined—and the D.C. Circuit has agreed ³⁰—that NEPA does not require consideration of induced "upstream" natural gas production related to increased natural gas production, contrary to the commenters' assertions.

Specifically, DOE determined that the current rapid development of natural gas resources in the United States will continue, with or without the export of natural gas to non-FTA nations. DOE also found that fundamental uncertainties constrain its ability to foresee and analyze with any particularity the incremental natural gas production that may be induced by permitting exports of LNG (or CNG) to non-FTA countries-whether from unconventional shale gas formations or otherwise. Nevertheless, a decision by DOE to authorize exports to non-FTA countries-including the small-scale exports at issue here—could accelerate that development by some increment.

For these reasons, and because DOE previously had received comments regarding the potential environmental impacts associated with unconventional production, DOE produced a document in 2014 entitled Addendum to **Environmental Review Documents** Concerning Exports of Natural Gas from the United States (Addendum), and made it available for public comment.³¹ The Addendum takes a broad look at unconventional natural gas production in the United States, with chapters covering water resources (including water quantity and quality), air quality, greenhouse gas emissions, induced seismicity, and land use.

The Addendum shows that there are potential environmental issues associated with unconventional natural gas production as a whole that need to be carefully managed, especially with respect to emissions of volatile organic compounds and methane, and the potential for groundwater contamination. These environmental concerns do not lead DOE to conclude, however, that the proposed small-scale

exports of natural gas are not in the public interest and/or should be prohibited. Rather, DOE believes the public interest is better served by addressing these concerns directlythrough federal, state, or local regulation, or through self-imposed industry guidelines where appropriaterather than by prohibiting exports of natural gas. Unlike DOE, environmental regulators have the legal authority to impose requirements on natural gas production that appropriately balance benefits and burdens, and to update these regulations from time to time as technological practices and scientific understanding evolve. Declining to approve (or to expedite) small-scale natural gas exports would cause the United States to forego the economic and international benefits discussed herein, but would have little more than a small, incremental impact on the environmental issues identified by these commenters. This is particularly true because—as the Addendum illustrates-DOE is unable to predict at a local level where any additional natural gas production would occur and in what quantity to support the small-scale exports.³² For these reasons, we conclude that the environmental concerns associated with natural gas production do not establish that the small-scale exports at issue in this rulemaking are inconsistent with the public interest. We also note that DOE's legal analysis in this regard has been upheld by the D.C. Circuit in the context of four different non-FTA authorizations together approving far more significant volumes of U.S. LNG for export.33

Next, one commenter questioned whether small-scale exports will, in fact, facilitate the transition of importing countries away from the use of diesel and fuel oil, and argued that DOE has not provided sufficient evidence of this displacement to justify the final rule. We emphasize that foreign demand for U.S. natural gas has increased as countries in the Caribbean, Central America, and South America seek to import cleaner sources of energy. DOE further observes that many of these countries are currently dependent on diesel and/or fuel oil for their generation needs. These energy needs are challenging from both a cost- and emissions-perspective. By importing

²⁹ Some commenters criticized the LNG export studies commissioned by DOE and cited in the proposed rule (82 FR 41571-41572; Sept. 1, 2017), including the 2014 and 2015 LNG Export Studies. They argued, for example, that these macroeconomic studies are flawed in various respects and have been refuted by peer-reviewed evidence. DOE notes, however, that each of those studies was published in the Federal Register. DOE received comments on each study-including on their models, assumptions, and design—and responded to the comments in other proceedings. Based upon the record evidence, DOE determined that these studies are fundamentally sound. See, e.g., Eagle LNG Partners Jacksonville II LLC, DOE/ FE Order No. 4078, at 27–28, supra note 5. Accordingly, criticisms of DOE's macroeconomic studies are outside the scope of this rulemaking.

³⁰ See Sierra Club v. U.S. Dep't of Energy, 867 F.3d 189, 201–02 (D.C. Cir. 2017).

³¹U.S. Dep't of Energy, Addendum to Environmental Review Documents Concerning Exports of Natural Gas From the United States, 79 FR 48132 (Aug. 15, 2014), available at: http:// energy.gov/fe/addendum-environmental-reviewdocuments-concerning-exports-natural-gas-unitedstates [hereinafter Addendum]. DOE takes administrative notice of the Addendum in this proceeding.

³² See, e.g., Golden Pass Products LLC, DOE/FE Order No. 3978, supra note 24, at 147–49.

³³ See Sierra Club, 867 F.3d at 198–200 (upholding DOE's conclusion that, *inter alia*, there was not sufficiently specific information to identify where incremental natural gas production would occur at the local level); Sierra Club v. U.S. Dep't of Energy, Nos. 16–1186, 16–1252, 16–1253, 703 Fed. Appx. 1, *2 (D.C. Cir. Nov. 1, 2017) (same).

LNG from the United States, these countries will have access to a more reliable, cost-effective supply of energy that also has emissions benefits over current energy sources. Small-scale natural gas exports will fulfill an important need for natural gas in importing countries that often lack the customer demand, waterway infrastructure, and transmission infrastructure necessary to handle large quantities of natural gas and large LNG carriers.

Additionally, increased diversity of fuel supplies and sources used for generating electricity are expected to make these importing countries more, not less, resilient against energy outages after hurricanes, earthquakes, and other natural disasters. At the same time, the United States will facilitate stronger relationships with these importing countries, while promoting U.S. leadership in the global energy market. In sum, the commenter's argument as to DOE's lack of "evidence" of this expected transition to U.S. natural gas misconceives DOE's public interest analysis and seeks to impose a burden of proof where none exists, although DOE anticipates numerous environmental benefits to the importing countries from this rulemaking.

Finally, some commenters argued that DOE should be focused on encouraging renewable sources of energy, rather than facilitating exports of natural gas through this rulemaking. They asserted that renewable sources of energy are more environmentally friendly than natural gas, whereas (in their view) the proposed exports of natural gas are not in the public interest. DOE notes, however, that imports of U.S. LNG can work in concert with the development of renewable generation in importing countries. Imported natural gas can provide reliable standby energy supply available immediately, while renewable development is occurring. Imported LNG also can provide continued reliability to enhance solar or other renewable sources once they are developed. For these reasons, smallscale natural gas exports approved under this rule may provide indirect benefits to the use of renewable energy in importing countries.

8. Administrative Procedures and Judicial Review Under the Natural Gas Act

Some commenters argued that DOE cannot, in interpreting the phrase "in the public interest" in NGA section 3(a), remove public notice and comment procedures for individual small-scale export applications. According to these commenters, the phrase "opportunity for hearing" in NGA section 3(a) means that members of the public must be afforded the opportunity to present evidence to DOE regarding each non-FTA export application on a case-bycase basis. These commenters expressed concern that the proposed rule would frustrate the design of the NGA by eliminating the opportunity for public comment on individual small-scale applications.

Some commenters also asserted that the final rule is inconsistent with the NGA's judicial review provisions set forth in NGA section 19 (15 U.S.C. 717r) and the implementing regulation (10 CFR 590.501(a)). They argued that these judicial review provisions are available only to a "party" to a proceeding, yet under the proposed rule, there would be no clear way for a member of the public to intervene in an individual small-scale application proceeding and become a party to that proceeding. In their view, absent the availability of this remedy, judicial review would be provided by the Administrative Procedure Act (APA) (5 U.S.C. 704) and thus lie in the district courts-creating tension with the NGA's intent to provide for direct review in the federal courts of appeals under NGA section 19(b).

As to the administrative concerns, we note that under NGA section 3(a), the Secretary of Energy "shall" issue an order upon application unless, after "opportunity for hearing," DOE finds that the proposed export will not be consistent with the public interest.34 Section 3(a) does not require adjudication of applications to be determined "on the record after opportunity for a hearing" under the APA.³⁵ That type of statutory language imposes the need for a formal adjudication under the APA. Section 3(a) also does not require the individual adjudication of each application. The statutory language in NGA section 3(a)—"opportunity for hearing"—allows DOE to conduct an informal (rather than a formal) adjudication and affords DOE broad discretion to determine that the notice and public comment period on the proposed rule constitutes the notice and opportunity for comment on all prospective small-scale natural gas export applications. In this proceeding, DOE sought public comment on the proposed rule for a 45-day period and received comments from a variety of stakeholders and interested persons. DOE has reviewed the comments and taken them into consideration in this final rule. Therefore, DOE disagrees that expediting the review and approval

process for qualifying small-scale natural gas applications under 10 CFR 590.208(a) would frustrate the design of NGA section 3(a). Rather, DOE believes it is has provided sufficient process under the APA to determine that all prospective small-scale natural gas export applications—if meeting the qualifying criteria—are in the public interest.

As to the judicial review comments, to the extent that small-scale export authorizations are reviewable, NGA section 19(b) vests exclusive jurisdiction in the appropriate federal court of appeals.³⁶ A federal district court thus would lack jurisdiction over the dispute.³⁷

B. Regulatory Criteria

In the final rule, DOE establishes a regulatory definition for "small-scale natural gas export," to be codified at 10 CFR 590.102(p). Under this provision, a small-scale natural gas export is any export of natural gas to non-FTA nations, provided that the application for the export authority satisfies both the volume and NEPA criteria identified in 10 CFR 590.102(p)(1) and (2).

1. Volume Limitation

10 CFR 590.102(p)(1) establishes the volume limitation for small-scale natural gas exports. Under this criterion, a qualifying application must propose to export natural gas in a volume up to and including 51.75 Bcf/yr—an annualized figure that corresponds to the 0.14 Bcf/d volume criterion proposed by DOE. In the proposed rule, DOE stated that this volume criterion is consistent with industry practice for the emerging small-scale export market, but invited comment on any other appropriate volume limitation (82 FR 41573; Sept. 1, 2017).

Some commenters generally disagreed with this volume criterion, asserting that exports up to and including 0.14 Bcf/d (51.75 Bcf/yr) are substantial and cannot reasonably be considered "small scale." These commenters, however, neither presented evidence supporting their claims in the context of small-scale natural gas exports nor suggested a

³⁴ 15 U.S.C. 717b(a).

³⁵ 5 U.S.C. 554.

 $^{^{36}}$ NGA section 19(b) states that ''[a]ny party to a proceeding under this chapter aggrieved by an order issued by the Commission in such proceeding may obtain a review of such order in the court of appeals of the United States for any circuit wherein the natural-gas company to which the order relates is located or has its principal place of business, or in the United States Court of Appeals for the District of Columbia . . . [S]uch court shall have jurisdiction, which upon the filing of the record with it shall be exclusive, to affirm, modify, or set aside such order in whole or in part.'' 15 U.S.C. 717r(b).

³⁷ See, e.g., Sierra Club, 867 F.3d at 202 (citing 15 U.S.C. 717r(b)).

different volume limitation they believe to be more appropriate. As explained in the proposed rule, DOE based the volume criterion on industry standards that define ''small-scale LNĞ'' as 1.0 million metric tons per annum (mtpa) or lower (82 FR 41573 note 21). Using DOE's conversion factor to convert mtpa of LNG to Bcf of natural gas (82 FR 41573), this amount equates to a volume of 0.14 Bcf/d, or 51.75 Bcf/yr, of natural gas. On this basis, DOE believes that it is reasonable to define small-scale natural gas exports as any export of natural gas up to and including a volume of 51.75 Bcf/yr.

One commenter expressed concern that the volume criterion is too large for a single project. This commenter pointed out that, of DOE's seven non-FTA export authorizations identified in the proposed rule as falling under this volume threshold (82 FR 41572), the volumes authorized in those orders were, in fact, smaller than 0.14 Bcf/d even if all of the volumes are combined. Specifically, the commenter states that the proposed volume criterion is approximately 25% larger than the combined total of those seven authorizations-0.14 Bcf/d for a single project, as opposed to a combined 0.112 Bcf/d for the seven authorizations identified in the proposed rule.

The seven authorizations identified in the proposed rule were not intended to suggest a limiting parameter for this rulemaking. Rather, they provide context in showing small-scale LNG export authorizations previously issued by DOE—particularly as compared to the large-scale LNG export authorizations issued by DOE in volumes up to and exceeding 2.0 Bcf/d of natural gas for a single project.³⁸ As discussed above, DOE proposed the volume criterion for this rulemaking based on industry sources that mark the boundary between large-scale and small-scale exports at 1 mtpa (82 FR 41573 note 21)—equivalent to the 51.75 Bcf/yr volume criterion in this final rule. DOE sees no basis to depart from this volume limitation on the basis of the information presented in the comments.

The same commenter argued that the proposed rule is overbroad insofar as it may apply in export circumstances beyond those identified by DOE as justifying the rule. The commenter therefore urged DOE to expand the mandatory criteria for small-scale exports to include specific export characteristics beyond the volume criterion—such as the exporter's use of ISO containers or other non-traditional transport, destination countries in specific regions, and evidence that the exports will displace diesel or fuel oil in the importing markets. DOE has considered this proposal but sees no reason to unnecessarily confine the development of the small-scale export market by adding criteria that are, in fact, already market-driven.

As explained in the proposed rule, many of the countries in the Caribbean, Central America, and South America do not generate enough demand to import the large volumes of natural gas supplied by the large-scale natural gas import/export market. Given these diseconomies of scale, a gap has emerged in the regional natural gas import/export market, and small-scale natural gas exports represent a marketdriven response to fill this gap. Because the small-scale market already reflects the specific characteristics identified by the commenter, imposing these characteristics as additional mandatory criteria is unlikely to benefit the public interest or otherwise enhance the objectives or implementation of this final rule. Further, imposing such criteria would be at odds with DOE's long-standing practice of minimizing regulatory impediments to a freely operating market and promoting market competition (82 FR 41571, 41574; Sept. 1, 2017). DOE has concluded that the volume criterion, in addition to the NEPA criterion discussed below, is sufficient in defining and regulating the small-scale export market.

Commenters asked DOE whether the proposed rule would allow exporters to submit multiple applications, each below the 0.14 Bcf/d (51.75 Bcf/yr) volume limitation, as a way to expand the authorized export volumes for their facilities without triggering the jurisdiction of FERC or the U.S. , Maritime Administration (MARAD) under NEPA. These types of applications—commonly referred to as "design increases" or expansionstypically arise from the improved engineering of proposed or existing LNG facilities that allows for additional LNG production without new construction. Some commenters asked DOE to add language to the final rule that would expressly allow this practice, so as to encourage investment in and innovation at LNG export facilities. Other commenters suggested that this practice, if allowed, would effectively change the nature of this rule by encouraging "segmentation" of additional export volumes at large-scale facilities, as

opposed to the intended small-scale facilities.

DOE declines to add the requested language to this final rule. DOE emphasizes that the final rule is intended to facilitate small-scale exports of natural gas for the reasons discussed herein. This rule does not preclude applicants from applying for more than one authorization for small-scale natural gas exports. Such flexibility may be useful, for example, for authorization holders seeking to export small-scale volumes from different facilities. DOE, however, will not accept requests by authorization holders seeking to combine more than one small-scale export authorization as an indirect means of expanding the DOE-approved export volume from their facility, including from large-scale facilities.

Further, DOE notes that, in the non-FTA export authorizations issued to date, DOE has approved an applicant's export volume from a specific facility (or facilities), based on the approved production (or export) capacity of that facility.³⁹ Likewise, approved export volumes for a particular facility under this rule may not, on their own or added together, exceed the maximum approved production (or export) capacity of that facility.⁴⁰ Finally, nothing in this final rule affects the authorities exercised by FERC under the NGA or by MARAD under the Deepwater Port Act.⁴¹

2. Categorical Exclusion From NEPA

10 CFR 590.102(p)(2) establishes the NEPA criterion for small-scale natural gas exports. As the second criterion for this final rule, DOE's approval of the application must not require an EIS or EA under NEPA—that is, the application must be eligible for a categorical exclusion under DOE's NEPA regulations.

As explained in the proposed rule, DOE's environmental review process under NEPA usually results in the preparation or adoption of an EIS or EA describing the potential environmental impacts associated with the application. In some cases, DOE may determine that an application is eligible for a categorical exclusion pursuant to DOE's

³⁸ See Eagle LNG Partners Jacksonville II LLC, DOE/FE Order No. 4078, *supra* note 5, at 34–37 (identifying DOE's 29 final non-FTA authorizations for LNG and CNG issued to date).

³⁹ See, e.g., 10 CFR 590.202(b)(1) (requiring applicants to identify the facilities to be utilized or constructed for the proposed export).

⁴⁰ See, e.g., Dominion Cove Point LNG, LP, DOE/ FE Order No. 3331–A, FE Docket No. 11–128–LNG, Final Opinion and Order Granting Long-Term, Multi-Contract Authorization to Export Liquefied Natural Gas from the Cove Point LNG Terminal in Calvert County, Maryland, to Non-Free Trade Agreement Nations, at 1–2 (May 7, 2015); see also Eagle LNG Partners Jacksonville II LLC, DOE/FE Order No. 4078, supra note 5, at 37. ⁴¹ 33 U.S.C. 1501, et seq.

regulations implementing NEPA, 10 CFR 1021.410, appendices A & B. The categorical exclusion most commonly used in this context is categorical exclusion B5.7 (10 CFR part 1021, subpart D, appendix B5.7), which applies to natural gas import or export activities requiring minor operational changes to existing projects, but no new construction.⁴²

This NEPA criterion is very conservative. Based on DOE's experience, this criterion will limit application of this final rule to a small subset of all export applications. For example, of the 29 final non-FTA export authorizations for LNG (and CNG) issued as of the date of this final rule, only seven would meet both the volume and NEPA criteria to qualify as smallscale natural gas exports.⁴³ Together, these seven authorizations approve exports in a combined volume of 0.074 Bcf/d—representing only 0.35% of the cumulative volume of non-FTA exports approved to date (21.35 Bcf/d of natural gas).

Nonetheless, some of the comments on the proposed rule reflected widespread confusion about the meaning and applicability of a categorical exclusion under NEPA. Several commenters expressed concern that this criterion will result in smallscale natural gas exports that have no environmental protections or oversight because they are not subject to an EIS or EA under NEPA. These commenters asserted that an EA or EIS must be prepared in every instance to consider a variety of perceived risks to the environment, public safety, and public health posed by natural gas exports. In their view, an export application approved by DOE on the basis of a categorical exclusion under NEPA will lead to "unregulated" natural gas export facilities and infrastructure.

⁴³ Carib Energy (USA) LLC (FE Docket No. 11– 141–LNG), 0.04 Bcf/d; American LNG Marketing LLC (FE Docket No. 14–209–LNG), 0.008 Bcf/d; Floridian Natural Gas Storage Company, LLC (FE Docket No. 15–38–LNG); Air Flow North American Corp. (FE Docket No. 15–206–LNG, 0.002 Bcf/d; Flint Hills Resources, LP (FE Docket No. 15–168– LNG, 0.01 Bcf/d; Carib Energy (USA), LLC (FE Docket No. 16–98–LNG), 0.004 Bcf/d; and Eagle LNG Partners Jacksonville II LLC (FE Docket No. 17–79–LNG), 0.01 Bcf/d. The Carib and Floridian orders are both 0.04 Bcf/d, yet are not additive to one another because the source of LNG approved under both orders is from the Floridian Facility.

DOE emphasizes that its determination that a particular application qualifies for a DOE categorical exclusion is the result of a thorough NEPA assessment process. A categorical exclusion does not circumvent or "relax" the NEPA review process (as some commenters suggest) but, in fact, is a means to comply with NEPA. Indeed, categorical exclusions facilitate NEPA by allowing federal agencies to focus their environmental review and resources on actions that could have significant impacts. The Council on Environmental Quality's NEPA regulations provide for categorical exclusions when an agency has identified a "category of actions which do not individually or cumulatively have a significant effect on the human environment and which have been found to have no such effect in procedures adopted by a federal agency. . .'' ⁴⁴ DOE has made such a determination with respect to categorical exclusion B5.7, Import or Export of Natural Gas, with Operational Changes. Accordingly, there is no basis to conclude that qualifying small-scale exports would originate from "unregulated" LNG export facilities lacking sufficient oversight of potential risks to the environment, public safety, and public health.

In determining that an export application is eligible for a categorical exclusion under DOE's NEPA regulations, DOE must not only determine that the application fits within a specific categorical exclusion, but it must also determine that "there are no extraordinary circumstances related to the proposal that may affect the significance of the environmental effects of the proposal."⁴⁵ For qualifying small-scale natural gas export applications, DOE will satisfy this requirement by conducting an assessment of appropriate environmental-related documents to determine whether there are "extraordinary circumstances" associated with the proposed exports. This review includes consideration of potential impacts to property of historic, archeological, or architectural significance; federally-listed threatened or endangered species and their habitat; and wetlands regulated under the Clean Water Act.⁴⁶ To ensure transparency, all categorical exclusions used by DOE to comply with NEPA are made publicly available on DOE's NEPA website.47

DOE will follow the same practice for qualifying small-scale natural gas export applications.

¹Finally, regardless of whether DOE determines that an application is subject to an EIS, an EA, or is eligible for a categorical exclusion under NEPA, DOE expressly conditions all of its non-FTA authorizations on the authorization holder's ongoing compliance with all preventative and mitigative measures at the facility imposed by federal, state, and/or local agencies.⁴⁸ Small-scale natural gas exports will be subject to the same conditions and oversight.⁴⁹

For these reasons, DOE does not agree that this criterion of this rule—whereby an application must be eligible for a categorical exclusion under NEPA—will lead to natural gas exports lacking in environmental protection and/or to unregulated LNG export facilities. DOE is committed to a thorough NEPA assessment process and, accordingly, DOE is not changing this criterion in the final rule.

C. Other Issues

Below, DOE addresses a variety of other comments on the proposed rule. To the extent commenters have urged DOE to take some different type of action with respect to natural gas exports, DOE notes that it may consider additional measures under section 3(a) of the Natural Gas Act as part of its regulatory reform efforts and welcomes suggestions, data, and information on this topic through its regulatory reform email inbox at *Regulatory.Review@ hq.doe.gov.*

One commenter asserted that this rulemaking is arbitrary and capricious because it lacks substantive analysis and viable alternatives. Under the APA, an

LLC, DOE/FE Order No. 4078, *supra* note 5, at 46.

discussed the environmental and health risks that. in their view, are associated with the siting and operation of LNG export facilities and related transportation infrastructure near their home or community. They asserted, for example, that they will suffer from any accidents at nearby LNG export facilities and pipelines, or explosions of ISO containers loaded onto trains or trucks. They expressed concern that such accidents could result in harm to air, water, and other natural resource They also assert that natural disasters, such as hurricanes and wildfires, in the vicinity of LNG export facilities and infrastructure can threaten public safety. DOE notes that these concerns generally involve the siting of natural gas-related infrastructure. These concerns are outside the scope of this rulemaking, which is based on existing facilities subject to a categorical exclusion under NEPA. Nonetheless, as stated above, DOE requires all authorization holders to comply with any preventative and mitigative measures at natural gas import and export facilities imposed by federal, state, and/or local agencies.

⁴² This categorical exclusion states in full: "B5.7 Import or export natural gas, with operational changes: Approvals or disapprovals of new authorizations or amendments of existing authorizations to import or export natural gas under section 3 of the Natural Gas Act that involve minor operational changes (such as changes in natural gas throughput, transportation, and storage operations) but not new construction." 10 CFR part 1021, subpart D, appendix B5.7.

^{44 40} CFR 1508.4.

^{45 10} CFR 1021.410(b)(2).

⁴⁶ Id.

⁴⁷ See U.S. Dep't of Energy, Office of NEPA Policy and Compliance, Categorical Exclusion (CX)

Determinations, available at: https://energy.gov/ nepa/categorical-exclusion-cx-determinations. ⁴⁸ See, e.g., Eagle LNG Partners Jacksonville II

agency decision is arbitrary and capricious only if the agency's decision is not based on a consideration of the relevant factors and where there is a clear error of judgment by the agency.⁵⁰ As explained above and in the proposed rule, DOE has determined that smallscale natural gas exports are consistent with the public interest after considering its obligations under NGA section 3(a), the public comments received on the proposed rule, and a wide range of information bearing on the public interest (82 FR 41573-41574; Sept. 1, 2017). Additionally, DOE has considered its 29 final non-FTA export authorizations issued to date, as well EIA's authoritative projections for natural gas supply, demand, and prices set forth in both the AEO 2017 and AEO 2018. DOE has thoroughly analyzed the many factors affecting the export of U.S. natural gas, as well as the unique characteristics and minimal adverse impacts of the emerging small-scale natural gas market. On this basis, DOE has determined that this rule is consistent with both NGA section 3(a) and DOE's established practice in authorizing such exports.

One commenter characterized this rulemaking as imposing redundant, burdensome administrative requirements and compliance costs, but did not specify the basis for that claim. DOE emphasizes that it is not imposing any administrative requirements or compliance costs through this rulemaking. To the contrary, as explained in the proposed rule (82 FR 41570), the regulation promulgated in this final rule is intended to expedite DOE's processing of small-scale applications, thereby reducing administrative burdens and costs for the small-scale natural gas market.

On the other hand, another commenter asserted that this rulemaking is not deregulatory because it creates a new regulation to define small-scale natural gas exports according to specified criteria. This commenter claimed that DOE is limiting its ability to adapt to market changes, should the parameters of the small-scale natural gas market change. As stated above, however, this rulemaking qualifies as a deregulatory action because DOE is reducing or eliminating administrative requirements and compliance costs for the small-scale export market under NGA section 3(a). DOE is satisfied that the criteria for this rulemaking, which are based in part on industry practice, are appropriate for

this developing market. Nonetheless, should unforeseeable changes in the small-scale export market require DOE to amend this regulation, DOE retains the regulatory authority to do so.

One commenter asserted that the 45day public comment period for the proposed rule should be extended because the link for submitting comments on the Federal eRulemaking Portal was not working when the commenter attempted to submit comments. In the proposed rule, DOE identified a variety of methods that could be used to submit comments, including email (82 FR 41570; Sept. 1, 2017). DOE also notes that no other commenter raised this issue and many commenters submitted comments through the Federal eRulemaking Portal. DOE therefore declines to extend or reopen the public comment period in this rulemaking.

One commenter argued that DOE failed to provide sufficient notice of this rule in local media outlets, print media, and online publications. As a matter of law, however, DOE provided sufficient notice of this rulemaking by publishing it in the **Federal Register**.⁵¹

Finally, separate from the NEPA regulatory criterion for small-scale natural gas exports, several commenters disagreed with DOE's application of categorical exclusion A6 under NEPA for this rulemaking itself, as discussed in the "Regulatory Review" portion of the proposed rule (82 FR 41575, "National Environmental Policy Act") and set forth below. In the proposed rule, DOE explained that neither an EIS nor an EA was required to support this rulemaking. These commenters disagreed with that assessment, asserting that DOE violated NEPA by not preparing an EIS or an EA that addressed all potential environmental impacts associated with this rulemaking and that considered reasonable alternatives to the proposed rule.

As explained in the proposed rule (as well as in this final rule), DOE has determined that this regulation "fall[s] into a class of actions that does not individually or cumulatively have a significant impact on the human environment as set forth under DOE's regulations implementing [NEPA]" (82 FR 41575). Specifically, DOE has determined that this rulemaking falls under categorical exclusion A6 (10 CFR part 1021, subpart D, appendix A6).

Categorical exclusion A6 applies to "rulemakings that are strictly procedural." ⁵² This rulemaking is

strictly procedural because it establishes expedited procedures applicable to qualifying small-scale natural gas export applications. Currently, DOE makes a public interest determination for all applications to export natural gas to non-FTA countries under NGA section 3(a), regardless of the proposed export volume. In making this determination, DOE imposes certain procedural requirements, which in turn lead to longer processing time for applications to export natural gas to non-FTA countries. This rulemaking expedites DOE's administrative processing for qualifying small-scale natural gas export applications by eliminating the notice of application and other procedures typically required under DOE's regulations (82 FR 41573). For these reasons, DOE has determined that categorical exclusion A6 applies to this rulemaking.

III. Regulatory Review

A. Executive Orders 12866 and 13563

This regulatory action has been determined to be an "economically significant regulatory action" under Executive Order 12866, "Regulatory Planning and Review," 58 FR 51735 (October 4, 1993). Accordingly, this action was subject to review under that Executive Order by the Office of Information and Regulatory Affairs of the Office of Management and Budget.

DOE has also reviewed this regulation pursuant to Executive Order 13563, issued on January 18, 2011. (76 FR 3281, Jan. 21, 2011.) E.O. 13563 is supplemental to and explicitly reaffirms the principles, structures, and definitions governing regulatory review established in Executive Order 12866. To the extent permitted by law, agencies are required by Executive Order 13563 to: (1) Propose or adopt a regulation only upon a reasoned determination that its benefits justify its costs (recognizing that some benefits and costs are difficult to quantify); (2) tailor regulations to impose the least burden on society, consistent with obtaining regulatory objectives, taking into account, among other things, and to the extent practicable, the costs of cumulative regulations; (3) select, in choosing among alternative regulatory approaches, those approaches that maximize net benefits (including potential economic, environmental, public health and safety, and other advantages; distributive impacts; and equity); (4) to the extent feasible, specify performance objectives, rather than specifying the behavior or manner of compliance that regulated entities must adopt; and (5) identify and assess

⁵⁰ See, e.g., 5 U.S.C. 706; Motor Vehicle Mfr. Ass'n v. State Farm Mut. Auto. Ins. Co., 463 U.S. 29, 43 (1983).

⁵¹ See 44 U.S.C. 1508 (notice sufficient when published in the **Federal Register**).

⁵² 10 CFR part 1021, subpart D, appendix A6.

available alternatives to direct regulation, including providing economic incentives to encourage the desired behavior, such as user fees or marketable permits, or providing information upon which choices can be made by the public.

DOE concludes that this final rule is consistent with these principles. Specifically, this final rule provides that DOE will issue an export authorization upon receipt of any complete application that seeks to export natural gas, including LNG, to non-FTA countries, provided that the application satisfies the following two criteria: (1) The application proposes to export natural gas in a volume up to and including 51.75 Bcf/yr, and (2) DOE's approval of the application does not require an EIS or EA under NEPA. DOE's regulations regarding notice of applications, 10 CFR 590.205, and procedures applicable to application proceedings, 10 CFR part 590, subpart C (10 CFR 590.303 to 10 CFR 590.317), do not apply to small-scale natural gas exports. The final rule is intended to expedite DOE's processing of these applications, thereby reducing administrative burdens for the smallscale natural gas export market.

B. Executive Orders 13771, 13777, and 13783

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

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

reform task force must attempt to identify regulations that:

(i) Eliminate jobs, or inhibit job creation;

(ii) Are outdated, unnecessary, or ineffective;

 (iii) Impose costs that exceed benefits;
 (iv) Create a serious inconsistency or otherwise interfere with regulatory reform initiatives and policies;

(v) Are inconsistent with the requirements of Information Quality Act, or the guidance issued pursuant to that Act, in particular those regulations that rely in whole or in part on data, information, or methods that are not publicly available or that are insufficiently transparent to meet the standard for reproducibility; or

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

Finally, on March 28, 2017, the President signed Executive Order 13783, entitled "Promoting Energy Independence and Economic Growth." Among other things, E.O. 13783 requires the heads of agencies to review all existing regulations, orders, guidance documents, policies, and any other similar agency actions (collectively, agency actions) that potentially burden the development or use of domestically produced energy resources, with particular attention to oil, natural gas, coal, and nuclear energy resources. Such review does not include agency actions that are mandated by law, necessary for the public interest, and consistent with the policy set forth elsewhere in that order.

Executive Order 13783 defined burden for purposes of the review of existing regulations to mean to unnecessarily obstruct, delay, curtail, or otherwise impose significant costs on the siting, permitting, production, utilization, transmission, or delivery of energy resources.

DOE concludes that this final rule is consistent with the directives set forth in these executive orders. Specifically, this final rule is a deregulatory action that requires DOE to issue an export authorization upon receipt of any complete application that seeks to export natural gas, including LNG, to non-FTA countries, provided that the application satisfies the following two criteria: (1) The application proposes to export natural gas in a volume up to and including 51.75 Bcf/yr, and (2) DOE's approval of the application does not require an EIS or an EA under NEPA. Applications that satisfy these criteria are requesting authorization for "smallscale natural gas exports" and, as such, the exports are deemed to be consistent

with the public interest under NGA section 3(a). DOE's regulations regarding notice of applications and procedures conducted on applications do not apply to applications that satisfy these criteria. The final rule will expedite DOE's processing of these applications, thereby reducing administrative burdens for the small-scale natural gas export market.

C. National Environmental Policy Act

DOE has determined that adoption of this final rule falls into a class of actions that does not individually or cumulatively have a significant impact on the human environment as set forth under DOE's regulations implementing the National Environmental Policy Act of 1969 (42 U.S.C. 4321 et seq). Specifically, this rulemaking is covered under the categorical exclusion found in the DOE's National Environmental Policy Act regulations at paragraph A6 of appendix A to subpart D, 10 CFR part 1021, which applies to rulemakings that are strictly procedural. Accordingly, neither an EIS nor an EA is required.

D. Regulatory Flexibility Act

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

DOE has reviewed this final rule under the provisions of the Regulatory Flexibility Act and the procedures and policies published on February 19, 2003. This final rule will require DOE to issue an export authorization upon receipt of any complete application that seeks to export natural gas, including LNG, to non-FTA countries, provided that the application satisfies the following two criteria: (1) The application proposes to export natural gas in a volume up to and including 51.75 Bcf/yr, and (2) DOE's approval of the application does not require an EIS or an EA under NEPA. DOE's regulations regarding notice of applications and procedures conducted

on applications do not apply to applications that satisfy these criteria.

To date, DOE has received—and granted—eight applications to export LNG in volumes below 51.75 Bcf/yr of natural gas to non-FTA countries.⁵³ Of these eight applicants, three qualify as small businesses under the Small Business Administration's size standards of 1000 employees or less under both NAICS 221210, Natural Gas Distribution, and NAICS 325120, Industrial Gas Manufacturing. Because the final rule will streamline the application and approval process for small-scale natural gas exports, it will not result in a significant economic impact on a substantial number of small entities. The final rule will, however, provide greater regulatory certainty for applicants by eliminating the individual application proceeding and public interest evaluation for qualifying applications. This, in turn, will both reduce the administrative burden associated with the application process and expedite authorization of qualifying applications, removing (at a minimum) the opportunity cost of receiving an application delayed by the current procedures.

DOE received no comments on this certification. Comments regarding the economic impact of the proposed rule are responded to in Section II of the preamble, and for the reasons explained in Section II, those comments did not affect this certification, or result in any changes from the proposal in this final rule.

Therefore, DOE certifies that this rulemaking will not have a significant economic impact on a substantial number of small entities. Accordingly, DOE did not prepare an IRFA for this rulemaking. DOE's certification and supporting statement of factual basis was provided to the Chief Counsel for Advocacy of the Small Business Administration for review under 5 U.S.C. 605(b).

E. Paperwork Reduction Act

The final rule does not change any requirements subject to review and approval by OMB pursuant to the Paperwork Reduction Act of 1995 (44 U.S.C. 3501 *et seq.*) and the procedures implementing that Act, 5 CFR 1320.1 *et seq.* Current natural gas import and export authorization holders, including any approved under this final rule, would be subject to the information collection requirements approved by the Office of Management and Budget under OMB Control No. 1901–0294. Public reporting burden for the certification is estimated to average 3 hours per response, including the time for reviewing instructions, searching existing data sources, gathering and maintaining the data needed, and completing and reviewing the collection of information.

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

F. Unfunded Mandates Reform Act of 1995

The Unfunded Mandates Reform Act of 1995 (Pub. L. 104-4) generally requires Federal agencies to examine closely the impacts of regulatory actions on tribal, state, and local governments. Subsection 101(5) of title I of that law defines a Federal intergovernmental mandate to include any regulation that would impose upon tribal, state, or local governments an enforceable duty, except a condition of Federal assistance or a duty arising from participating in a voluntary Federal program. Title II of that law requires each Federal agency to assess the effects of Federal regulatory actions on tribal, state, and local governments, in the aggregate, or to the private sector, other than to the extent such actions merely incorporate requirements specifically set forth in a statute. Section 202 of that title requires a Federal agency to perform a detailed assessment of the anticipated costs and benefits of any rule that includes a Federal mandate which may result in costs to tribal, state, or local governments, or to the private sector, of \$100 million or more in any one year (adjusted annually for inflation). 2 U.S.C. 1532(a) and (b). Section 204 of that title requires each agency that proposes a rule containing a significant Federal intergovernmental mandate to develop an effective process for obtaining meaningful and timely input from elected officers of tribal, state, and local governments. 2 U.S.C. 1534.

This final rule will streamline procedures for small-scale natural gas exports. DOE has determined that the final rule will not result in the expenditure by tribal, state, and local governments in the aggregate, or by the private sector, of \$100 million or more in any one year. Accordingly, no assessment or analysis is required under the Unfunded Mandates Reform Act of 1995.

G. Treasury and General Government Appropriations Act, 1999

Section 654 of the Treasury and General Government Appropriations Act, 1999 (Pub. L. 105–277) requires Federal agencies to issue a Family Policymaking Assessment for any final rule that may affect family well-being. The final rule will not have any impact on the autonomy or integrity of the family as an institution. Accordingly, DOE has concluded that it is not necessary to prepare a Family Policymaking Assessment.

H. Executive Order 13132

Executive Order 13132, "Federalism," 64 FR 43255 (August 4, 1999) imposes certain requirements on agencies formulating and implementing policies or regulations that preempt state law or that have Federalism implications. Agencies are required to examine the constitutional and statutory authority supporting any action that would limit the policymaking discretion of the states and carefully assess the necessity for such actions. DOE has examined this final rule and has determined that it will not preempt state law and will not have a substantial direct effect on the states, on the relationship between the national government and the states, or on the distribution of power and responsibilities among the various levels of government. No further action is required by Executive Order 13132.

I. Executive Order 12988

With respect to the review of existing regulations and the promulgation of new regulations, section 3(a) of Executive Order 12988, "Civil Justice Reform," 61 FR 4729 (February 7, 1996), imposes on Executive agencies the general duty to adhere to the following requirements: (1) Eliminate drafting errors and ambiguity; (2) write regulations to minimize litigation; and (3) provide a clear legal standard for affected conduct rather than a general standard and promote simplification and burden reduction. With regard to the review required by section 3(a), section 3(b) of Executive Order 12988 specifically requires that Executive agencies make every reasonable effort to ensure that the regulation: (1) Clearly specifies the preemptive effect, if any; (2) clearly specifies any effect on existing Federal law or regulation; (3) provides a clear legal standard for affected conduct while promoting simplification and burden reduction; (4) specifies the retroactive effect, if any; (5) adequately defines key terms; and (6)

⁵³ Seven of the eight applications are identified in section I.C of the proposed rule (82 FR 41572; Sept. 1, 2017). The eighth authorization was issued on September 15, 2017, after the NOPR was published. See Eagle LNG Partners Jacksonville II LLC, DOE/ FE Order No. 4078, supra note 5.

addresses other important issues affecting clarity and general draftsmanship under any guidelines issued by the Attorney General. Section 3(c) of Executive Order 12988 requires Executive agencies to review regulations in light of applicable standards in section 3(a) and section 3(b) to determine whether they are met or it is unreasonable to meet one or more of them. DOE has completed the required review and determined that, to the extent permitted by law, the final rule meets the relevant standards of Executive Order 12988.

J. Treasury and General Government Appropriations Act, 2001

The Treasury and General Government Appropriations Act, 2001 (44 U.S.C. 3516 note) provides for agencies to review most disseminations of information to the public under guidelines established by each agency pursuant to general guidelines issued by OMB.

OMB's guidelines were published at 67 FR 8452 (February 22, 2002), and DOE's guidelines were published at 67 FR 62446 (October 7, 2002). DOE has reviewed this final rule under the OMB and DOE guidelines and has concluded that it is consistent with applicable policies in those guidelines.

K. Executive Order 13211

Executive Order 13211, "Actions **Concerning Regulations That** Significantly Affect Energy Supply, Distribution, or Use," 66 FR 28355 (May 22, 2001) requires Federal agencies to prepare and submit to the OMB, a Statement of Energy Effects for any proposed significant energy action. A 'significant energy action'' is defined as any action by an agency that promulgated or is expected to lead to promulgation of a final rule, and that: (1) Is a significant regulatory action under Executive Order 12866, or any successor order; and (2) is likely to have a significant adverse effect on the supply, distribution, or use of energy, or (3) is designated by the Administrator of OIRA as a significant energy action. For any proposed significant energy action, the agency must give a detailed statement of any adverse effects on energy supply, distribution, or use should the proposal be implemented, and of reasonable alternatives to the action and their expected benefits on energy supply, distribution, and use. This regulatory action, which is intended to streamline the application and approval process for small-scale natural gas exports, will not have a significant adverse effect on the supply, distribution, or use of energy, and

therefore is not a significant energy action. Accordingly, DOE has not prepared a Statement of Energy Effects.

L. Congressional Notification

As required by 5 U.S.C. 801, DOE will report to Congress on the promulgation of this rule prior to its effective date. The report will state that it has been determined that the rule is not a "major rule" as defined by 5 U.S.C. 804(2).

IV. Approval of the Office of the Secretary

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

List of Subjects in 10 CFR Part 590

Administrative practice and procedure, Exports, Natural gas, Reporting and recordkeeping requirements.

Signed in Washington, DC, on July 19, 2018.

Steven E. Winberg,

Assistant Secretary, Office of Fossil Energy.

For the reasons stated in the preamble, DOE amends part 590, chapter II of title 10, subchapter G, Code of Federal Regulations as set forth below:

PART 590—ADMINISTRATIVE **PROCEDURES WITH RESPECT TO** THE IMPORT AND EXPORT OF NATURAL GAS

■ 1. The authority citation for part 590 continues to read as follows:

Authority: Secs. 301(b), 402(f), and 644, Pub. L. 95-91, 91 Stat. 578, 585, and 599 (42 U.S.C. 7151(b), 7172(f), and 7254), Sec. 3, Act of June 21, 1938, c. 556, 52 Stat. 822 (15 U.S.C. 717b); E.O. 12009 (42 FR 46267) September 15, 1977); DOE Delegation Order Nos. 0204-111 and 0204-127 (49 FR 6684, February 22, 1984; 54 FR 11437, March 20, 1989).

■ 2. Section 590.102 is amended by redesignating paragraph (p) as paragraph (q) and adding new paragraph (p) to read as follows:

§590.102 Definitions. *

*

* (p) Small-scale natural gas export means an export of natural gas to nations with which there is not in effect a free trade agreement with the United States requiring national treatment for trade in natural gas and with which trade is not prohibited by U.S. law or policy, provided that the application for such export authority satisfies the following two criteria:

(1) The application proposes to export natural gas in a volume up to and including 51.75 billion cubic feet per year, and

(2) DOE's approval of the application does not require an environmental impact statement or an environmental assessment under the National Environmental Policy Act, 42 U.S.C. 4321 et seq.

*

■ 3. Section 590.208 is revised to read as follows:

§ 590.208 Small volume exports.

(a) Small-scale natural gas exports. Small-scale natural gas exports are deemed to be consistent with the public interest under section 3(a) of the Natural Gas Act, 15 U.S.C. 717b(a). DOE will issue an export authorization upon receipt of any complete application to conduct small-scale natural gas exports. DOE's regulations regarding notice of applications, 10 CFR 590.205, and procedures applicable to application proceedings, 10 CFR part 590, subpart C (10 CFR 590.303 to 10 CFR 590.317), are not applicable to small-scale natural gas exports.

(b) Scientific, experimental, or other non-utility natural gas exports. Any person may export up to 100,000 cubic feet of natural gas (14.73 pounds per square inch at 60 degrees Fahrenheit) or the liquefied or compressed equivalent thereof, in a single shipment for scientific, experimental, or other nonutility gas use without prior authorization of the Assistant Secretary. [FR Doc. 2018-15903 Filed 7-24-18; 8:45 am]

BILLING CODE 6450-01-P

DEPARTMENT OF TRANSPORTATION

Federal Aviation Administration

14 CFR Part 23

[Docket No. FAA-2018-0678; Special Conditions No. 23–290–SC]

Special Conditions: TCW Technologies, LLC; Piper Aircraft PA-32 Series Airplanes; Installation of **Rechargeable Lithium Batteries**

AGENCY: Federal Aviation Administration (FAA), DOT. **ACTION:** Final special conditions; request for comments.

SUMMARY: These special conditions are issued for the Piper Aircraft Model PA-32-series airplanes. These airplanes, as modified by TCW Technologies, LLC, will have a novel or unusual design feature associated with the installation of a rechargeable lithium battery. The applicable airworthiness regulations do not contain adequate or appropriate safety standards for this design feature.

These special conditions contain the additional safety standards the Administrator considers necessary to establish a level of safety equivalent to that established by the existing airworthiness standards.

DATES: The effective date of these special conditions is July 25, 2018.

We must receive your comments by September 10, 2018.

ADDRESSES: Send comments identified by docket number FAA–2018–0678 using any of the following methods:

• Federal eRegulations Portal: Go to http://www.regulations.gov and follow the online instructions for sending your comments electronically.

• *Mail:* Send comments to Docket Operations, M–30, U.S. Department of Transportation (DOT), 1200 New Jersey Avenue SE, Room W12–140, West Building Ground Floor, Washington, DC 20590–0001.

• Hand Delivery of Courier: Take comments to Docket Operations in Room W12–140 of the West Building Ground Floor at 1200 New Jersey Avenue SE, Washington, DC, between 9 a.m. and 5 p.m., Monday through Friday, except Federal holidays.

• *Fax:* Fax comments to Docket Operations at 202–493–2251.

Privacy: The FAA will post all comments it receives, without change, to http://regulations.gov, including any personal information the commenter provides. Using the search function of the docket website, anyone can find and read the electronic form of all comments received into any FAA docket, including the name of the individual sending the comment (or signing the comment for an association, business, labor union, etc.). DOT's complete Privacy Act Statement can be found in the **Federal Register** published on April 11, 2000 (65 FR 19477-19478), as well as at http://DocketsInfo.dot.gov.

Docket: Background documents or comments received may be read at http://www.regulations.gov at any time. Follow the online instructions for accessing the docket or go to the Docket Operations in Room W12–140 of the West Building Ground Floor at 1200 New Jersey Avenue SE, Washington, DC, between 9 a.m. and 5 p.m., Monday through Friday, except Federal holidays. FOR FURTHER INFORMATION CONTACT:

Ruth Hirt, Federal Aviation

Administration, Aircraft Certification Service, Small Airplane Directorate, AIR–694, 901 Locust, Room 301, Kansas City, MO; telephone (816) 329–4108; facsimile (816)–329–4090.

SUPPLEMENTARY INFORMATION:

The FAA has determined that notice and opportunity for prior public

comment are unnecessary because the substance of these special conditions has been subjected to the public comment process in several prior instances with no substantive comments received. It is unlikely that prior public comment would result in a significant change from the substance contained herein. The FAA therefore finds that good cause exists for making these special conditions effective upon issuance. The FAA is requesting comments to allow interested persons to submit views that may not have been submitted in response to the prior opportunities for comment.

Special conditions No.	Company/airplane model
23–15–01–SC ¹	Kestrel Aircraft Company/ Model K-350.
23–09–02–SC ²	Cessna Aircraft Company/ Model 525C (CJ4).
23–08–05–SC ³	Spectrum Aeronautical, LLC/ Model 40.

Comments Invited

We invite interested people to take part in this rulemaking by sending written comments, data, or views. The most helpful comments reference a specific portion of the special conditions, explain the reason for any recommended change, and include supporting data. We ask that you send us two copies of written comments.

We will consider all comments we receive on or before the closing date for comments. We will consider comments filed late if it is possible to do so without incurring expense or delay. We may change these special conditions based on the comments we receive.

Background

On May 5, 2017, TCW Technologies, LLC (TCW) applied for a supplemental type certificate (STC) to install a rechargeable lithium battery on Piper Aircraft Model PA–32–series airplanes. These airplanes are normal category airplanes with a maximum of 7 seats (including flightcrew), powered by a Lycoming O–540–series engine with 3,400 to 3,600 pounds maximum takeoff

¹ http://rgl.faa.gov/Regulatory_and_Guidance_ Library/rgSC.nsf/0/39B156C006 EB842E86257EF3004BB13C?Open Document&Highlight=installation%20of %20rechargeable%20lithium%20battery.

² http://rgl.faa.gov/Regulatory_and_Guidance_ Library/rgSC.nsf/0/902232309C19F0 D4862575CB0045AC0D?Open Document&Highlight=installation%20

of%20rechargeable%20lithium%20battery. ³ http://rgl.faa.gov/Regulatory_and_Guidance_ Library/rgSC.nsf/0/28E630294 DCC27B986257513005968A3?Open Document&Highlight=installation%20of %20rechargeable%20lithium%20battery. weight, depending on the specific model.

The current regulatory requirements for part 23 airplanes do not contain adequate requirements for use of rechargeable lithium batteries in airborne applications. This type of battery possesses certain failure and operational characteristics with maintenance requirements that differ significantly from that of the nickelcadmium (Ni-Cd) and lead-acid rechargeable batteries currently approved in other normal, utility, acrobatic, and commuter category airplanes. Therefore, the FAA is issuing this special condition to address—

• All characteristics of the rechargeable lithium batteries and their installation that could affect safe operation of the modified PA-32-series airplanes; and

• Appropriate Instructions for Continued Airworthiness (ICA) that include maintenance requirements to ensure the availability of electrical power from the batteries when needed.

Type Certification Basis

Under the provisions of § 21.101, TCW must show that the PA–32 seriesairplanes, as changed, continue to meet the applicable provisions of the regulations incorporated by reference in Type Certificate Data Sheet (TCDS) No. A3SO⁴ or the applicable regulations in effect on the date of application for the change. The regulations incorporated by reference in the type certificate are commonly referred to as the "original type certification basis." The regulations incorporated by reference are located in TCDS A3SO, pages 24 through 28.

If the Administrator finds that the applicable airworthiness regulations (*i.e.*, 14 CFR part 23) do not contain adequate or appropriate safety standards for the PA–32–series airplanes because of a novel or unusual design feature, special conditions are prescribed under the provisions of § 21.16.

The FAA issues special conditions, as defined in § 11.19, under § 11.38 and they become part of the type certification basis under § 21.101.

Special conditions are initially applicable to the models for which they are issued. Should the applicant apply for an STC to modify any other model(s) included on the same type certificate to incorporate the same novel or unusual design feature, the FAA would apply these special conditions to the other model(s) under § 21.101.

⁴ http://rgl.faa.gov/Regulatory_and_Guidance_ Library/rgMakeModel.nsf/0/ 44c795c1c122b21286257d74004d1952/\$FILE/ A3SO Rev 33.pdf.pdf

Novel or Unusual Design Features

The Piper PA–32–series airplanes will incorporate the following novel or unusual design features:

The installation of a rechargeable lithium battery as backup power for avionics systems.

Discussion

The applicable regulations governing the installation of batteries in general aviation airplanes were derived from Civil Air Regulations (CAR) 3 as part of the recodification that established 14 CFR part 23. The battery requirements identified in § 23.1353 were a rewording of the CAR requirements. Additional rulemaking activities—resulting from increased incidents of Ni-Cd battery fire or failures—incorporated § 23.1353(f) and (g), amendments 23-20 and 23-21, respectively. The FAA did not envision the introduction of lithium battery installations at the time these regulations were published.

The proposed use of rechargeable lithium batteries prompted the FAA to review the adequacy of these existing regulations. We determined the existing regulations do not adequately address the safety of lithium battery installations.

Current experience with rechargeable lithium batteries in commercial or general aviation is limited. However, other users of this technology—ranging from personal computers, to wireless telephone manufacturers, to the electric vehicle industry—have noted safety problems with rechargeable lithium batteries. These problems, as described in the following paragraphs, include overcharging, over-discharging, flammability of cell components, cell internal defects, and hazards resulting from exposure to extreme temperatures.

1. Overcharging: In general, rechargeable lithium batteries are significantly more susceptible than their Ni-Cd or lead-acid counterparts to thermal runway, which is an internal failure that can result in self-sustaining increases in temperature and pressure. This is especially true for overcharging, which causes heating and destabilization of the components of the cell, leading to the formation (by plating) of highly unstable metallic lithium. The metallic lithium can ignite, resulting in a self-sustaining fire or explosion. Finally, the severity of thermal runaway due to overcharging increases with increasing battery capacity due to the higher amount of electrolyte in large batteries.

2. Over-discharging: Discharge of some types of rechargeable lithium battery cells beyond the manufacturer's recommended specification can cause corrosion of the electrodes of the cell, resulting in loss of battery capacity that cannot be reversed by recharging. This loss of capacity may not be detected by the simple voltage measurements commonly available to flight crews as a means of checking battery status—a problem shared with Ni-Cd batteries. In addition, over-discharging has the potential to lead to an unsafe condition (creation of dendrites that could result in internal short circuit during the recharging cycle).

3. Flammability of Cell Components: Unlike Ni-Cd and lead-acid batteries, some types of rechargeable lithium batteries use liquid electrolytes that are flammable. The electrolyte can serve as a source of fuel for an external fire, if there is a breach of the battery container.

4. *Cell Internal Defects:* The rechargeable lithium batteries and rechargeable battery systems have a history of undetected cell internal defects. These defects may or may not be detected during normal operational evaluation, test, and validation. This may lead to an unsafe condition during in-service operation.

5. *Extreme Temperatures:* Exposure to an extreme temperature environment has the potential to create major hazards. Care must be taken to ensure that the lithium battery remains within the manufacturer's recommended specification.

Applicability

As discussed above, these special conditions are applicable to the PA–32– series airplanes. Should TCW apply at a later date for a supplemental type certificate to modify any other model added to Type Certificate No. A3SO with the same novel or unusual design feature, the FAA would apply these special conditions to that model as well.

Conclusion

This action affects only certain novel or unusual design features on the PA– 32–series airplanes. It is not a rule of general applicability and affects only the applicant who applied to the FAA for approval of these features on the airplane.

The substance of these special conditions has been subjected to the notice and comment period in several prior instances and has been derived without substantive change from those previously issued. It is unlikely that prior public comment would result in a significant change from the subject contained herein. Therefore, notice and opportunity for prior public comment hereon are unnecessary and the FAA finds good cause, in accordance with 5 U.S.C. 553(b)(3)(B) and 553(d)(3), for making these special conditions effective upon issuance. The FAA is requesting comments to allow interested persons to submit views that may not have been submitted in response to the prior opportunities for comment described above.

List of Subjects in 14 CFR Part 23

Aircraft, Aviation safety, Signs and symbols.

Citation

The authority citation for these special conditions is as follows:

Authority: 49 U.S.C. 106(f), 106(g), 40113, 44701–44702, 44704; Pub. L. 113–53, 127 Stat 584 (49 U.S.C. 44704) note; 14 CFR 21.16 and 21.101; and 14 CFR 11.38 and 11.19.

The Special Conditions

Accordingly, pursuant to the authority delegated to me by the Administrator, the following special conditions are issued as part of the type certification basis for Piper Aircraft PA– 32–series airplanes modified by TCW Technologies, LLC.

1. Installation of Lithium Battery

The FAA adopts the following special conditions for lithium battery installations on Piper Aircraft PA–32– series airplanes in lieu of the requirements in § 23.1353(a), (b), (c), (d), and (e), amendment 23–62.

Lithium battery installations on PA– 32–series airplanes must be designed and installed as follows:

 (1) Safe cell temperatures and pressures must be maintained during i. Normal operations;

ii. Any probable failure conditions of charging or discharging or battery monitoring system; and

iii. Any failure of the charging or battery monitoring system shown to not be extremely remote.

(2) The rechargeable lithium battery installation must be designed to preclude explosion or fire in the event of a failure under (1)(1)(ii) and (1)(1)(iii) above.

(3) Design of the rechargeable lithium batteries must preclude the occurrence of self-sustaining, uncontrolled increases in temperature or pressure.

(4) No explosive or toxic gasses emitted by any rechargeable lithium battery in normal operation or as the result of any failure of the battery charging system, monitoring system, or battery installation, which is shown to not be extremely remote, may accumulate in hazardous quantities within the airplane.

(5) Installations of rechargeable lithium batteries must meet the requirements of § 23.863(a) through (d), amendment 23–34.

(6) No corrosive fluids or gases that may escape from any rechargeable lithium battery, may damage surrounding structure or any adjacent systems, equipment, electrical wiring, or the airplane in such a way as to cause a major or more severe failure condition, in accordance with § 23.1309, amendment 23–62, and applicable regulatory guidance.

(7) Each rechargeable lithium battery installation must have provisions to prevent any hazardous effect on structure or essential systems that may be caused by the maximum amount of heat the battery can generate during a short circuit of the battery or of its individual cells.

(8) Rechargeable lithium battery installations must have a system to automatically control the charging rate of the battery to prevent battery overheating and overcharging, and either:

i. A battery temperature sensing and over-temperature warning system with a means for automatically disconnecting the battery from its charging source in the event of an over-temperature condition; or

ii. A battery failure sensing and warning system with a means for automatically disconnecting the battery from its charging source in the event of battery failure.

(9) Any rechargeable lithium battery installation, the function of which is required for safe operation of the aircraft, must incorporate a monitoring and warning feature that will provide an indication to the appropriate flight crewmembers whenever the state of charge of the batteries has fallen below levels considered acceptable for dispatch of the aircraft.

Note 1 to paragraph (9): Reference § 23.1353(h) for dispatch consideration.

(10) The Instructions for Continued Airworthiness (ICA) required by § 23.1529 must contain maintenance requirements to assure that the battery has been sufficiently charged at appropriate intervals specified by the battery manufacturer and the equipment manufacturer that contain the rechargeable lithium battery or rechargeable lithium battery system. The lithium rechargeable batteries and lithium rechargeable battery systems must not degrade below specified ampere-hour levels sufficient to power the aircraft system. The ICA must also contain procedures for the maintenance of replacement batteries to prevent the installation of batteries that have degraded charge retention ability or

other damage due to prolonged storage at a low state of charge. Replacement batteries must be of the same manufacturer and part number as approved by the FAA.

Note 2 to paragraph (10): Maintenance requirements include procedures that check battery capacity, charge degradation at manufacturers recommended inspection intervals, and replace batteries at manufacturer's recommended replacement schedule/time to prevent age-related degradation.

Note 3 to paragraph (10): The term "sufficiently charged" means that the battery must retain enough charge, expressed in ampere-hours, to ensure that the battery cells will not be damaged. A battery cell may be damaged by low charge (*i.e.*, below certain level), resulting in a reduction in the ability to charge and retain a full charge. This reduction would be greater than the reduction that may result from normal operational degradation.

Note 4 to paragraph (10): Replacement battery in spares storage may be subject to prolonged storage at a low state of charge.

Issued in Kansas City, Missouri on July 19, 2018.

Pat Mullen,

Manager, Small Airplane Standards Branch, Aircraft Certification Service.

[FR Doc. 2018–15912 Filed 7–24–18; 8:45 am] BILLING CODE 4910–13–P

ENVIRONMENTAL PROTECTION AGENCY

40 CFR Part 63

[EPA-HQ-OAR-2016-0442; FRL-9981-06-OAR]

RIN 2060-AS92

National Emission Standards for Hazardous Air Pollutants From the Portland Cement Manufacturing Industry Residual Risk and Technology Review

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

SUMMARY: This action finalizes the residual risk and technology review (RTR) conducted for the Portland Cement Manufacturing Industry source category regulated under national emission standards for hazardous air pollutants (NESHAP). These final amendments include no revisions to the numerical emission limits of the rule based on the RTR. The amendments reflect corrections and clarifications of the rule requirements and provisions. While the amendments do not result in reductions in emissions of hazardous air pollutants (HAP), this action results in improved monitoring, compliance, and implementation of the rule. **DATES:** This final action is effective on July 25, 2018.

ADDRESSES: The Environmental Protection Agency (EPA) has established a docket for this action under Docket ID No. EPA-HQ-OAR-2016-0442. All documents in the docket are listed on the https://www.regulations.gov website. Although listed, 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 either electronically through https:// www.regulations.gov, or in hard copy at the EPA Docket Center, WJC West Building, Room Number 3334, 1301 Constitution Ave. NW, Washington, DC. The Public Reading Room hours of operation are 8:30 a.m. to 4:30 p.m. Eastern Standard Time (EST), Monday through Friday. The telephone number for the Public Reading Room is (202) 566–1744, and the telephone number for the Docket Center is (202) 566-1742.

FOR FURTHER INFORMATION CONTACT: For questions about this final action, contact Mr. Brian Storey, Sector Policies and Programs Division (D243-04), Office of Air Quality Planning and Standards, U.S. Environmental Protection Agency, Research Triangle Park, North Carolina 27711; telephone number: (919) 541-1103; fax number: (919) 541-4991; and email address: storev.brian@epa.gov. For specific information regarding the risk modeling methodology, contact Mr. James Hirtz, Health and Environmental Impacts Division (C539-02), Office of Air Quality Planning and Standards, U.S. Environmental Protection Agency, Research Triangle Park, North Carolina 27711; telephone number: (919) 541-0881; fax number: (919) 541-0840; and email address: hirtz.james@epa.gov. For information about the applicability of the NESHAP to a particular entity, contact Ms. Sara Ayres, Office of Enforcement and Compliance Assurance, U.S. Environmental Protection Agency, U.S. EPA Region 5 (E-19J), 77 West Jackson Boulevard, Chicago, Illinois 60604; telephone number: (312) 353-6266; email address: ayres.sara@epa.gov.

SUPPLEMENTARY INFORMATION:

Preamble Acronyms and Abbreviations. We use multiple acronyms and terms in this preamble. While this list may not be exhaustive, to ease the reading of this preamble and for reference purposes, the EPA defines the following terms and acronyms here:

- ACI activated carbon injection
- CAA Clean Air Act
- CFR Code of Federal Regulations
- CISWI commercial and industrial solid waste
- incinerators
- D/F dioxins and furans
- EPA Environmental Protection Agency
- HAP hazardous air pollutants
- HCl hydrochloric acid
- HI hazard index
- HQ hazard quotient
- lb pounds
- MACT maximum achievable control technology
- MIR maximum individual risk
- ng/dscm nanograms per dry standard cubic meters
- NAICS North American Industry **Classification System**
- NEI National Emissions Inventory
- NESHAP national emission standards for hazardous air pollutants
- NTTAA National Technology Transfer and Advancement Act
- OAQPS Office of Air Quality Planning and Standards
- OMB Office of Management and Budget
- PAH polyaromatic hydrocarbons
- PM particulate matter
- ppmvd parts per million by volume, dry basis
- PRA Paperwork Reduction Act
- RFA Regulatory Flexibility Act
- regenerative thermal oxidizers RTO
- RTR residual risk and technology review
- sulfur dioxide SO_2
- TEF toxicity equivalence factors
- TEQ toxic equivalents
- THC total hydrocarbons
- TOSHI target organ-specific hazard index tpy tons per year
- TŘIM.FaTÉ Ťotal Risk Integrated Methodology. Fate, Transport, and
- Ecological Exposure model
- UMRA Unfunded Mandates Reform Act U.S.C. United States Code

Background information. On September 21, 2017, the EPA proposed revisions to the Portland Cement Manufacturing Industry NESHAP based on our RTR. In this action, we are finalizing decisions and revisions for the rule. We summarize some of the more significant comments we timely received regarding the proposed rule and provide our responses in this preamble. A summary of all other public comments on the proposal and the EPA's responses to those comments is available in "Summary of Public Comments and Responses on Proposed Rules," Docket ID No. EPA-HQ-OAR-2016-0442. A "track changes" version of the regulatory language that incorporates the changes in this action is available in the docket.

Organization of this Document. The information in this preamble is organized as follows:

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 - C. Paperwork Reduction Act (PRA)
 - D. Regulatory Flexibility Act (RFA) E. Unfunded Mandates Reform Act
 - (UMRA)
 - F. Executive Order 13132: Federalism
 - G. Executive Order 13175: Consultation and Coordination with Indian Tribal Governments
 - H. Executive Order 13045: Protection of Children from Environmental Health **Risks and Safety Risks**
 - I. Executive Order 13211: Actions **Concerning Regulations That** Significantly Affect Energy Supply, Distribution, or Use
 - J. National Technology Transfer and Advancement Act (NTTAA)

- K. Executive Order 12898: Federal Actions To Address Environmental Justice in Minority Populations and Low-Income Populations
- L. Congressional Review Act (CRA)

I. General Information

A. Does this action apply to me?

Table 1 of this preamble lists the NESHAP and associated regulated industrial source category that is the subject of this final rule. Table 1 is not intended to be exhaustive, but rather provides a guide for readers regarding the entities that this action is likely to affect. The rule standards will be directly applicable to the affected sources. Federal, state, local, and tribal government entities are not affected by this action. As defined in the Initial List of Categories of Sources Under Section 112(c)(1) of the Clean Air Act Amendments of 1990 (57 FR 31576), the Portland Cement Manufacturing Industry source category is any facility engaged in manufacturing portland cement by either the wet or dry process. The category includes, but is not limited to, the following process units: kiln, clinker cooler, raw mill system, finish mill system, raw mill dryer, raw material storage, clinker storage, finished product storage, conveyor transfer points, bagging, and bulk loading and unloading systems. The source category does not include those kilns that burn hazardous waste and are subject to and regulated under 40 CFR part 63, subpart EEE, or kilns that burn solid waste and are subject to the Commercial and Industrial Solid Waste Incineration (CISWI) rule under 40 Code of Federal Regulations (CFR) part 60, subpart CCCC, and 40 CFR part 60, subpart DDDD.

TABLE 1-NESHAP AND INDUSTRIAL SOURCE CATEGORIES AFFECTED BY THIS FINAL ACTION

NESHAP and source category	NAICS ¹ code	
Portland Cement Manufac- turing Industry	327310	

¹North American Industry Classification System.

To determine whether your facility is affected, you should examine the applicability criteria in the appropriate NESHAP. If you have any questions regarding the applicability of any aspect of this NESHAP, please contact the appropriate person listed in the preceding FOR FURTHER INFORMATION **CONTACT** section of this preamble.

B. Where can I get a copy of this document and other related information?

In addition to being available in the docket, an electronic copy of this final action will also be available on the internet. Following signature by the EPA Administrator, the EPA will post a copy of this final action at: https:// www.epa.gov/stationary-sources-airpollution/portland-cementmanufacturing-industry-nationalemission-standards. Following publication in the Federal Register, the EPA will post the Federal Register version and key technical documents at this same website.

Additional information is available on the RTR website at *https:// www.epa.gov/ttn/atw/rrisk/rtrpg.html.* This information includes an overview of the RTR program, links to project websites for the RTR source categories, and detailed emissions and other data we used as inputs to the risk assessments.

C. Judicial Review and Administrative Reconsideration

Under Clean Air Act (CAA) section 307(b)(1), judicial review of this final action is available only by filing a petition for review in the United States Court of Appeals for the District of Columbia Circuit (the Court) by September 24, 2018. Under CAA section 307(b)(2), the requirements established by this final rule may not be challenged separately in any civil or criminal proceedings brought by the EPA to enforce the requirements.

Section 307(d)(7)(B) of the CAA further provides that only an objection to a rule or procedure which was raised with reasonable specificity during the period for public comment (including any public hearing) may be raised during judicial review. This section also provides a mechanism for the EPA to reconsider the rule if the person raising an objection can demonstrate to the Administrator that it was impracticable to raise such objection within the period for public comment or if the grounds for such objection arose after the period for public comment (but within the time specified for judicial review) and if such objection is of central relevance to the outcome of the rule. Any person seeking to make such a demonstration should submit a Petition for Reconsideration to the Office of the Administrator, U.S. EPA, Room 3000, EPA WJC South Building, 1200 Pennsylvania Ave. NW, Washington, DC 20460, with a copy to both the person(s) listed in the preceding FOR FURTHER INFORMATION **CONTACT** section, and the Associate

General Counsel for the Air and Radiation Law Office, Office of General Counsel (Mail Code 2344A), U.S. EPA, 1200 Pennsylvania Ave. NW, Washington, DC 20460.

II. Background

A. What is the statutory authority for this action?

Section 112 of the CAA establishes a two-stage regulatory process to address emissions of HAP from stationary sources. In the first stage, we must identify categories of sources emitting one or more of the HAP listed in CAA section 112(b) and then promulgate technology-based NESHAP for those sources. "Major sources" are those that emit, or have the potential to emit, any single HAP at a rate of 10 tons per year (tpv) or more, or 25 tpv or more of any combination of HAP. For major sources, these standards are commonly referred to as maximum achievable control technology (MACT) standards and must reflect the maximum degree of emission reductions of HAP achievable (after considering cost, energy requirements, and non-air quality health and environmental impacts). In developing MACT standards, CAA section 112(d)(2) directs the EPA to consider the application of measures, processes, methods, systems, or techniques, including, but not limited to, those that reduce the volume of or eliminate HAP emissions through process changes, substitution of materials, or other modifications; enclose systems or processes to eliminate emissions; collect, capture, or treat HAP when released from a process, stack, storage, or fugitive emissions point; are design, equipment, work practice, or operational standards; or any combination of the above.

For these MACT standards, the statute specifies certain minimum stringency requirements, which are referred to as MACT floor requirements, and which may not be based on cost considerations. See CAA section 112(d)(3). For new sources, the MACT floor cannot be less stringent than the emission control achieved in practice by the best-controlled similar source. The MACT standards for existing sources can be less stringent than floors for new sources, but they cannot be less stringent than the average emission limitation achieved by the bestperforming 12 percent of existing sources in the category or subcategory (or the best-performing five sources for categories or subcategories with fewer than 30 sources). In developing MACT standards, we must also consider control options that are more stringent

than the floor under CAA section 112(d)(2). We may establish standards more stringent than the floor, based on the consideration of the cost of achieving the emissions reductions, any non-air quality health and environmental impacts, and energy requirements.

In the second stage of the regulatory process, the CAA requires the EPA to undertake two different analyses, which we refer to as the technology review and the residual risk review. Under the technology review, we must review the technology-based standards and revise them "as necessary (taking into account developments in practices, processes, and control technologies)" no less frequently than every 8 years, pursuant to CAA section 112(d)(6). Under the residual risk review, we must evaluate the risk to public health remaining after application of the technology-based standards and revise the standards, if necessary, to provide an ample margin of safety to protect public health or to prevent, taking into consideration costs, energy, safety, and other relevant factors, an adverse environmental effect. The residual risk review is required within 8 years after promulgation of the technology-based standards, pursuant to CAA section 112(f). In conducting the residual risk review, if the EPA determines that the current standards provide an ample margin of safety to protect public health, it is not necessary to revise the MACT standards pursuant to CAA section 112(f).¹ For more information on the statutory authority for this rule, see 82 FR 44254, September 21, 2017.

B. What is the Portland Cement Manufacturing Industry source category and how does the NESHAP regulate HAP emissions from the source category?

The EPA initially promulgated the Portland Cement Manufacturing Industry NESHAP on June 14, 1999 (64 FR 31898), under title 40, part 63, subpart LLL of the CFR. The rule was amended on April 5, 2002 (67 FR 16614); July 5, 2002 (67 FR 44766); December 6, 2002 (67 FR 72580); December 20, 2006 (71 FR 76518); September 9, 2010 (75 FR 54970); January 18, 2011 (76 FR 2832); February 12, 2013 (78 FR 10006); July 27, 2015 (80 FR 44772); September 11, 2015 (80 FR 54728); and July 25, 2016 (81 FR

¹ The Court has affirmed this approach of implementing CAA section 112(f)(2)(A): *NRDC* v. *EPA*, 529 F.3d 1077, 1083 (DC Cir. 2008) ("If EPA determines that the existing technology-based standards provide an 'ample margin of safety,' then the Agency is free to readopt those standards during the residual risk rulemaking.").

48356). The amendments further defined affected cement kilns as those used to manufacture portland cement, except for kilns that burn hazardous waste, and are subject to and regulated under 40 CFR part 63, subpart EEE, and kilns that burn solid waste, which are subject to the CISWI rule under 40 CFR part 60, subpart CCCC, and 40 CFR part 60, subpart DDDD. Additionally, onsite sources that are subject to standards for nonmetallic mineral processing plants in 40 CFR part 60, subpart OOO, are not subject to 40 CFR part 63, subpart LLL. Crushers are not covered by 40 CFR part 63, subpart LLL, regardless of their location. The subpart LLL NESHAP regulates HAP emissions from new and existing portland cement production facilities that are major or area sources of HAP, with one exception. Kilns located at facilities that are area sources

are not regulated for hydrochloric acid (HCl) emissions.

Portland cement manufacturing is an energy-intensive process in which cement is made by grinding and heating a mixture of raw materials such as limestone, clay, sand, and iron ore in a rotary kiln. The kiln is a large furnace that is fueled by coal, oil, gas, coke, and/ or various waste materials. The product, known as clinker, from the kiln is cooled, ground, and then mixed with a small amount of gypsum to produce portland cement.

The main source of air toxics emissions from a portland cement plant is the kiln. Emissions originate from the burning of fuels and heating of feed materials. Air toxics are also emitted from the grinding, cooling, and materials handling steps in the manufacturing process. Pollutants

regulated under the 40 CFR part 63, subpart LLL, are particulate matter (PM) as a surrogate for non-mercury HAP metals, total hydrocarbons (THC) as a surrogate for organic HAP other than dioxins and furans (D/F), organic HAP as an alternative to the limit for THC, mercury, HCl (from major sources only), and D/F expressed as toxic equivalents (TEQ). The kiln is regulated for all HAP and raw material dryers are regulated for THC or the alternative organic HAP. Clinker coolers are regulated for PM. Finish mills and raw mills are regulated for opacity. During periods of startup and shutdown, the kiln, clinker cooler, and raw material dryer are regulated by work practice standards. Open clinker storage piles are regulated by work practice standards. The emission standards for the affected sources are summarized in Table 2.

TABLE 2-EMISSION LIMITS FOR KILNS, CLINKER COOLERS, RAW MATERIAL DRYERS, RAW AND FINISH MILLS

If your source is a (an):	And the operating mode is:	And it is located at a:	Your emissions limits are:	And the units of the emissions limit are:	The oxygen correction factor is:
1. Existing kiln	Normal operation	Major or area source	PM ¹ 0.07	Pounds (lb)/ton clink- er.	NA.
			D/F ² 0.2	Nanograms/dry standard cubic me- ters (ng/dscm) (TEQ).	7 percent.
			Mercury 55	lb/million (MM) tons clinker.	NA.
			THC ³⁴ 24	Parts per million, vol- umetric dry (ppmvd).	7 percent.
2. Existing kiln	Normal operation	Major source	HCI 3	ppmvd	7 percent.
3. Existing kiln	Startup and shut- down.	Major or area source	Work practice standards (63.1346(g)).	NA	NA.
4. New kiln	Normal operation	Major or area source	PM ¹ 0.02	lb/ton clinker	NA.
			D/F ² 0.2	ng/dscm (TEQ)	7 percent.
			Mercury 21	Ib/MM tons clinker	NA.
			THC ³⁴ 24	ppmvd	7 percent.
5. New kiln	Normal operation	Major source	HCI 3	ppmvd	7 percent.
6. New kiln	Startup and shut- down.	Major or area source	Work practice standards (63.1346(g)).	NA	NA.
 Existing clinker cooler. 	Normal operation	Major or area source	PM 0.07	lb/ton clinker	NA.
 Existing clinker cooler. 	Startup and shut- down.	Major or area source	Work practice standards (63.1348(b)(9)).	NA	NA.
9. New clinker cooler	Normal operation	Major or area source	PM 0.02	lb/ton clinker	NA.
10. New clinker cool- er.	Startup and shut- down.	Major or area source	Work practice standards (63.1348(b)(9)).	NA	NA.
11. Existing or new raw material dryer.	Normal operation	Major or area source	THC 34 24	ppmvd	NA.
12. Existing or new raw material dryer.	Startup and shut- down.	Major or area source	Work practice standards (63.1348(b)(9)).	NA	NA.
13. Existing or new raw or finish mill.	All operating modes	Major source	Opacity 10	percent	NA.

¹ The initial and subsequent PM performance tests are performed using Method 5 or 5I and consist of three test runs.

² If the average temperature at the inlet to the first PM control device (fabric filter or electrostatic precipitator) during the D/F performance test is 400 degrees Fahrenheit or less, this limit is changed to 0.40 ng/dscm (TEQ).

³Measured as propane.

⁴ Any source subject to the 24 ppmvd THC limit may elect to meet an alternative limit of 12 ppmvd for total organic HAP.

C. What changes did we propose for the Portland Cement Manufacturing Industry source category in our September 21, 2017, proposed rule?

On September 21, 2017, the EPA published a proposed rule in the Federal Register for the Portland Cement Manufacturing Industry NESHAP, 40 CFR part 63, subpart LLL, that took into consideration the RTR analyses (82 FR 44254). In the proposed rule, we found that risks due to emissions of air toxics from this source category are acceptable and that the standards provide an ample margin of safety to protect public health, and we identified no new cost-effective controls under the technology review to achieve further emissions reductions. We proposed no revisions to the numerical emission limits based on these analyses. However, the EPA did propose amendments to correct and clarify rule requirements and provisions.

III. What is included in this final rule?

This action finalizes the EPA's determinations pursuant to the RTR provisions of CAA section 112 for the Portland Cement Manufacturing Industry source category. This action also finalizes other changes to the NESHAP including amendments to correct and clarify rule requirements and provisions.

A. What are the final rule amendments based on the risk review for the Portland Cement Manufacturing Industry source category?

The EPA proposed no changes to 40 CFR part 63, subpart LLL, based on the risk review conducted pursuant to CAA section 112(f). Specifically, we determined that risks from the Portland Cement Manufacturing Industry source category are acceptable, that the standards provide an ample margin of safety to protect public health, and that it is not necessary to set a more stringent standard to prevent an adverse environmental effect. The EPA received no new data or other information during the public comment period that changed this determination. Therefore, we are not requiring additional controls under CAA section 112(f)(2).

B. What are the final rule amendments based on the technology review for the Portland Cement Manufacturing Industry source category?

The EPA proposed no changes to 40 CFR part 63, subpart LLL, based on the

technology review conducted pursuant to CAA section 112(d)(6). Specifically, we determined that there are no developments in practices, processes, and control technologies that warrant revisions to the MACT standards for this source category. The EPA received no new data or other information during the public comment period that affected the technology review determination. Therefore, we are not requiring additional control under CAA section 112(d)(6).

C. What other changes have been made to the NESHAP?

In the September 21, 2017, proposed rule, we proposed additional revisions, which included changes to clarify monitoring, testing, and recordkeeping, and reporting requirements and the correction of typographical errors. Based on the comments received, we are now finalizing the following amendments to the rule:

• We correct a paragraph in the reporting requirements that mistakenly required that affected sources report their 30-operating day rolling average for D/F temperature monitoring.

• We correct a provision that required facility owners or operators to keep records of both daily clinker production and kiln feed rates.

• We clarify that the submittal dates for semiannual summary reports required under 40 CFR 63.1354(b)(9) are 60 days after the end of the reporting period.

• We resolve conflicting provisions that apply when a sulfur dioxide (SO₂) continuous parametric monitoring system is used to monitor HCl compliance.

• We clarify that the requirement in 40 CFR 63.1349(b)(1)(vi) only applies to kilns with inline raw mills.

• We clarify that the 40 CFR part 63, subpart LLL D/F standards were developed based on toxic equivalency factors (TEFs) developed in 1989, as referenced in the TEQ definition section of the rule (40 CFR 63.1341).

• We clarify that the performance test requirements for affected sources that have been idle through one or more periods that required a performance test to demonstrate compliance.

• We remove 40 ČFR 63.1343(d) and Table 2 that contain emission limits that were applicable prior to September 2015.

• We revise Equation 18 of the rule to include a missing term in the equation.

• We revise 40 CFR 63.1350(g)(4) to say "record" instead of "report."

D. What are the effective and compliance dates of the standards?

Because these amendments only provide corrections and clarifications to the current rule and do not impose new requirements on the industry, we are making these amendments effective and are requiring compliance upon promulgation of the final rule.

IV. What is the rationale for our final decisions and amendments for the Portland Cement Manufacturing Industry source category?

This section provides a description of our proposed action and this final action, the EPA's rationale for the final decisions and amendments, and a summary of key comments and responses. Other comments, comment summaries, and the EPA's responses can be found "National Emission Standards for Hazardous Air Pollutants from Portland Cement Manufacturing (40 CFR part 63, subpart LLL) Residual Risk and Technology Review, Final Amendments: Summary of Public Comments and Responses on Proposed Rules," which is available in the docket for this action (EPA-HQ-OAR-2016-0442).

A. Residual Risk Review for the Portland Cement Manufacturing Industry Source Category

1. What did we propose pursuant to CAA section 112(f) for the Portland Cement Manufacturing Industry source category?

Pursuant to CAA section 112(f), the EPA conducted a residual risk review and presented the results of this review, along with our proposed decisions regarding risk acceptability, ample margin of safety, and adverse environmental effects, in the September 21, 2017, proposed rule (82 FR 44254). The results of the risk assessment are presented briefly in Table 3, and in more detail in the document titled "Residual Risk Assessment for the Portland Cement Manufacturing Source Category in Support of the July 2018 Final Rule," available in the docket for this rulemaking (Docket ID No. EPA-HQ-OAR-2016-0442).

TABLE 3—INHALATION RISK ASSESSMENT SUMMARY FOR PORTLAND CEMENT MANUFACTURING INDUSTRY SOURCE CATEGORY

	Cancer MIR (in-1 million)		Cancer	Population with risk of	Population with risk of	Max chronic
	Based on actual emissions	Based on allowable emissions	incidence (cases per year) ¹	1-in-1 million or greater 1	10-in-1 million or greater ¹	noncancer HI
Source Category	1 (formaldehyde, benzene)	4 (formaldehyde, benzene)	0.01	130	0	HI < 1 (Actuals and Allowables).
Whole Facility	70 (arsenic and chromium VI)		0.02	20,000	690	HI = 1 (Actuals).

¹ Cancer incidence and populations exposed are based upon actual emissions.

The results of the chronic inhalation cancer risk assessment based on actual emissions from the Portland Cement Manufacturing Industry source category indicate that the maximum lifetime individual cancer risk posed by the 91 facilities is 1-in-1 million or less. The total estimated cancer incidence from this source category is 0.01 excess cancer cases per year, or one excess case in every 100 years. Regarding the noncancer risk assessment, the maximum chronic noncancer target organ-specific hazard index (TOSHI) for the source category could be up to 0.02 (for respiratory health effects) from the portland cement manufacturing processes. Regarding short-term (acute) health hazards posed by actual baseline emissions, the highest screening acute hazard quotient (HQ) for the source category is estimated to be 0.2. No facilities were found to have an acute HO greater than 1 for any of the acute benchmarks examined.

Potential multipathway health risks under a fisher and farmer scenario were identified using a 3-tier screening analysis of HAP known to be persistent and bio-accumulative in the environment emitted by facilities in this source category and, if necessary, a sitespecific assessment utilizing TRIM.FaTE. Based on the results of the multipathway cancer screening analyses of arsenic and dioxin emissions, we conclude that the cancer risk from ingestion exposure to the individual most exposed is less than 1-in-1 million for arsenic, and, based on a tier 3 analysis, less than 20-in-1 million for dioxins. Based on the tier 1 multipathway screening analysis of cadmium emissions and the refined sitespecific multipathway analysis of mercury emissions, the maximum chronic noncancer TOSHI due to ingestion exposure is less than 1 for actual emissions.

Finally, potential differences between actual emission levels and the maximum emissions allowable under the EPA's standards (*i.e.*, "allowable emissions") were also calculated for the source category. Allowable emissions were calculated using the emission

limits for existing sources in the current NESHAP in conjunction with the emission factors for metallic HAP, organic HAP and D/F congeners, as appropriate, the annual production capacity, and, when the emission limit was a concentration-based limit, the annual hours of operation reported by each source. Risk results from the inhalation risk assessment indicate that the maximum lifetime individual cancer risk could increase from 1-in-1 million for actual emissions to as high as 4-in-1 million for allowable emissions. At the allowable emissions level, the maximum chronic noncancer TOSHI was 0.06 (for respiratory health effects). The total estimated cancer incidence from this source category at the allowable emissions level was about 0.03 excess cancer cases per year, or 3 excess cases in every 100 years.

In determining whether risk is acceptable, the EPA considered all available health information and risk estimation uncertainty, as described above. The results indicate that inhalation cancer risk to the individual most exposed under both actual and allowable emissions scenarios are considerably less than 100-in-1 million, which is the presumptive limit of acceptability. The maximum chronic noncancer TOSHI due to inhalation exposures is less than 1 for both actual emissions and up to 1 due to allowable emissions. The multipathway analysis indicates a cancer risk less than 20-in-1 million from ingestion based upon our tier 3 screening analysis, while a refined site-specific multipathway analysis indicates that the HI for ingestion exposures is less than 1. Finally, the conservative evaluation of acute noncancer risk concluded that acute risk is below a level of concern. Taking into account this information, we proposed that the risks remaining after implementation of the existing MACT standards for the Portland Cement Manufacturing Industry were acceptable.

As directed by CAA section 112(f)(2), we also evaluated whether the existing MACT standards for the Portland Cement Manufacturing Industry provide

an ample margin of safety to protect public health. In addition to considering all of the health risks and other health information considered in the risk acceptability determination, in the ample margin of safety analysis we evaluated the cost and feasibility of available control technologies and other measures (including the controls, measures, and costs reviewed under the technology review) that could be applied in this source category to further reduce the risks due to emissions of HAP. Our inhalation risk analysis indicated very low risk from the facilities in the source category based upon actual emissions (1-in-1 million), and just slightly higher risk based upon allowable emissions (4-in-1 million). Therefore, very little reduction in inhalation risk could be realized regardless of the availability of control options.

The HAP risk drivers contributing to the inhalation maximum individual risk (MIR) were gaseous organic HAP: formaldehyde, benzene, naphthalene, and acetaldehyde. More than 62 percent of the mass emissions of these compounds originated from kiln operations. The first technology we considered in our ample margin of safety analysis was a regenerative thermal oxidizer (RTO) used to control organic HAP emissions from the kiln exhaust. It is expected that an RTO, when used in conjunction with the existing activated carbon injection (ACI), only offers an additional 50percent removal efficiency of organic HAP from the kiln exhaust, due to the reduced THC concentration leaving the ACI. ACI control devices are currently used by industry, and the addition of an RTO as control would include configuring the RTO in series, following the ACI. We found that the use of an RTO in series with the existing ACI control was not cost effective for this industry, and given the small reduction in organic HAP emissions, the addition of an RTO would have little effect on the source category risks.

Other technologies evaluated included the use of an existing ACI with the addition of wet scrubbers to help control organic HAP, including D/F emissions, from the kiln exhaust. For the March 24, 1998, proposal of the Portland Cement Manufacturing Industry NESHAP (63 FR 14182), we performed a beyond-the-floor analysis and determined that, based on the additional costs and the level of D/F emissions reduction achievable, the costs were not justified (63 FR 14199-14201). In this technology review, we conclude that, as with the findings of the 1998 rule, the use of the combination of an ACI system in series with a wet scrubber is not cost effective for the industry to reduce organic HAP or D/F emissions, and would have little effect on the source category risk.

Although our multipathway screening analysis results did not indicate risks of concern from mercury emissions, we also performed an evaluation of halogenated carbon injection as a control of mercury emissions from the kiln exhaust. In the May 6, 2009, beyond-the-floor analysis for the Portland Cement Manufacturing Industry NESHAP, we determined that, based on the costs of control, and the negligible level of mercury emission reduction achieved by the controls, the costs of using a halogenated carbon injection system were not justified (74 FR 21149). As we determined in the 2009 rule, we do not consider the use of halogenated carbon injection system to be cost effective for the industry to use to reduce mercury emissions, and it would have little effect on the low risks identified for this source category.

Due to the low risk, the minimal risk reductions that could be achieved with the various control options that we evaluated, and the substantial costs associated with additional control options, we proposed that the current standards provide an ample margin of safety to protect public health.

The EPA conducted a screening assessment to examine the potential for an adverse environmental effect as required under section 112(f)(2)(A) of the CAA. Section 112(a)(7) of the CAA defines "adverse environmental effect" as "any significant and widespread adverse effect, which may reasonably be anticipated, to wildlife, aquatic life, or other natural resources, including adverse impacts on populations of endangered or threatened species or significant degradation of environmental quality over broad areas." Based on the results of the environmental risk screening assessment, the EPA concluded that there was not an adverse environmental effect from the Portland Cement Manufacturing Industry source category. 2. How did the risk review change for the Portland Cement Manufacturing Industry source category?

We received comments both supporting and opposing the proposed residual risk review and our proposed determination that no revisions are warranted under CAA section 112(f)(2). After review of these comments, we determined that no changes to our risk review are necessary. The following section provides a summary of the major comments received and our responses to those comments. All comments and our specific responses can be found in the document titled "National Emission Standards for Hazardous Air Pollutants from Portland Cement Manufacturing (40 CFR part 63, subpart LLL) Residual Risk and Technology Review, Final Amendments: Summary of Public Comments and Responses on Proposed Rules," which is available in the docket for this action.

3. What key comments did we receive on the risk review, and what are our responses?

Generally, comments that were not supportive of the proposed determination suggested changes to the underlying risk assessment methodology. One comment specific to the source category stated that the EPA's National Emissions Inventory (NEI) data from 2014 documented 1,447.25 tons of polycyclic aromatic hydrocarbons (PAH) emitted by the source category, yet PAH emission data were not included in Table 3.1-1, "Summary of Emissions from the Portland Cement Manufacturing Source Category and Dose-Response Values Used in the Residual Risk Assessment'' (Docket ID No. EPA-HQ-OAR-2016-0442-0153), nor were PAH quantitatively assessed elsewhere in the risk assessment.

The EPA disagrees with the commenter that the risk assessment did not address PAH. The Portland Cement Manufacturing Industry NESHAP regulates organic HAP emissions indirectly with an emissions limit for THC. As an alternative, the EPA established an emissions limit for nondioxin organic HAP. In developing the MACT standard, the EPA reviewed the results of 18 test reports where organic HAP were measured (Docket ID No. EPA-HQ-OAR-2002-0051-3429). Naphthalene was the only PAH reported. Based on a review of emissions test data where organic HAP were measured simultaneously with THC, the EPA found that, on average, organic HAP emissions comprise about 35 percent of the THC. In the test data reviewed for the 2009 proposed rule (74 FR 21136), nine specific organic HAP were identified and are the pollutants that must be tested for when choosing to comply with the organic HAP limit. One of the nine organic HAP identified was the PAH naphthalene. No other PAH species were present in measurable amounts in the test data reviewed. Naphthalene is one of the PAH listed in Table 3.1–1 of the risk assessment report. Based on our review of the test data for organic HAP, the only PAH emitted above detection limits is naphthalene.

The EPA also disputes the commenter's claim that PAH emissions, as reported in the 2014 NEI, totaled over 1,400 tons. Our inspection of the 2014 NEI data for total PAH from the cement sector showed annual emissions of 1,449 pounds, not tons. That is less than 1 tpy for total PAH, whereas our risk assessment used total naphthalene emissions of 38 tpy from the Portland Cement Manufacturing Industry source category. Furthermore, no additional PAH emissions data were submitted to the EPA by the commenter or other commenters to support their claims.

EPA also received comments and information from representatives of portland cement manufacturing facilities who, while supportive of EPA's residual risk determination, stated that the EPA's risk estimates were based on flawed data, such that emission rates were overestimated for several pollutants. In response, the EPA acknowledges that our risk assessment results for the Portland Cement Manufacturing Industry source category are dependent on the emission rates used in the assessment. If we were to lower emission rates based on more accurate data, we expect lower risk estimates. Because the EPA has determined that the risk is acceptable, and that the existing standards provide an ample margin of safety to protect public health, using the emissions data provided by the commenters would potentially reduce risk further but would not change our determinations under the risk review. Accordingly, we concluded that it was reasonable to not update the risk assessment following proposal. We, therefore, finalized the risk assessment report and re-submitted it to the docket as [•] 'Residual Risk Assessment for the Portland Cement Manufacturing Source Category in Support of the July 2018 Final Rule."

4. What is the rationale for our final approach and final decisions for the risk review?

For the reasons explained in the proposed rule, the Agency determined that the risks from the Portland Cement Manufacturing Industry source category are acceptable, and the current standards provide an ample margin of safety to protect public health and prevent an adverse environmental effect. Since proposal, our determinations regarding risk acceptability, ample margin of safety, and adverse environmental effects have not changed. Therefore, we are not revising 40 CFR part 63, subpart LLL, to require additional controls pursuant to CAA section 112(f)(2) based on the residual risk review and are readopting the existing emissions standards under CAA section 112(f)(2).

B. Technology Review for the Portland Cement Manufacturing Industry Source Category

1. What did we propose pursuant to CAA section 112(d)(6) for the Portland Cement Manufacturing Industry source category?

Pursuant to CAA section 112(d)(6), the EPA conducted a technology review and summarized the results of the review in the September 21, 2017, proposed rule (82 FR 44277). The results of the technology review are briefly discussed below, and in more detail in the memorandum. "Technology Review for the Portland Cement Production Source Category," which is available in the docket for this action (Docket ID No. EPA-HQ-OAR-2016-0442-0189). The technology review focused on identifying and evaluating developments in practices, processes, and control technologies for the Portland Cement Manufacturing Industry source category. We reviewed technologies currently available to industry, and reviewed previous beyond-the-floor analyses, to determine if there had been any developments in existing technologies, or whether previous conclusions made by the EPA had changed. Additionally, we reviewed new developments in control technologies and determined the availability of each control, the costs associated with the installation and annual maintenance associated with each control, and the effectiveness of each technology in reducing HAP emissions. Based on information available to the EPA, the technologies reviewed do not provide sufficient reductions in HAP to support changing the standard to reflect technological developments (82 FR 44277).

2. How did the technology review change for the Portland Cement Manufacturing Industry source category?

The technology review for the Portland Cement Manufacturing Industry source category has not changed since proposal. As proposed, the EPA is not making changes to the standards pursuant to CAA section 112(d)(6).

3. What key comments did we receive on the technology review, and what are our responses?

We received comments in support of the proposed determination that no revisions to the standards are necessary under CAA section 112(d)(6).

We also received comments opposing our proposed technology review determination. Of the comments received, one commenter specifically opposed the technology review determination, and suggested that the EPA did not consider or recommend the use of selective catalytic reduction technologies (SCR) as mercury control, to control D/F emissions, as THC and volatile organic compound control, and as metallic HAP control.

The EPA disagrees with the commenter's argument that EPA failed to accurately assess SCR as a technology development capable of controlling HAP emissions. SCR technology is used to control nitrogen oxide (NOx) emissions from gas turbines, internal combustion engines, and fossil fuelfired utility boilers. The use of SCR by the Portland Cement Manufacturing Industry source category is, however, problematic for various reasons. For example, the chemical composition of raw materials used to manufacture portland cement varies by location across the United States. This variability in raw materials means that the stack gas chemistry also varies across cement plants, often requiring plant-specific controls for certain pollutants, such as NOx. The presence of pyritic sulfur in raw materials and the resulting SO₂ emissions, for example, requires that higher temperatures be maintained at the kiln to avoid the formation of ammonium bisulfate salt, which can foul SCR catalysts. Additionally, high dust levels and the nature of dusts typical of the portland cement manufacturing process also creates difficulties not found in other industries where SCR works well for NOx control. In the case of mercury, SCR does not directly reduce mercury emissions. Instead, SCR oxidizes mercury from its elemental form and the oxidized form can then be more easily captured in

scrubbers. However, since scrubbers are uncommon in the cement industry, SCR would have little impact in reducing mercury emissions from cement kilns, unless a scrubber was also installed. Regarding D/F emissions control, the primary method of D/F control at U.S. cement plants is temperature control, which is already a requirement of the current subpart LLL standard. In general, no information is available by facilities operating SCR in the U.S. relevant to the effectiveness of an SCR for HAP control.

Review of comments on our technology review did not change our proposed determination under CAA section 112(d)(6), These comments and our specific responses to those comments can be found in the comment summary and response document titled, "National Emission Standards for Hazardous Air Pollutants from Portland Cement Manufacturing (40 CFR part 63, subpart LLL) Residual Risk and Technology Review, Final Amendments: Summary of Public Comments and Responses on Proposed Rules," which is available in the docket for this action.

4. What is the rationale for our final approach for the technology review?

For the reasons explained in the preamble to the proposed rule, we determined there were several technologies that have the potential for reducing HAP emissions from cement kiln. However, as stated in the proposed rule, most of these technologies have not been widely used in the United States by the Portland Cement Manufacturing Industry, so source category-specific data on their long-term performance and costs are lacking (82 FR 44278). Since proposal, neither the technology review nor our determination as a result of the technology review has changed, and we are not revising 40 CFR part 63, subpart LLL, pursuant to CAA section 112(d)(6).

C. Other Amendments to the Portland Cement Manufacturing Industry NESHAP

1. What amendments did we propose?

In the September 21, 2017, action, we proposed the following amendments to the rule to clarify monitoring, testing, and recordkeeping and reporting requirements and to correct typographical errors:

• We proposed to remove the reference to the D/F temperature monitoring system in 40 CFR 63.1354(b)(9)(vi).

• We proposed to correct a provision that requires facility owners or operators

to keep records of both daily clinker production and kiln feed rates.

• We proposed to clarify that the submittal dates for semiannual summary reports required under 40 CFR 63.1354(b)(9) are 60 days after the end of the reporting period consistent with the Agency's statement in the October 2016 rule guidance for 40 CFR part 63, subpart LLL.

• We proposed to resolve conflicting provisions in 40 CFR 63.1349(b)(8)(x) and 40 CFR 63.1350(l)(3).

• We proposed to clarify the requirement in 40 CFR 63.1349(b)(1)(vi) to state that the provision of the section only applies to kilns with inline raw mills.

• We proposed that the 1989 TEFs be incorporated into the rule to clarify that they are the appropriate factors for calculating TEQ.

• We proposed to clarify the performance test requirements after extended shutdowns of existing kilns.

• We proposed to remove 40 CFR 63.1343(d) and Table 2 that contain emission limits that were applicable prior to September 2015.

2. What key comments did we receive and what are our responses?

Several commenters stated they generally supported the September 21, 2017, proposed rule, with several stating that the proposed revisions to 40 CFR part 63, subpart LLL, would improve monitoring, compliance, and implementation of the rule.

There were some comments that favored, and some that opposed the EPA's proposal to allow facilities 180 days to demonstrate that a kiln can comply with the standards when coming out of an extended idle period (82 FR 44279). These comments are discussed in the following paragraphs.

One commenter in favor of the proposal requested that the EPA clarify that units that were idled during the time when compliance was required to be demonstrated, have 180 days after coming out of the idle period to demonstrate compliance. To accomplish this, the commenter recommended that EPA revise the language of proposed 40 CFR 63.1348(a) to state: "For an affected source subject to this subpart, you must demonstrate compliance with the emissions standards and operating limits by using the test methods and procedures in §§ 63.1349 and 63.7. Any affected source that was unable to demonstrate compliance before the compliance date due to being idled, or that had demonstrated compliance but was idled during the normal window for the next compliance test, must demonstrate compliance within 180

days after coming out of the idle period." The EPA believes this request provides additional clarification to the proposed rule amendment, and has revised the rule text to incorporate the suggested change.

In contrast, the EPA received comments opposed to our decision to allow facilities 180 days to demonstrate that a kiln can comply with the rule standards when coming out of an extended idle period. The commenter took issue with the fact that the regulatory language does not make clear whether the 180-day non-compliant period would be just a 6-month exemption or could be even longer, and requested a clear trigger start or enddate, or sources could use this repeatedly after any shutdown, simply by citing the new provision. Further, the commenter noted that the proposed rule does not define the term "due to being idled," nor does it include language to limit the use of this exemption. The commenter stated that the EPA's proposal would contravene the CAA's requirement for "enforceable" emission limits, and any cement plant that took advantage of the EPA's proposed 180day compliance exemption would violate its permit requirements. As stated by the commenter, a facility that restarted operations after being idled and then ran for 6 months without demonstrating compliance could not possibly certify that it was "in compliance" with permit requirements because it would not know if it was in compliance; likewise, it could not "promptly report any deviations" because it would not know if deviations occurred.

The EPA's response regarding the commenter's concerns regarding the 180-day exemption is based, in part, on the decision made on March 16, 1994 (59 FR 12425), and promulgated in 40 CFR 63.7(a)(2) to allow new facilities 180 days to demonstrate initial compliance. The provisions of 40 CFR 63.1348(a) are to allow previously idled kilns to reach a steady-state condition and schedule and perform compliance testing, as provided for new emission sources in 40 CFR 63.7(a)(2). It is reasonable to expect that a kiln operating the same controls that previously resulted in compliance would continue to be in compliance when operating the same equipment in the same manner, and the 180-day extension is simply a period during which they must complete the process of demonstrating compliance. There is no change to the facilities obligation to operate in compliance.

Additionally, it is unreasonable to assume that portland cement

manufacturing facilities would cease operations of a kiln for a period of time in order to circumvent compliance demonstration requirements. It is our opinion that this would not be in the best economic interest of the facility, by potentially limiting production, and profitability, for the sake of circumventing a rule requirement for demonstrating compliance.

Lastly, we believe the recommended amendment to the proposed rule suggested by the previous commenter would allow a specific time to demonstrate compliance, and therefore, are revising the rule to state, "Any affected source that was unable to demonstrate compliance before the compliance date due to being idled, or that had demonstrated compliance but was idled during the normal window for the next compliance test, must demonstrate compliance within 180 days after coming out of the idle period."

These comments and our specific responses to those comments can be found in the comment summary and response document titled, "National Emission Standards for Hazardous Air Pollutants from Portland Cement Manufacturing (40 CFR part 63, subpart LLL) Residual Risk and Technology Review, Final Amendments: Summary of Public Comments and Responses on Proposed Rules," which is available in the docket for this action.

3. How did the requirements change since proposal?

Based on the comments received, we are now finalizing the following amendments to the rule:

• We correct a paragraph in the reporting requirements that mistakenly required that affected sources report their 30-operating day rolling average for D/F temperature monitoring, including a revision to 40 CFR 63.1350(g)(4) to say "record" instead of "report."

• We correct a provision that required facility owners or operators to keep records of both daily clinker production and kiln feed rates.

• We clarify that the submittal dates for semiannual summary reports required under 40 CFR 63.1354(b)(9) are 60 days after the end of the reporting period.

• We resolve conflicting provisions that apply when an SO_2 continuous parametric monitoring system is used to monitor HCl compliance.

• We clarify the requirement in 40 CFR 63.1349(b)(1)(vi) only applies to kilns with inline raw mills.

• We clarify that the 40 CFR part 63, subpart LLL, D/F standards were

developed based on TEFs developed in 1989, as referenced in the TEQ definition section of the rule (40 CFR 63.1341).

• We clarify the performance test requirements for affected sources that have been idle through one or more periods that required a performance test to demonstrate compliance.

• We remove 40 CFR 63.1343(d) and Table 2 that contain emission limits that were applicable prior to September 2015.

• We revise Equation 18 of the rule to include a missing term in the equation.

V. Summary of Cost, Environmental, and Economic Impacts, and Additional Analyses Conducted

A. What are the affected sources?

We anticipate that the 91 portland cement manufacturing facilities currently operating in the United States will be affected by this final rule.

B. What are the air quality impacts?

We are not establishing new emission limits and are not requiring additional controls; therefore, no air quality impacts are expected as a result of the final amendments to the rule.

C. What are the cost impacts?

Recent amendments to the Portland Cement Manufacturing Industry NESHAP have addressed electronic reporting and changes in policies regarding startup, shutdown, and malfunction. Additionally, there are no changes to emission standards or add-on controls associated with this action. Therefore, the final amendments impose no additional costs.

D. What are the economic impacts?

No economic impacts result from this final action.

E. What are the benefits?

While the amendments in this final rule do not result in reductions in emissions of HAP, this action results in improved monitoring, compliance, and implementation of the rule.

VI. Statutory and Executive Order Reviews

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

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

This action is not a significant regulatory action and was, therefore, not

submitted to the Office of Management and Budget (OMB) for review.

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

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

C. Paperwork Reduction Act (PRA)

This action does not impose any new information collection burden under the PRA. OMB has previously approved the information collection activities contained in the existing regulations (40 CFR part 63, subpart LLL) and has assigned OMB control number 2060– 0416. This action does not change the information collection requirements.

D. Regulatory Flexibility Act (RFA)

I certify that this action will not have a significant economic impact on a substantial number of small entities under the RFA. In making this determination, the impact of concern is any significant adverse economic impact on small entities. An agency may certify that a rule will not have a significant economic impact on a substantial number of small entities if the rule relieves regulatory burden, has no net burden, or otherwise has a positive economic effect on the small entities subject to the rule. We estimate that three of the 26 existing Portland cement entities are small entities and comprise three plants. After considering the economic impacts of this final action on small entities, we have concluded that this action will have no net regulatory burden for all directly regulated small entities.

E. Unfunded Mandates Reform Act (UMRA)

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

F. Executive Order 13132: Federalism

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

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

This action does not have tribal implications as specified in Executive Order 13175. It will neither impose substantial direct compliance costs on federally recognized tribal governments, nor preempt tribal law. The EPA is aware of one tribally owned Portland cement facility currently subject to 40 CFR part 63, subpart LLL, that will be subject to this final action. However, the provisions of this rule are not expected to impose new or substantial direct compliance costs on tribal governments since the provisions in this final action are clarifying and correcting monitoring and testing requirements and recordkeeping and reporting requirements. This final action also provides clarification for owners and operators on bringing new or previously furloughed kilns back on line. Thus, Executive Order 13175 does not apply to this action.

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

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

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

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

J. National Technology Transfer and Advancement Act (NTTAA)

This rulemaking does not involve technical standards.

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

The EPA believes that this action does not have disproportionately high and adverse human health or environmental effects on minority populations, lowincome populations, and/or indigenous peoples, as specified in Executive Order 12898 (59 FR 7629).

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 U.S.C. 804(2).

List of Subjects for 40 CFR Part 63

Environmental protection, Administrative practice and procedures, Air pollution control, Hazardous substances, Intergovernmental relations, Reporting and recordkeeping requirements.

Dated: July 13, 2018.

Andrew R. Wheeler,

Acting Administrator.

For the reasons stated in the preamble, title 40, chapter I, part 63 of the Code of Federal Regulations (CFR) is amended as follows:

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

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

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

Subpart LLL—National Emission Standards for Hazardous Air Pollutants for the Portland Cement Manufacturing Industry

■ 2. Section 63.1341 is amended by: a. Removing the definition of "affirmative defense"; and ■ b. Revising the definitions of "dioxins and furans (D/F)," "in-line coal mill," and ''TEQ.'

The revisions read as follows:

*

§63.1341 Definitions. *

Dioxins and furans (D/F) means tetra-, penta-, hexa-, hepta-, and octachlorinated dibenzo dioxins and furans.

In-line coal mill means a coal mill using kiln exhaust gases in their process. A coal mill with a heat source other than the kiln or a coal mill using exhaust gases from the clinker cooler is not an in-line coal mill.

TEQ means the international method of expressing toxicity equivalents for dioxins and furans as defined in U.S. EPA, Interim Procedures for Estimating Risks Associated with Exposures to Mixtures of Chlorinated Dibenzo-pdioxins and -dibenzofurans (CDDs and CDFs) and 1989 Update, March 1989. The 1989 Toxic Equivalency Factors (TEFs) used to determine the dioxin and

furan TEQs are listed in Table 2 to subpart LLL of Part 63.

§63.1343 [Amended]

■ 3. Section 63.1343 is amended by removing paragraph (d) and Table 2.

■ 4. Section 63.1348 is amended by:

■ a. Adding a sentence after the first sentence in paragraph (a) introductory text:

■ b. Revising paragraph (a)(3)(i), the second sentence in paragraph (a)(3)(iv), and paragraphs $(a)(\overline{4})(ii)$, (a)(7)(ii), (b)(3)(ii), and (b)(4);

■ c. Adding a heading to paragraph (b)(5); and

■ d. Revising paragraph (b)(5)(i). The additions and revisions read as follows:

§63.1348 Compliance requirements.

(a) Initial Performance Test Requirements. * * * Any affected source that was unable to demonstrate compliance before the compliance date due to being idled, or that had demonstrated compliance but was idled during the normal window for the next compliance test, must demonstrate compliance within 180 days after coming out of the idle period. * * * * * *

(3) D/F compliance. (i) If you are subject to limitations on D/F emissions under §63.1343(b), you must demonstrate initial compliance with the D/F emissions standards by using the performance test methods and procedures in §63.1349(b)(3). The owner or operator of a kiln with an inline raw mill must demonstrate initial compliance by conducting separate performance tests while the raw mill is operating and the raw mill is not operating. Determine the D/F TEO concentration for each run and calculate the arithmetic average of the TEQ concentrations measured for the three runs to determine continuous compliance.

*

(iv) * * * Compliance is demonstrated if the system is maintained within ±5 percent accuracy during the performance test determined in accordance with the procedures and criteria submitted for review in your monitoring plan required in §63.1350(p).

(4) * *

(ii) Total Organic HAP Emissions Tests. If you elect to demonstrate compliance with the total organic HAP emissions limit under §63.1343(b) in lieu of the THC emissions limit, you must demonstrate compliance with the total organic HAP emissions standards

by using the performance test methods and procedures in § 63.1349(b)(7).

* (7) * * *

(ii) Perform required emission monitoring and testing of the kiln exhaust prior to the reintroduction of the coal mill exhaust, and also testing the kiln exhaust diverted to the coal mill. All emissions must be added together for all emission points, and must not exceed the limit per each pollutant as listed in §63.1343(b).

- (b) * * *
- (3) * * *

(ii) Bag Leak Detection System (BLDS). If you install a BLDS on a raw mill or finish mill in lieu of conducting the daily visible emissions testing, you must demonstrate compliance using a BLDS that is installed, operated, and maintained in accordance with the requirements of § 63.1350(f)(4)(ii).

(4) D/F Compliance. If you are subject to a D/F emissions limitation under §63.1343(b), you must demonstrate compliance using a continuous monitoring system (CMS) that is installed, operated and maintained to record the temperature of specified gas streams in accordance with the requirements of §63.1350(g).

(5) Activated Carbon Injection Compliance. (i) If you use activated carbon injection to comply with the D/ F emissions limitation under §63.1343(b), you must demonstrate compliance using a CMS that is installed, operated, and maintained to record the rate of activated carbon injection in accordance with the requirements § 63.1350(h)(1).

■ 5. Section 63.1349 is amended by: ■ a. Revising paragraphs (b)(1)(vi), (b)(3)(iv), (b)(4)(i), (b)(6)(i)(A),(b)(7)(viii)(A), (b)(8)(vi), and (b)(8)(vii)(B); and ■ b. Removing and reserving paragraph

(d).

The revisions read as follows:

§63.1349 Performance testing requirements.

* *

(b)(1) * * *

(vi) For each performance test, conduct at least three separate test runs under the conditions that exist when the affected source is operating at the level reasonably expected to occur. Conduct each test run to collect a minimum sample volume of 2 dscm for determining compliance with a new source limit and 1 dscm for determining compliance with an existing source limit. Calculate the time weighted average of the results from three

consecutive runs, including applicable sources as required by paragraph (b)(1)(viii) of this section, to determine compliance. You need not determine the particulate matter collected in the impingers "back half" of the Method 5 or Method 5I particulate sampling train to demonstrate compliance with the PM standards of this subpart. This shall not preclude the permitting authority from requiring a determination of the "back half" for other purposes. For kilns with inline raw mills, testing must be conducted while the raw mill is on and while the raw mill is off. If the exhaust streams of a kiln with an inline raw mill and a clinker cooler are comingled, then the comingled exhaust stream must be tested with the raw mill on and the raw mill off.

*

(3) * * *

(iv) The run average temperature must be calculated for each run, and the average of the run average temperatures must be determined and included in the performance test report and will determine the applicable temperature limit in accordance with §63.1346(b). *

(4) * * * (i) If you are subject to limitations on THC emissions, you must operate a CEMS in accordance with the requirements in §63.1350(i). For the purposes of conducting the accuracy and quality assurance evaluations for CEMS, the THC span value (as propane) is 50 to 60 ppmvw and the reference method (RM) is Method 25A of appendix A to part 60 of this chapter. * * *

$$\bar{x} = \frac{1}{n} \sum_{i=1}^{n} X_i, \bar{y} = \frac{1}{n} \sum_{i=1}^{n} Y_i$$

n = The number of data points.

* * *

(8) * * *

(vi) If your kiln has an inline kiln/raw mill, you must conduct separate performance tests while the raw mill is operating ("mill on") and while the raw

$$R = (y * t) + x * (1 - t)$$
 (Eq. 17)

Where:

Where:

ppmvw.

ppmvw.

test runs i.

three test runs i.

 $R = Operating limit as SO_2, ppmvw.$

 \bar{x} = The THC CEMS average values in

 \bar{y} = The organic HAP average values in

X_i = The THC CEMS data points for all three

Y_i = The organic HAP concentrations for all

- y = Average SO₂ CEMS value during mill on operations, ppmvw.
- t = Percentage of operating time with mill on, expressed as a decimal.
- x = Average SO₂ CEMS value during mill off operations, ppmvw. $1-t = \hat{P}ercentage of operating time with mill$
- off, expressed as a decimal.

$$\bar{x} = \frac{1}{n} \sum_{i=1}^{n} X_{1}, \bar{y} = \frac{1}{n} \sum_{i=1}^{n} Y_{1}$$

text, (g)(4), (h)(2)(ii), (j), (k)(2) introductory text, (k)(2)(ii) and (iii), (k)(5)(ii), (l)(1) introductory text, and (l)(3) to read as follows:

§63.1350 Monitoring requirements. * *

*

(g) D/F monitoring requirements. If you are subject to an emissions limitation on D/F emissions, you must comply with the monitoring requirements of paragraphs (g)(1) through (5) and (m)(1) through (4) of

(i)(A) If the source is equipped with a wet scrubber, tray tower or dry scrubber, you must conduct performance testing using Method 321 of appendix A to this part unless you have installed a CEMS that meets the requirements § 63.1350(l)(1). For kilns with inline raw mills, testing must be conducted for the raw mill on and raw mill off conditions.

- * *
- (7) * * *
- (viii) * * *

(A) Determine the THC CEMS average values in ppmvw, and the average of your corresponding three total organic HAP compliance test runs, using Equation 12.

mill is not operating ("mill off"). Using the fraction of time the raw mill is on and the fraction of time that the raw mill is off, calculate this limit as a weighted average of the SO₂ levels measured during raw mill on and raw mill off compliance testing with Equation 17.

(vii) * * *

(Eq. 18)

(B) Determine your SO₂ CEMS instrument average ppm, and the average of your corresponding three HCl compliance test runs, using Equation 18.

(4) Every hour, record the calculated rolling three-hour average temperature using the average of 180 successive oneminute average temperatures. See §63.1349(b)(3).

*

* * *

* * *

Where:

- \bar{x} = The SO₂ CEMS average values in ppmvw. X_1 = The SO₂ CEMS data points for the three runs constituting the performance test.
- \bar{y} = The HCl average values in ppmvw.
- Y_1 = The HCl emission concentration
- expressed as ppmv corrected to 7 percent oxygen for the three runs constituting the performance test.
- n = The number of data points.
- * * *

■ 6. Section 63.1350 is amended by revising paragraphs (g) introductory

- (h) * * * (2) * * *

(ii) Each hour, calculate the 3-hour rolling average of the selected parameter value for the previous 3 hours of process operation using all of the one-minute data available (*i.e.*, the CMS is not outof-control).

*

(j) Total organic HAP monitoring requirements. If you are complying with the total organic HAP emissions limits, you must continuously monitor THC according to paragraphs (i)(1) and (2) of this section or in accordance with Performance Specification 8 or Performance Specification 8A of appendix B to part 60 of this chapter and comply with all of the requirements for continuous monitoring systems found in the general provisions, subpart A of this part. You must operate and maintain each CEMS according to the quality assurance requirements in Procedure 1 of appendix F in part 60 of this chapter. You must also develop an

emissions monitoring plan in accordance with paragraphs (p)(1) through (4) of this section. (k) * * *

(2) In order to quality assure data measured above the span value, you must use one of the four options in paragraphs (k)(2)(i) through (iv) of this section.

*

(ii) Quality assure any data above the span value by proving instrument linearity beyond the span value established in paragraph (k)(1) of this section using the following procedure. Conduct a weekly "above span linearity" calibration challenge of the monitoring system using a reference gas with a certified value greater than your highest expected hourly concentration or greater than 75 percent of the highest measured hourly concentration. The "above span" reference gas must meet the requirements of PS 12A, Section 7.1 and must be introduced to the measurement system at the probe.

Record and report the results of this procedure as you would for a daily calibration. The ''above span linearity'' challenge is successful if the value measured by the Hg CEMS falls within 10 percent of the certified value of the reference gas. If the value measured by the Hg CEMS during the above span linearity challenge exceeds ±10 percent of the certified value of the reference gas, the monitoring system must be evaluated and repaired and a new ''above span linearity'' challenge met before returning the Hg CEMS to service, or data above span from the Hg CEMS must be subject to the quality assurance procedures established in paragraph (k)(2)(iii) of this section. In this manner all hourly average values exceeding the span value measured by the Hg CEMS during the week following the above span linearity challenge when the CEMS response exceeds ±20 percent of the certified value of the reference gas must be normalized using Equation 22.

 $\frac{Certified\ reference\ gas\ value}{Measured\ value\ of\ reference\ gas}\ x\ Measured\ stack\ gas\ result = Normalized\ stack\ gas\ result\ (Eq.\ 22)$

(iii) Quality assure any data above the span value established in paragraph (k)(1) of this section using the following procedure. Any time two consecutive 1hour average measured concentrations of Hg exceeds the span value you must, within 24 hours before or after, introduce a higher, "above span" Hg reference gas standard to the Hg CEMS. The "above span" reference gas must meet the requirements of PS 12A, Section 7.1, must target a concentration level between 50 and 150 percent of the highest expected hourly concentration measured during the period of measurements above span, and must be introduced at the probe. While this target represents a desired concentration range that is not always achievable in practice, it is expected that the intent to meet this range is demonstrated by the value of the reference gas. Expected values may include "above span" calibrations done before or after the above span measurement period. Record and report the results of this procedure as you would for a daily calibration. The "above span" calibration is successful if the value measured by the Hg CEMS is within 20 percent of the certified value of the reference gas. If the value measured by the Hg CEMS exceeds 20 percent of the certified value of the reference gas, then you must normalize the one-hour average stack gas values measured above the span during the 24hour period preceding or following the

"above span" calibration for reporting based on the Hg CEMS response to the reference gas as shown in Equation 22. Only one "above span" calibration is needed per 24-hour period. * * *

(5) * * *

(ii) On a continuous basis, determine the mass emissions of mercury in lb/hr from the alkali bypass and coal mill exhausts by using the mercury hourly emissions rate and the exhaust gas flow rate to calculate hourly mercury emissions in lb/hr.

- (1) * * *

(1) If you monitor compliance with the HCl emissions limit by operating an HCl CEMS, you must do so in accordance with Performance Specification (PS) 15 or PS 18 of appendix B to part 60 of this chapter, or, upon promulgation, in accordance with any other performance specification for HCl CEMS in appendix B to part 60 of this chapter. You must operate, maintain, and quality assure a HCl CEMS installed and certified under PS 15 according to the quality assurance requirements in Procedure 1 of appendix F to part 60 of this chapter except that the Relative Accuracy Test Audit requirements of Procedure 1 must be replaced with the validation requirements and criteria of sections 11.1.1 and 12.0 of PS 15. If you choose

to install and operate an HCl CEMS in accordance with PS 18, you must operate, maintain, and quality assure the HCl CEMS using the associated Procedure 6 of appendix F to part 60 of this chapter. For any performance specification that you use, you must use Method 321 of appendix A to this part as the reference test method for conducting relative accuracy testing. The span value and calibration requirements in paragraphs (l)(1)(i) and (ii) of this section apply to HCl CEMS other than those installed and certified under PS 15 or PS 18.

(3) If the source is equipped with a wet or dry scrubber or tray tower, and you choose to monitor SO₂ emissions, monitor SO_2 emissions continuously according to the requirements of § 60.63(e) and (f) of this chapter. If SO₂ levels increase above the 30-day rolling average SO₂ operating limit established during your performance test by 10 percent or more, you must:

*

(i) As soon as possible but no later than 30 days after you exceed the established SO₂ value conduct an inspection and take corrective action to return the SO₂ emissions to within the operating limit; and

(ii) Within 90 days of the exceedance or at the time of the next compliance test, whichever comes first, conduct an HCl emissions compliance test to determine compliance with the HCl

emissions limit and to verify or reestablish the SO₂ CEMS operating limit.

■ 7. Section 63.1354 is amended by: ■ a. Revising paragraphs (b)(9)

introductory text and (b)(9)(vi); ■ b. Redesignating paragraph (b)(9)(viii) as paragraph (b)(11)(i) introductory text

and revising newly redesignated paragraph (b)(11)(i);

■ c. Adding paragraphs (b)(11)(i)(A) through (C);

 d. Redesignating paragraph (b)(9)(ix) as paragraph (b)(11)(ii);

■ e. Redesignating paragraph (b)(9)(x) as paragraph (b)(12) and revising newly redesignated paragraph (b)(12); and

■ f. Revising paragraphs (b)(10) and (c). The revisions read as follows:

§63.1354 Reporting requirements. *

* *

(b) * * *

(9) The owner or operator shall submit a summary report semiannually within 60 days of the reporting period to the EPA via the Compliance and **Emissions Data Reporting Interface** (CEDRI). (CEDRI can be accessed through the EPA's Central Data Exchange (CDX) (*https://cdx.epa.gov/*). You must use the appropriate electronic report in CEDRI for this subpart. Instead of using the electronic report in CEDRI for this subpart, you may submit an alternate electronic file consistent with the extensible markup language (XML) schema listed on the CEDRI website (https://www.epa.gov/electronicreporting-air-emissions/complianceand-emissions-data-reporting-interfacecedri), once the XML schema is available. If the reporting form specific to this subpart is not available in CEDRI at the time that the report is due, you must submit the report the Administrator at the appropriate address listed in §63.13. You must begin submitting reports via CEDRI no later than 90 days after the form becomes available in CEDRI. The excess emissions and summary reports must be submitted no later than 60 days after the end of the reporting period, regardless of the method in which the reports are submitted. The report must contain the information specified in

§63.10(e)(3)(vi). In addition, the summary report shall include:

(vi) For each PM CPMS, HCl, Hg, and THC CEMS, SO₂ CEMS, or Hg sorbent trap monitoring system, within 60 days after the reporting periods, you must report all of the calculated 30-operating day rolling average values derived from the CPMS, CEMS, CMS, or Hg sorbent trap monitoring systems.

(10) If the total continuous monitoring system downtime for any CEM or any CMS for the reporting period is 10 percent or greater of the total operating time for the reporting period, the owner or operator shall submit an excess emissions and continuous monitoring system performance report along with the summary report.

(11)(i) You must submit the information specified in paragraphs (b)(11)(i)(A) and (B) of this section no later than 60 days following the initial performance test. All reports must be signed by a responsible official.

(A) The initial performance test data as recorded under §63.1349(a).

(B) The values for the site-specific operating limits or parameters established pursuant to § 63.1349(b)(1), (3), (6), (7), and (8), as applicable, and a description, including sample calculations, of how the operating parameters were established during the initial performance test.

(C) As of December 31, 2011, and within 60 days after the date of completing each performance evaluation or test, as defined in § 63.2, conducted to demonstrate compliance with any standard covered by this subpart, you must submit the relative accuracy test audit data and performance test data, except opacity data, to the EPA by successfully submitting the data electronically via CEDRI and by using the Electronic Reporting Tool (ERT) (see https:// www.epa.gov/electronic-reporting-airemissions/electronic-reporting-tool-ert). For any performance evaluations with no corresponding RATA pollutants listed on the ERT website, you must submit the results of the performance

evaluation to the Administrator at the appropriate address listed in §63.13.

(12) All reports required by this subpart not subject to the requirements in paragraphs (b)(9) introductory text and (b)(11)(i) of this section must be sent to the Administrator at the appropriate address listed in §63.13. The Administrator or the delegated authority may request a report in any form suitable for the specific case (e.g., by commonly used electronic media such as Excel spreadsheet, on CD or hard copy). The Administrator retains the right to require submittal of reports subject to paragraphs (b)(9) introductory text and (b)(11)(i) of this section in paper format.

(c) For each failure to meet a standard or emissions limit caused by a malfunction at an affected source, you must report the failure in the semiannual compliance report required by §63.1354(b)(9). The report must contain the date, time and duration, and the cause of each event (including unknown cause, if applicable), and a sum of the number of events in the reporting period. The report must list for each event the affected source or equipment, an estimate of the amount of each regulated pollutant emitted over the emission limit for which the source failed to meet a standard, and a description of the method used to estimate the emissions. The report must also include a description of actions taken by an owner or operator during a malfunction of an affected source to minimize emissions in accordance with §63.1348(d), including actions taken to correct a malfunction.

■ 8. Section 63.1355 is amended by revising paragraph (e) to read as follows:

§63.1355 Recordkeeping requirements.

*

* *

*

(e) You must keep records of the daily clinker production rates according to the clinker production monitoring requirements in §63.1350(d). *

■ 9. Table 1 to subpart LLL of part 63 is amended by adding the entry "63.10(e)(3)(v)" in alphanumeric order to read as follows:

TABLE 1 TO SUBPART LLL OF PART 63—APPLICABILITY OF GENERAL PROVISIONS

Citation	Requirement		Applies to subpart LLL		Explanation	
*	*	*	*	*	*	*
63.10(e)(3)(v)	Due Dates formance F		ons and No CMS Per-			§63.1354(b)(9) specifies due date.
*	*	*	*	*	*	*

■ 10. Add table 2 to subpart LLL of part 63 to read as follows:

TABLE 2 TO SUBPART LLL OF PART 63-1989 TOXIC EQUIVALENCY FAC-TORS (TEFS)

Dioxins/Furans	TEFs 1989
2,3,7,8-TCDD 1,2,3,7,8-PeCDD 1,2,3,4,7,8-HxCDD 1,2,3,6,7,8-HxCDD 1,2,3,7,8,9-HxCDD 1,2,3,4,6,7,8-HpCDD 2,3,7,8-TCDF 1,2,3,7,8-PeCDF 2,3,4,7,8-PeCDF 1,2,3,4,7,8-PeCDF 1,2,3,4,7,8-HxCDF 1,2,3,6,7,8-HxCDF 1,2,3,4,6,7,8-HxCDF 1,2,3,4,6,7,8-HpCDF 1,2,3,4,6,7,8-HpCDF 1,2,3,4,7,8,9-HpCDF 1,2,3,4,7,8,9-HpCDF	1 0.5 0.1 0.1 0.01 0.01 0.05 0.5 0.1 0.1 0.1 0.1 0.01 0.0
	0.001

[FR Doc. 2018-15718 Filed 7-24-18; 8:45 am] BILLING CODE 6560-50-P

ENVIRONMENTAL PROTECTION AGENCY

40 CFR Part 81

[EPA-HQ-OAR-2017-0548; FRL-9981-17-OAR]

RIN 2060-AU13

Additional Air Quality Designations for the 2015 Ozone National Ambient Air Quality Standards—San Antonio, **Texas Area**

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

SUMMARY: The Environmental Protection Agency (EPA) is establishing initial air quality designations for the eight counties in the San Antonio-New Braunfels, Texas Core Based Statistical Area (CBSA) for the 2015 primary and secondary national ambient air quality standards (NAAQS) for ozone. The EPA is designating Bexar County as the San Antonio, Texas nonattainment area and the remaining seven counties as attainment/unclassifiable areas. The San Antonio, Texas nonattainment area is also being classified as Marginal by operation of law according to the severity of its air quality problem. Of the five classification categories, Marginal nonattainment areas have ozone levels that are closest to the ozone NAAQS at the time of designation. This action completes the initial designations for the 2015 ozone NAAQS. The EPA designated all other areas of the country

for the 2015 ozone NAAOS in actions signed by the Administrator on November 6, 2017, and April 30, 2018. DATES: The effective date of this rule is September 24, 2018.

ADDRESSES: The EPA has established a docket for this action under Docket ID No. EPA-HQ-OAR-2017-0548. All documents in the docket are listed in the index at *http://www.regulations.gov.* Although listed in the index, some information is not publicly available, i.e., Confidential Business Information or other information whose disclosure is restricted by statute. Certain other material, such as copyrighted material, is not placed on the internet and will be publicly available only in hard copy form. Publicly available docket materials are available either electronically in the docket or in hard copy at the EPA Docket Center, EPA WJC West Building, Room 3334, 1301 Constitution Avenue NW, Washington, DC. The Public Reading Room is open from 8:30 a.m. to 4:30 p.m., Monday through Friday, excluding legal holidays. The telephone number for the Public Reading Room is (202) 566-1744, and the telephone number for the Office of Air and Radiation Docket and Information Center is (202) 566-1742.

In addition, the EPA has established a website for rulemakings for the initial area designations for the 2015 ozone NAAQS at https://www.epa.gov/ozone*designations*. The website includes the EPA's final designations, as well as designation recommendation letters from states and tribes, the EPA's 120letters notifying the states whether the EPA intends to modify the state's recommendation, technical support documents, responses to comments and other related technical information.

The public may also inspect this rule and state-specific technical support information in hard copy at EPA Region 6, 1445 Ross Avenue, Suite 700, Dallas, Texas 75202-2733.

FOR FURTHER INFORMATION CONTACT:

Denise Scott. Office of Air Ouality Planning and Standards, U.S. Environmental Protection Agency, Mail Code C539–01, Research Triangle Park, NC 27711, phone number (919) 541-4280, email: scott.denise@epa.gov or Carrie Paige, U.S. Environmental Protection Agency, Region 6, Mail Code: 6MM-AB, 445 Ross Avenue, Dallas, TX 75202, telephone (214) 665-6521, email: paige.carrie@epa.gov.

SUPPLEMENTARY INFORMATION:

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I. Preamble Glossary of Terms and Acronyms

The following are abbreviations of terms used in the preamble.

- APA Administrative Procedure Act
- CAA Clean Air Act
- CFR Code of Federal Regulations
- CBSA Core Based Statistical Area
- DC District of Columbia
- EPA Environmental Protection Agency
- FR Federal Register
- NAAQS National Ambient Air Quality Standards
- NO_X Nitrogen Oxides
- NTTAA National Technology Transfer and Advancement Act
- PPM Parts per million
- RFA Regulatory Flexibility Act
- UMRA Unfunded Mandate Reform Act of 1995
- TAR Tribal Authority Rule
- U.S. United States U.S.C. United States Code
- VOC Volatile Organic Compounds

II. What is the purpose of this action?

The purpose of this action is to announce and promulgate initial area designations for the eight counties in the San Antonio-New Braunfels, Texas CBSA with respect to the 2015 primary and secondary NAAQS for ozone, in accordance with the requirements of Clean Air Act (CAA) section 107(d). The EPA is designating Bexar County as the San Antonio, Texas nonattainment area and the remaining seven counties as attainment/unclassifiable areas. With this designation action, the EPA has completed the initial designations for all areas of the country for the 2015 ozone NAAOS.

In addition, this action announces the classification for the San Antonio, Texas nonattainment area as Marginal. The classification occurs by operation of law at the time of designation based on the severity of the area's ozone air quality problem. The classification categories are Marginal, Moderate, Serious, Severe and Extreme. The EPA established the air quality thresholds that define the classifications in a separate rule titled, "Implementation of the 2015 National Ambient Air Quality Standards for **Ozone:** Nonattainment Area Classifications Approach" (Classifications Rule) (83 FR 10376; March 9, 2018).

The list of the areas being designated in this action appears in the regulatory table for Texas included at the end of this final rule. This table, which will amend 40 CFR part 81, identifies the designation for each area and the classification for the nonattainment area.

The EPA is basing the designations on the most recent 3 years of certified ozone air quality monitoring data (2015-2017) and on an evaluation of factors to assess contributions to nonattainment in nearby areas. State areas designated as nonattainment are subject to planning and emission reduction requirements as specified in CAA part D. Requirements vary according to an area's classification. On November 17, 2016, the EPA proposed an implementation rule for the 2015 ozone NAAQS (81 FR 81276). The EPA anticipates issuing the final implementation rule in 2018. This final implementation rule, along with additional forthcoming tools and guidance documents related to provisions for regulatory relief to address background and international ozone concentrations, should help nonattainment areas to address these emissions in state plans. In particular, the EPA recognizes that the information provided by Texas regarding likely

future ozone trends and the role of international transport may provide an avenue to help the state demonstrate this area attains the 2015 ozone NAAQS by the attainment date or is otherwise entitled to regulatory relief.

III. What is ozone and how is it formed?

Ground-level ozone is a gas that is formed by the reaction of volatile organic compounds (VOCs) and oxides of nitrogen (NO_X) in the atmosphere in the presence of sunlight. These precursor emissions are emitted by many types of pollution sources, including power plants and industrial emissions sources, on-road and off-road motor vehicles and engines and smaller sources, collectively referred to as area sources. Ozone is predominately a summertime air pollutant. However, high ozone concentrations have also been observed in cold months, where a few areas in the western United States (U.S.) have experienced high levels of local VOC and NO_X emissions that have formed ozone when snow is on the ground and temperatures are near or below freezing. Ozone and ozone precursors can be transported to an area from sources in nearby areas or from sources located hundreds of miles away. For purposes of determining ozone nonattainment area boundaries, the CAA requires the EPA to include areas that contribute to nearby violations of the NAAQS.

IV. What are the 2015 ozone NAAQS and the health and welfare concerns they address?

On October 1, 2015, the EPA revised both the primary and secondary NAAQS for ozone to a level of 0.070 parts per million (ppm) (annual fourth-highest daily maximum 8-hour average concentration, averaged over 3 years).¹ The level of both the primary and secondary ozone NAAQS previously set in 2008 is 0.075 ppm. The 2015 ozone NAAQS retain the same general form and averaging time as the 2008 ozone NAAQS.

The primary ozone standards provide protection for children, older adults, people with asthma or other lung diseases and other at-risk populations against an array of adverse health effects that include reduced lung function, increased respiratory symptoms and pulmonary inflammation; effects that contribute to emergency department visits or hospital admissions; and mortality. The secondary ozone standards protect against adverse effects to the public welfare, including those related to impacts on sensitive vegetation and forested ecosystems.

V. What are the CAA requirements for air quality designations?

When the EPA promulgates a new or revised NAAQS, the EPA is required to designate all areas in the country as nonattainment, attainment or unclassifiable, pursuant to section 107(d)(1) of the CAA. Section 107(d)(1)(A)(i) of the CAA defines a nonattainment area as, "any area that does not meet (or that contributes to ambient air quality in a nearby area that does not meet) the national primary or secondary ambient air quality standard for the pollutant." If an area meets either prong of this definition, states should recommend and the EPA is obligated to designate the area as "nonattainment." CAA section 107(d)(1)(A)(ii) defines an attainment area as any area that does not meet the definition of nonattainment and that meets the NAAQS. CAA section 107(d)(1)(A)(iii) provides that any area that the EPA cannot designate on the basis of available information as meeting or not meeting the standards should be designated as "unclassifiable." Historically for ozone, the EPA has designated most areas that do not meet the definition of nonattainment as "unclassifiable/ attainment." This category includes areas that have air quality monitoring data meeting the NAAQS and areas that do not have monitors but for which the EPA has no evidence that the areas may be violating the NAAQS or contributing to a nearby violation. In the designations for the 2015 ozone NAAQS, the EPA has reversed the order of the label to be attainment/ unclassifiable to better convey the definition of the designation category and so that the category is more easily distinguished from the separate unclassifiable category. In a few instances, based on circumstances where some monitoring data are available but are not sufficient for a determination that an area is or is not attaining the NAAQS, the EPA has designated an area as "unclassifiable." Section 107(d)(1)(B) of the CAA

Section 107(d)(1)(B) of the CAA requires the EPA to issue initial area designations within 2 years of promulgating a new or revised NAAQS. However, if the Administrator has insufficient information to make these designations within that time frame, the EPA has the authority to extend the deadline for designation decisions by up to 1 additional year.

By not later than 1 year after the promulgation of a new or revised

¹ See 80 FR 65296; October 26, 2015, for a detailed explanation of the calculation of the 3-year 8-hour average and 40 CFR part 50, Appendix U.

NAAQS, each state governor is required to recommend air quality designations, including the appropriate boundaries for areas, to the EPA. (See CAA section 107(d)(1)(A).) The EPA reviews those state recommendations and is authorized to make any modifications the Administrator deems necessary. The statute does not define the term "necessary," but the EPA interprets this to authorize the Administrator to modify designation recommendations that are inconsistent with the statutory language, including modification of recommended boundaries for nonattainment areas that are not supported by the facts or analysis. If the EPA intends to modify a state's recommendation, section 107(d)(1)(B) of the CAA requires the EPA to notify the state of any such intended modifications not less than 120 days prior to the EPA's promulgation of the final designation. These notifications are commonly known as the "120-day letters." If the state does not agree with the EPA's intended modification, the 120-day period provides an opportunity for the state to demonstrate to the EPA why it believes any modification proposed by the EPA is inappropriate. If a state fails to provide any recommendation for an area, in whole or in part, the EPA must promulgate a designation that the Administrator deems appropriate.

The terms "contributes to" and "nearby" in the definition of a nonattainment area are not defined in the statute and the EPA has discretion to interpret these ambiguous terms, based on considerations such as the nature of a specific pollutant, the types of sources that may contribute to violations, the form of the relevant NAAQS and any other relevant information. The EPA does not interpret the statute to require the agency to establish bright line tests or thresholds for what constitutes "contribution" or "nearby" for purposes of designations.²

Section 301(d) of the CAA authorizes the EPA to approve eligible Indian tribes to implement provisions of the CAA on Indian reservations and other areas within the tribes' jurisdiction. The Tribal Authority Rule (TAR) (40 CFR part 49), which implements section 301(d) of the CAA, sets forth the criteria and process for tribes to apply to the EPA for eligibility to administer CAA programs. The designations process contained in section 107(d) of the CAA is included among those provisions determined to be appropriate by the EPA for treatment of tribes in the same manner as states. Under the TAR, tribes

generally are not subject to the same submission schedules imposed by the CAA on states. As authorized by the TAR, tribes may seek eligibility to submit designation recommendations to the EPA.

VI. What is the chronology for this designations rule and what guidance did the EPA provide?

On February 25, 2016, the EPA issued guidance for states and tribal agencies to use for purposes of making designation recommendations as required by CAA section 107(d)(1)(A). (See February 25, 2016, memorandum from Janet G. McCabe, Acting Assistant Administrator, to Regional Administrators, Regions 1–10, titled, "Area Designations for the 2015 Ozone National Ambient Air Quality Standards" (Designations Guidance)). The Designations Guidance provided the anticipated timeline for designations and identified important factors that the EPA recommended states and tribes consider in making their recommendations and that the EPA intended to consider in promulgating designations. These factors include air quality data, emissions and emissionsrelated data, meteorological data, geography/topography and jurisdictional boundaries. In the Designations Guidance, the EPA asked that states and tribes submit their designation recommendations, including appropriate area boundaries, to the EPA by October 1, 2016.³ In the guidance, the EPA indicated the agency expected to complete the initial designations for the 2015 ozone NAAQS on a 2-year schedule, by October 1, 2017, consistent with CAA 107(d)(1)(B)(i).

On November 6, 2017, the EPA designated about 85 percent of the counties in the U.S., including tribal lands within those counties.⁴ Consistent

⁴ Although the EPA commonly uses the term "counties" when speaking of designations, we note that the reference to "counties" also includes noncounty administrative or statistical areas that are comparable to counties. For example, Louisiana parishes; the organized boroughs of Alaska; the District of Columbia and the independent cities of the states of Virginia, Maryland, Missouri and with the EPA's Tribal Designation Guidance, the EPA designated two areas of Indian country as separate areas.

On December 4, 2017, a coalition of environmental and health organizations filed suit against the EPA claiming that the EPA failed to meet its mandatory obligation to designate all areas of the U.S. for the 2015 ozone NAAQS by October 1, 2017. American Lung Association, et al v. Pruitt (N.D. Cal. No. 4:17-cv-06900). A coalition of 15 states also filed a similar suit on December 5, 2017. State of California v. Pruitt (N.D. Cal. No. 4:17-cv-06936). In a March 12, 2018, order, the court granted the motions in part and ordered the EPA "to promulgate final designations for all areas of the country except for the eight undesignated counties composing the San Antonio area no later than April 30, 2018" and "to promulgate final designations for the San Antonio area no later than 127 days from the date of this order." Thus, the designation deadline for the San Antonio area was set to July 17, 2018.

On March 19, 2018, the EPA sent a 120-day letter to the Governor of Texas notifying the state of the EPA's preliminary response to the state's recommendations for the eight counties in the San Antonio-New Braunfels, Texas CBSA. The EPA requested that Texas submit by May 11, 2018, any additional information the state wanted the EPA to consider in making final designation decisions for the area. Although not required by section 107(d)(2)(B) of the CAA, the EPA also provided a 30-day public comment period specific to this area (83 FR 13719; March 30, 2018). The comment period closed on April 30, 2018.

On April 30, 2018, the EPA designated all remaining undesignated areas except the eight counties in the San Antonio area (83 FR 25776; June 4, 2018).

This action designating the eight counties in the San Antonio area completes the initial designations for the 2015 ozone NAAQS. The **ADDRESSES** section earlier in this preamble provides detail on where to find the information supporting this designation action and the prior two actions.

VII. What air quality data has the EPA used to designate the counties in the San Antonio-New Braunfels, Texas CBSA for the 2015 ozone NAAQS?

The final ozone designations for the counties in the San Antonio-New

² This view was confirmed in *Catawba County* v. *EPA*, 571 F.3d 20 (D.C. Cir. 2009).

³ The EPA previously issued two guidance memoranda related to designating areas of Indian country that also apply for designations for the 2015 ozone NAAQS. (*See* December 20, 2011, memorandum from Stephen D. Page, Director, Office of Air Quality Planning and Standards, to Regional Air Directors, Regions I–X, titled, "Policy for Establishing Separate Air Quality Designations for Areas of Indian Country" and December 20, 2011, memorandum from Stephen D. Page, Director, Office of Air Quality Planning and Standards, to Regional Air Directors, Regions I–X, titled, "Guidance to Regions for Working with Tribes during the National Ambient Air Quality Standards (NAAQS) Designations Process.")

Nevada are equivalent to counties for administrative purposes. In addition, Alaska's Unorganized Borough is divided into 10 census areas that are statistically equivalent to counties.

Braunfels, Texas CBSA are based on air quality monitoring data from the 3 most recent years of certified data, which are 2015–2017. Under 40 CFR 58.16, states are required to report all monitored ozone air quality data and associated quality assurance data within 90 days after the end of each quarterly reporting period, and under 40 CFR part 58.15(a)(2) states are required to submit annual summary reports and a data certification letter to the EPA by May 1 for ozone air quality data collected in the previous calendar year. On March 19, 2018, when the EPA notified Texas of the EPA's intended designations for the San Antonio area, the most recent certification obligation was for air quality data from 2016. On May 1, 2018, Texas submitted certified air quality monitoring data for 2017. The violating

monitors for the 2015–2017 period are the same monitors that showed violations for the 2014–2016 period.

VIII. What are the ozone air quality classifications?

In accordance with CAA section 181(a)(1), each area designated as nonattainment for the ozone NAAQS is classified by operation of law at the same time as the area is designated by the EPA. Under subpart D of title I of the CAA, state planning and emissions control requirements for ozone are determined, in part, by a nonattainment area's classification. The ozone nonattainment areas are classified based on the severity of their ozone levels (as determined based on the area's "design value," which represents air quality in the area for the most recent 3 years).⁵

The five classification categories are Marginal, Moderate, Serious, Severe and Extreme. Nonattainment areas with a "lower" classification have ozone levels that are closer to the standard than areas with a "higher" classification. Areas in the lower classification levels have fewer and/or less stringent mandatory air quality planning and control requirements than those in higher classifications. On March 9, 2018 (83 FR 10376), the EPA published the Classifications Rule that establishes the ozone level threshold for each classification for the 2015 ozone NAAQS. Each nonattainment area's design value, based on the most recent 3 years of certified air quality monitoring data, is used to establish the classification for the area. See Table 1.

TABLE 1—CLASSIFICATION THRESHOLDS FOR THE 2015 OZONE NAAQS (0.070 ppm)

Nonattainment area classification		8-Hour ozone design value (ppm) ª
Marginal	from	0.071
ů	up to ^b	0.081
Moderate	from	0.081
	up to ^b	0.093
Serious	from	0.093
	up to ^b	0.105
Severe-15	from	0.105
	up to ^b	0.111
Severe-17	from	0.111
	up to ^b	0.163
Extreme	equal to or above	0.163

a parts per million.

^b but not including.

The most recent 3 years of certified air quality monitoring data for Bexar County, Texas are from the period 2015–2017. The ozone design value is 0.074 ppm. Therefore, in accordance with Table 1 above, the San Antonio, Texas nonattainment area is classified by operation of law as a Marginal area for the 2015 ozone NAAQS. The regulatory table for Texas included at the end of this action provides the classification for the nonattainment area.

IX. Where can I find information forming the basis for this rule and exchanges between the EPA and the state?

Information providing the basis for this action is provided in the docket for this rulemaking. The applicable EPA guidance memoranda and copies of correspondence regarding this process between the EPA and the state and other parties are also available for review at the EPA Docket Center listed above in the addresses section of this document, and on the EPA's ozone designation website at *https://www.epa.gov/ozonedesignations.* State-specific information is also available from the EPA Region 6 office at the address at the beginning of this Preamble.

X. Environmental Justice Concerns

When the EPA establishes a new or revised NAAQS, the CAA requires the EPA to designate all areas of the U.S. as either nonattainment, attainment or unclassifiable. This final action addresses designation determinations for eight counties in Texas for the 2015 ozone NAAQS. Seven counties are being designated as attainment/unclassifiable and one county is being designated as nonattainment. In addition, the nonattainment area is being classified as Marginal according to the severity of its ozone air quality problem. Area designations address environmental justice concerns by ensuring that the public is properly informed about the air quality in an area. In locations where air quality does not meet the NAAQS, the CAA requires relevant state authorities to initiate appropriate air quality management actions to ensure that all those residing, working, attending school or otherwise present in those areas are protected, regardless of minority and economic status.

XI. Statutory and Executive Order Reviews

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

This action is exempt from review by the Office of Management and Budget because it responds to the CAA requirement to promulgate air quality designations after promulgation of a new or revised NAAQS.

⁵ The air quality design value for the 8-hour ozone NAAQS is the 3-year average of the annual

⁴th highest daily maximum 8-hour average ozone concentration. *See* 40 CFR part 50, Appendix U.

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

This action is not an Executive Order 13771 regulatory action because actions such as air quality designations after promulgating a new revised NAAQS are exempt from review under Executive Order 12866.

C. Paperwork Reduction Act (PRA)

This action does not impose an information collection burden under the PRA. This action fulfills the nondiscretionary duty for the EPA to promulgate air quality designations after promulgation of a new or revised NAAQS and does not contain any information collection activities.

D. Regulatory Flexibility Act (RFA)

This designation action under CAA section 107(d) is not subject to the RFA. The RFA applies only to rules subject to notice-and-comment rulemaking requirements under the Administrative Procedure Act (APA), 5 U.S.C. 553, or any other statute. Section 107(d)(2)(B) of the CAA explicitly provides that designations are exempt from the notice-and-comment provisions of the APA. In addition, designations under CAA section 107(d) are not among the list of actions that are subject to the notice-and-comment rulemaking requirements of CAA section 307(d).

E. Unfunded Mandates Reform Act (UMRA)

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

F. Executive Order 13132: Federalism

This action does not have federalism implications. It will not have substantial direct effects on the states, on the relationship between the national government and the states or on the distribution of power and responsibilities among the various levels of government. The division of responsibility between the federal government and the states for purposes of implementing the NAAQS is established under the CAA. *G.* Executive Order 13175: Consultation and Coordination With Indian Tribal Governments

This action does not have tribal implications. It will neither impose substantial direct compliance costs on federally recognized tribal governments, nor preempt tribal law. There are no tribes affected by this action.

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

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

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

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

J. National Technology Transfer and Advancement Act (NTTAA)

This rulemaking does not involve technical standards.

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

The EPA believes that this action does not have disproportionately high and adverse human health or environmental effects on minority populations, lowincome populations and/or indigenous peoples, as specified in Executive Order 12898 (59 FR 7629, February 16, 1994). The documentation for this determination is contained in Section X of this preamble, "Environmental Justice Concerns."

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 U.S. This action is not a "major rule" as defined by 5 U.S.C. 804(2).

M. Judicial Review

Under section 307(b)(1) of the Act, petitions for judicial review of this action must be filed in the U.S. Court of Appeals for the appropriate circuit by September 24, 2018. Under section 307(b)(2) of the Act, the requirements of this final action may not be challenged later in civil or criminal proceedings for enforcement.

List of Subjects in 40 CFR Part 81

Environmental protection, Air pollution control, National parks, Wilderness areas.

Dated: July 17, 2018.

Andrew R. Wheeler,

Acting Administrator.

For the reasons set forth in the preamble, 40 CFR part 81 is amended as follows:

PART 81—DESIGNATIONS OF AREAS FOR AIR QUALITY PLANNING PURPOSES

■ 1. The authority citation for part 81 continues to read as follows:

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

Subpart C—Section 107 Attainment Status Designations

■ 2. In § 81.344, the table titled "Texas—2015 8-Hour Ozone NAAQS (Primary and Secondary)" is amended by:

■ a. Adding an entry for San Antonio, TX before the entry for Rest of State;

■ b. Adding an entry for Atascosa County before the entry for Austin County;

■ c. Adding an entry for Bandera County before the entry for Bastrop County;

■ d. Adding an entry for Comal County before the entry for Comanche County;

■ e. Adding an entry for Guadalupe County before the entry for Hale County;

■ f. Adding an entry for Kendall County before the entry for Kenedy County;

■ g. Adding an entry for Medina County before the entry for Menard County; and

■ h. Adding an entry for Wilson County before the entry for Winkler County. The additions read as follows:

§81.344 Texas.

* * * *

TEXAS—2015 8-HOUR OZONE NAAQS

	Designated area ¹			Designation		Classification	
	Designated area			Date ²	Туре	Date ²	Туре
*	*	*	*	•	*	*	*
an Antonio, TX Bexar County.				9/24/2018	Nonattainment	9/24/2018	Marginal.
*	*	*	*	,	k	*	*
est of State:							
*	*	*	*	,	k	*	*
Atascosa County				9/24/2018	Attainment/ Unclassifiable.		
*	*	*	*	,	*	*	*
Bandera County				9/24/2018	Attainment/ Unclassifiable.		
*	*	*	*	,	k	*	*
Comal County				9/24/2018	Attainment/ Unclassifiable.		
*	*	*	*	,	*	*	*
Guadalupe County				9/24/2018	Attainment/ Unclassifiable.		
*	*	*	*	,	*	*	*
Kendall County				9/24/2018	Attainment/ Unclassifiable.		
*	*	*	*	,	k	*	*
Medina County				9/24/2018	Attainment/ Unclassifiable.		
*	*	*	*	•	*	*	*
Wilson County				9/24/2018	Attainment/ Unclassifiable.		
*	*	*	*	,	k	*	*

¹ Includes any Indian country in each county or area, unless otherwise specified. EPA is not determining the boundaries of any area of Indian country in this table, including any area of Indian country located in the larger designation area. The inclusion of any Indian country in the designation area is not a determination that the state has regulatory authority under the Clean Air Act for such Indian country. ² This date is August 3, 2018, unless otherwise noted.

[FR Doc. 2018–15919 Filed 7–24–18; 8:45 am] BILLING CODE 6560–50–P

ENVIRONMENTAL PROTECTION AGENCY

40 CFR Part 180

[EPA-HQ-OPP-2017-0226; FRL-9979-81]

Florasulam; Pesticide Tolerances

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

SUMMARY: This regulation establishes tolerances for residues of florasulam in or on teff forage, teff grain, teff hay, and teff straw. Interregional Research Project Number 4 (IR–4) requested these tolerances under the Federal Food, Drug, and Cosmetic Act (FFDCA). **DATES:** This regulation is effective July 25, 2018. Objections and requests for hearings must be received on or before September 24, 2018, and must be filed in accordance with the instructions provided in 40 CFR part 178 (see also Unit I.C. of the **SUPPLEMENTARY INFORMATION**).

ADDRESSES: The docket for this action, identified by docket identification (ID) number EPA–HQ–OPP–2017–0226, is available at *http://www.regulations.gov* or at the Office of Pesticide Programs Regulatory Public Docket (OPP Docket) in the Environmental Protection Agency Docket Center (EPA/DC), West William Jefferson Clinton Bldg., Rm. 3334, 1301 Constitution Ave. NW, Washington, DC 20460–0001. The Public Reading Room is open from 8:30 a.m. to 4:30 p.m., Monday through Friday, excluding legal holidays. The telephone number for the

Public Reading Room is (202) 566–1744, and the telephone number for the OPP Docket is (703) 305–5805. Please review the visitor instructions and additional information about the docket available at *http://www.epa.gov/dockets*.

FOR FURTHER INFORMATION CONTACT:

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

SUPPLEMENTARY INFORMATION:

I. General Information

A. Does this action apply to me?

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

• Crop production (NAICS code 111).

• Animal production (NAICS code 112).

• Food manufacturing (NAICS code 311).

• Pesticide manufacturing (NAICS code 32532).

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

You may access a frequently updated electronic version of EPA's tolerance regulations at 40 CFR part 180 through the Government Printing Office's e-CFR site at http://www.ecfr.gov/cgi-bin/textidx?&c=ecfr&tpl=/ecfrbrowse/Title40/ 40tab 02.tpl.

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

Under FFDCA section 408(g), 21 U.S.C. 346a, any person may file an objection to any aspect of this regulation and may also request a hearing on those objections. You must file your objection or request a hearing on this regulation in accordance with the instructions provided in 40 CFR part 178. To ensure proper receipt by EPA, you must identify docket ID number EPA-HQ-OPP-2017-0226 in the subject line on the first page of your submission. All objections and requests for a hearing must be in writing, and must be received by the Hearing Clerk on or before September 24, 2018. Addresses for mail and hand delivery of objections and hearing requests are provided in 40 CFR 178.25(b).

In addition to filing an objection or hearing request with the Hearing Clerk as described in 40 CFR part 178, please submit a copy of the filing (excluding any Confidential Business Information (CBI)) for inclusion in the public docket. Information not marked confidential pursuant to 40 CFR part 2 may be disclosed publicly by EPA without prior notice. Submit the non-CBI copy of your objection or hearing request, identified by docket ID number EPA–HQ–OPP– 2017–0226, by one of the following methods:

• Federal eRulemaking Portal: http:// www.regulations.gov. Follow the online instructions for submitting comments. Do not submit electronically any information you consider to be CBI or other information whose disclosure is restricted by statute.

• *Mail:* OPP Docket, Environmental Protection Agency Docket Center (EPA/ DC), (28221T), 1200 Pennsylvania Ave. NW, Washington, DC 20460–0001.

• *Hand Delivery:* To make special arrangements for hand delivery or delivery of boxed information, please follow the instructions at *http://www.epa.gov/dockets/contacts.html.*

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

II. Summary of Petitioned-For Tolerance

In the Federal Register of October 23, 2017 (82 FR 49020) (FRL-9967-37), EPA issued a document pursuant to FFDCA section 408(d)(3), 21 U.S.C. 346a(d)(3), announcing the filing of a pesticide petition (PP 7E8549) by IR-4, Rutgers, The State University of New Jersey, 500 College Road East, Suite 201 W, Princeton, NJ 08540. The petition requested that 40 CFR part 180 be amended by establishing tolerances for residues of the herbicide florasulam N-(2,6-difluorophenyl)-8-fluoro-5-methoxy (1,2,4)triazolo(1,5-c)pyrimidine-2sulfonamide in or on the raw agricultural commodities teff, forage at 0.05 parts per million (ppm); teff, grain at 0.01 ppm; teff, straw at 0.05 ppm; and teff, hay at 0.05 ppm. That document referenced a summary of the petition prepared by Dow AgroSciences, the registrant, which is available in the docket, http://www.regulations.gov. A comment was received on the notice of filing. EPA's response to this comment is discussed in Unit IV.C.

III. Aggregate Risk Assessment and Determination of Safety

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

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

A. Toxicological Profile

EPA has evaluated the available toxicity data and considered its validity, completeness, and reliability as well as the relationship of the results of the studies to human risk. EPA has also considered available information concerning the variability of the sensitivities of major identifiable subgroups of consumers, including infants and children.

There was slight nephrotoxicity (increased kidney weights, hypertrophy, and degeneration/regeneration and inflammation of the descending portion of proximal tubules) observed in the kidneys of rats (both sexes) after subchronic exposure to florasulam (90 days) at or greater than 500 milligrams/ kilogram/day (mg/kg/day). Chronic exposure in rats led to slight nephrotoxicity (increased kidney weights, hypertrophy, and slight multifocal mineralization of the papilla) at 250 and 500 mg/kg/day in males only. Additionally, at 500 mg/kg/day, papillary necrosis and hyperplasia of the transitional epithelium (papilla) were observed in the kidney (males). Decreases in body weight and body weight gain were also observed in females after subchronic (500 mg/kg/ day) and chronic exposure (250 mg/kg/ day). Liver toxicity was observed in dogs (both sexes) in the form of increased alkaline phosphatase activity (59–127%), increased liver weights, hypertrophy, and hepatic vacuolation at 50 mg/kg/day after 90 days. After 1 year, there were increases in alkaline phosphatase (233-783%) in dogs (both sexes) but no changes in liver weights or gross or microscopic pathology at 50 mg/kg/day. Additionally, there were decreases in body weight, body weight gain and food consumption, as well as vacuolation of the zona reticularis and zona fasciculate in the adrenal gland (consistent with fatty change) in both sexes. There were no adverse effects noted after subchronic/chronic exposure to florasulam in mice up to the limit dose of 1,000 mg/kg/day.

There was no evidence of developmental toxicity or indications of

neonatal sensitivity in the developmental and reproduction toxicity studies (rats and rabbits). In the rat developmental toxicity study, decreased body weights and decreased food consumption were observed. There were also slight decreases observed in fetal body weight and delays in ossification observed in fetuses at the high dose. However, the minor differences were not considered adverse since there was no clear dose-response relationship and the values (both findings) fell within historical control values. Furthermore, the findings were attributed to the associated decreases in maternal body weights. There were no treatment-related effects observed in dams or offspring in the developmental toxicity study in rabbits. In the reproduction toxicity study in rats, there were decreased body weights, body weight gains, and food consumption, as well as increased kidney weights and hypertrophy in both sexes at 500 mg/kg/ day. Additionally, at 500 mg/kg/day, transient decreases in pup body weights were observed on post-natal day 4 preculling (F1 and F2 males) and post-natal day 7 (F1 females and F2 males and females); however, by post-natal day 21, all treated groups were similar to controls. The decreases observed were associated with decreased maternal body weight and food consumption and were transient in nature; thus, they were not considered adverse.

Dermal exposure to florasulam did not result in systemic toxicity up to the limit dose of 1,000 mg/kg/day. There is no evidence of neurotoxicity, mutagenicity, or carcinogenicity after exposure to florasulam. In addition, there is no evidence of endocrine related toxicity.

Specific information on the studies received and the nature of the adverse effects caused by florasulam as well as the no-observed-adverse-effect-level (NOAEL) and the lowest-observedadverse-effect-level (LOAEL) from the toxicity studies can be found at http:// www.regulations.gov in the document titled "Florasulam: Human Health Risk Assessment for proposed use on *Turfgrass*" ("2009 Florasulam Turfgrass Assessment") on pages 35–39 in docket ID number EPA-HQ-OPP-2017-0226. The Agency is relying on this risk assessment because the toxicological profile for florasulam has not changed since that risk assessment was conducted and as indicated in a more recent assessment for use on teff, the Agency has concluded that registering use on teff would not alter the Agency's previously assessed exposure estimates for florasulam. See "Florasulam: Human Health Risk Assessment for Proposed Use on Teff' (Dec. 6, 2017) ("2017 Florasulam Teff Assessment"), which can also be found in http:// www.regulations.gov in docket ID number EPA-HQ-OPP-2017-0226.

B. Toxicological Points of Departure/ Levels of Concern

Once a pesticide's toxicological profile is determined, EPA identifies

toxicological points of departure (POD) and levels of concern to use in evaluating the risk posed by human exposure to the pesticide. For hazards that have a threshold below which there is no appreciable risk, the toxicological POD is used as the basis for derivation of reference values for risk assessment. PODs are developed based on a careful analysis of the doses in each toxicological study to determine the dose at which no adverse effects are observed (the NOAEL) and the lowest dose at which adverse effects of concern are identified (the LOAEL). Uncertainty/ safety factors are used in conjunction with the POD to calculate a safe exposure level—generally referred to as a population-adjusted dose (PAD) or a reference dose (RfD)—and a safe margin of exposure (MOE). For non-threshold risks, the Agency assumes that any amount of exposure will lead to some degree of risk. Thus, the Agency estimates risk in terms of the probability of an occurrence of the adverse effect expected in a lifetime. For more information on the general principles EPA uses in risk characterization and a complete description of the risk assessment process, see http:// www2.epa.gov/pesticide-science-andassessing-pesticide-risks/assessinghuman-health-risk-pesticides.

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

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

Exposure/scenario	Point of departure and uncertainty/safety factors	RfD, PAD, LOC for risk assessment	Study and toxicological effects
Acute dietary (All populations)	No appropriate endpoi	nt identified.	·
Chronic dietary (All populations)	NOAEL = 5 mg/kg/ day. UF _A = 10x UF _H = 10x FQPA SF = 1x	Chronic RfD = 0.05 mg/kg/day. cPAD = 0.05 mg/kg/ day.	Chronic toxicity—dogs. LOAEL = 50 mg/kg/day, based on decreased body weights (17%), body weight gains (68%), and food consumption in the females; adverse liver alterations; slight vacuolation of the zona reticularis and zona fasciculata in the adrenal gland (fatty change) in both sexes.
Incidental oral short-term (1–30 days).	NOAEL = 5 mg/kg/ day. $UF_A = 10x$ $UF_H = 10x$ FQPA SF = 1x	LOC for MOE = 100	Subchronic toxicity—dogs. LOAEL = 50 mg/kg/day based on hepatotoxicity (increases in alkaline phosphatase activity and hepatic vacuolation) ob- served in both sexes.
Inhalation short-term (1–30 days).	Oral study NOAEL = 5 mg/kg/day (inha- lation absorption rate = 100%). UF _A = 10x UF _H = 10x FQPA SF = 1x	LOC for MOE = 100	Subchronic toxicity—dogs. LOAEL = 50 mg/kg/day based on hepatotoxicity (increases in alkaline phosphatase activity and hepatic vacuolation) ob- served in both sexes.

TABLE 1—SUMMARY OF TOXICOLOGICAL DOSES AND ENDPOINTS FOR FLORASULAM FOR USE IN HUMAN HEALTH RISK ASSESSMENT—Continued

Exposure/scenario	Point of departure and uncertainty/safety factors	RfD, PAD, LOC for risk assessment	Study and toxicological effects
Cancer (Oral, dermal, inhala- tion).	Not Likely to be Carcir	nogenic to Humans.	

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

C. Exposure Assessment

1. Dietary exposure from food and feed uses. EPA's most recent quantitative dietary assessment was conducted in connection with the registration of turfgrass uses for florasulam. See 2009 Florasulam Turfgrass Assessment. That document considered dietary exposure for residues of florasulam in food associated with the all existing florasulam tolerances in 40 CFR 180.633 as described in Unit III.C.1. of the 2007 rulemaking establishing those tolerances. 72 FR 55073 (Sept. 28, 2007). EPA has determined that approval of the use on teff will not change those dietary exposure estimates for residues of florasulam in or on food. The Agency expects residues on teff to be similar to those residues in or on wheat because of the similarity in use pattern and application rates. Teff is prepared like other whole grains, such as rice and barley, and may also be used to make flour in a manner similar to wheat and other cereal grains. As a flour, the Agency expects that teff will likely substitute in the diet for cereal grain foods rather than add to dietary exposure. With respect to livestock commodities, residues of florasulam in teff livestock feeds are expected to be similar to those in other forages, hays, and silages for which florasulam is currently registered. Therefore, there would be no increase in the livestock dietary burden should teff be substituted in the livestock diet for other hays and silages; residues in meat, milk, poultry and eggs will remain the same

2. Dietary exposure from drinking water. In the 2009 Florasulam Turfgrass Assessment, the Agency used screeninglevel water exposure models in the dietary exposure analysis and risk assessment for florasulam in drinking water. These simulation models take into account data on the physical, chemical, and fate/transport characteristics of florasulam. Further information regarding EPA drinking water models used in pesticide exposure assessment can be found at http://www2.epa.gov/pesticide-scienceand-assessing-pesticide-risks/aboutwater-exposure-models-used-pesticide.

To arrive at the total EDWC (estimated drinking water concentrations), the maximum surface water and ground water values for the parent was added to the maximum surface water and ground water value for the major degradate. Based on the FQPA Index Reservoir Screening Tool (FIRST), and Screening Concentration in Ground Water (SCI–GROW) models, the estimated drinking water concentrations (EDWCs) of florasulam use on turfgrass for chronic exposures are estimated to be 1.36 parts per billion (ppb) for surface water and 0.06 ppb for ground water.

The Agency has concluded that the teff use will not increase drinking water exposure estimates because the teff use pattern is similar to the use patterns on wheat and barley. The wheat and barley use patterns yield EDWCs that are approximately nine times lower than the use on turfgrass and thus would not be used to assess dietary exposure. Therefore, the Agency used the same modeled estimates of drinking water concentrations from the 2009 Florasulam Turfgrass Assessment: For the chronic dietary risk assessment, the water concentration of value 1.36 ppb was used to assess the contribution to drinking water.

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

Florasulam is currently registered for the following uses that could result in residential exposures: Turf. The new use on teff is not a residential use. Therefore, EPA is relying on its 2009 Florasulam Turfgrass Assessment to assess residential exposures. EPA assessed residential exposure using the following assumptions: Short-term inhalation exposure is expected to handlers as a result of applying florasulam to turf. There is no shortterm dermal endpoint for florasulam, and therefore, no dermal risks were assessed for residential handlers. The scenarios assessed for handlers was mixing/loading/applying florasulam to turf with various application equipment.

For post-application, the Agency determined there is a potential for exposure from entering florasulamtreated residential areas, such as lawns, sports fields, and golf courses that could lead to post-application exposures to adults and children. No short-term dermal point of departure was identified for florasulam. Therefore, no dermal risks were assessed for residential postapplication exposures.

The Agency assumed that inhalation exposures are minimal following outdoor applications of an active ingredient with low vapor pressure. Since the proposed use of florasulam include only outdoor applications and florasulam has a low vapor pressure, post-application inhalation exposures and risks were not assessed. The scenario resulting in the highest exposure was short-term incidental oral risks for toddlers after applications of florasulam to lawns. The exposure scenarios include hand to mouth, object to mouth, incidental soil ingestion and the combination of all three of these scenarios.

Further information regarding EPA standard assumptions and generic inputs for residential exposures may be found at http://www2.epa.gov/pesticidescience-and-assessing-pesticide-risks/ standard-operating-proceduresresidential-pesticide.

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

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

D. Safety Factor for Infants and Children

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

2. Prenatal and postnatal sensitivity. There was no evidence of developmental toxicity or indications of neonatal sensitivity in the developmental and reproduction toxicity studies (rats and rabbits). In the rat developmental toxicity study (750 mg/kg/day) body weights were decreased by 4–6% during gestation days 6–19, resulting in a 16% decrease in body weight gains during treatment (gestation days 6-16); food consumption was also decreased (not statistically analyzed) by 6-13% during the treatment period. Additionally, at this dose, absolute and relative (to body weight) kidney weights were increased $(p \le 0.05)$ by 8 and 12%, respectively. At 250 and 750 mg/kg/day, slight decreases (3-4%) were observed in fetal body weight. Additionally, there were delays in ossification observed in fetuses at 750 mg/kg/day. However, the minor differences were not considered adverse since there was no clear doseresponse and the values (both findings) fell within historical control values.

Furthermore, the findings were attributed to the associated decreases in maternal body weights. There were no treatment-related effects observed in dams or offspring in the developmental toxicity study in rabbits. In the reproduction toxicity study in rats, there were decreased body weights, body weight gains, and food consumption, as well as increased kidney weights and hypertrophy in both sexes at 500 mg/kg/ day. Additionally, at 500 mg/kg/day, transient decreases in pup body weights were observed on post-natal day 4 preculling (F1 and F2 males) and post-natal day 7 (F1 females and F2 males and females); however, by post-natal day 21, all treated groups were similar to controls. The decreases observed were associated with decreased maternal body weight and food consumption and were transient in nature; thus, they were not considered adverse

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

i. The toxicity database for florasulam is complete.

ii. There is no indication that florasulam is a neurotoxic chemical and there is no need for a developmental neurotoxicity study or additional UFs to account for neurotoxicity.

iii. There is no evidence that florasulam results in increased susceptibility in *in utero* rats or rabbits in the prenatal developmental studies or in young rats in the 2-generation reproduction study.

iv. There are no residual uncertainties identified in the exposure databases. The dietary food exposure assessments were performed based on 100 PCT and tolerance-level residues. EPA made conservative (protective) assumptions in the ground and surface water modeling used to assess exposure to florasulam in drinking water. EPA used similarly conservative assumptions to assess postapplication exposure of children as well as incidental oral exposure of toddlers. These assessments will not underestimate the exposure and risks posed by florasulam.

E. Aggregate Risks and Determination of Safety

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

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

2. Chronic risk. Using the exposure assumptions described in this unit for chronic exposure, EPA has concluded that chronic exposure to florasulam from food and water will utilize less than 1% of the cPAD for all population groups. Based on the explanation in Unit III.C.3., regarding residential use patterns, chronic residential exposure to residues of florasulam is not expected.

3. *Short-term risk*. Short-term aggregate exposure takes into account short-term residential exposure plus chronic exposure to food and water (considered to be a background exposure level).

Florasulam is currently registered for uses that could result in short-term residential exposure, and the Agency has determined that it is appropriate to aggregate chronic exposure through food and water with short-term residential exposures to florasulam.

Using the exposure assumptions described in this unit for short-term exposures, EPA has concluded the combined short-term food, water, and residential exposures result in aggregate MOEs of 14,000 for children, 98,000 for the general U.S. population, and 114,000 for adult females. Because EPA's level of concern for florasulam is a MOE of 100 or below, these MOEs are not of concern.

4. Intermediate-term risk. Intermediate-term aggregate exposure takes into account intermediate-term residential exposure plus chronic exposure to food and water (considered to be a background exposure level).

An intermediate-term adverse effect was identified; however, florasulam is not registered for any use patterns that would result in intermediate-term residential exposure. Intermediate-term risk is assessed based on intermediateterm residential exposure plus chronic dietary exposure. Because there is no intermediate-term residential exposure and chronic dietary exposure has already been assessed under the appropriately protective cPAD (which is at least as protective as the POD used to assess intermediate-term risk), no further assessment of intermediate-term risk is necessary, and EPA relies on the chronic dietary risk assessment for evaluating intermediate-term risk for florasulam.

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

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

IV. Other Considerations

A. Analytical Enforcement Methodology

Adequate enforcement methodology (capillary gas chromatography and mass selective detection (GC–MSD)) is available to enforce the tolerance expression.

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

B. International Residue Limits

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

The Codex has not established a MRL for florasulam on teff.

C. Response to Comments

A single comment was received that appeared to be in support of the petition and read in part that "the proposed regulation of pesticide residuals is . . . a very reasonable proposal." The commenter also expressed concern regarding the consequences for not meeting the residue levels. The commenter's concern is outside the scope of this rulemaking, which is concerned with assessing the safety of these tolerances.

V. Conclusion

Therefore, tolerances are established for residues of florasulam, including its metabolites and degradates, in or on teff, forage at 0.05 ppm; teff, grain at 0.01 ppm; teff, hay at 0.05 ppm; and teff, straw at 0.05 ppm.

In addition, in accordance with Agency policy, EPA is revising the introductory language in paragraph (a) to clarify (1) that, as provided in FFDCA section 408(a)(3), the tolerance covers metabolites and degradates of florasulam not specifically mentioned; and (2) that compliance with the specified tolerance levels is to be determined by measuring only the specific compounds mentioned in the tolerance expression. EPA has determined that it is reasonable to make this change final without prior proposal and opportunity for comment, because public comment is not necessary, in that the change has no substantive effect on the tolerance, but rather is merely intended to clarify the existing tolerance expression.

VI. Statutory and Executive Order Reviews

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

Populations'' (59 FR 7629, February 16, 1994).

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

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

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

VII. Congressional Review Act

Pursuant to the Congressional Review Act (5 U.S.C. 801 *et seq.*), EPA will submit a report containing this rule and other required information to the U.S. Senate, the U.S. House of Representatives, and the Comptroller General of the United States prior to publication of the rule in the **Federal Register**. This action is not a "major rule" as defined by 5 U.S.C. 804(2).

List of Subjects in 40 CFR Part 180

Environmental protection, Administrative practice and procedure, Agricultural commodities, Pesticides and pests, Reporting and recordkeeping requirements. Dated: July 16, 2018. Michael Goodis, Director, Registration Division, Office of Pesticide Programs.

Therefore, 40 CFR chapter I is amended as follows:

PART 180—[AMENDED]

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

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

■ 2. In § 180.633:

■ i. Revise paragraph (a) introductory text; and

■ ii. Add alphabetically the commodities "Teff, forage," "Teff, grain," "Teff, hay," and "Teff, straw" to the table in paragraph (a).

The revision and additions read as follows:

§ 180.633 Florasulam; tolerances for residues.

(a) *General.* Tolerances are established for residues of the herbicide florasulam, including its metabolites and degradates, in or on the commodities below. Compliance with the tolerance levels specified below is to be determined by measuring only florasulam, N-(2, 6-difluorophenyl)-8fluoro-5-methoxy (1, 2, 4) triazole (1, 5*c*)pyrimidine-2-sulfonamide, in or on the commodities.

			Parts per million		
٩	k	*	*	*	*
Teff	, forag	e			0.05
					0.01
					0.05
Teff	, straw				0.05
,	ł	*	*	*	*
*	*	*	* *		
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DEPARTMENT OF HOMELAND SECURITY

Federal Emergency Management Agency

44 CFR Part 64

[Docket ID FEMA-2018-0002: Internal Agency Docket No. FEMA-8539]

Suspension of Community Eligibility

AGENCY: Federal Emergency Management Agency, DHS. **ACTION:** Final rule.

SUMMARY: This rule identifies communities where the sale of flood insurance has been authorized under the National Flood Insurance Program (NFIP) that are scheduled for suspension on the effective dates listed within this rule because of noncompliance with the floodplain management requirements of the program. If the Federal Emergency Management Agency (FEMA) receives documentation that the community has adopted the required floodplain management measures prior to the effective suspension date given in this rule, the suspension will not occur and a notice of this will be provided by publication in the Federal Register on a subsequent date. Also, information identifying the current participation status of a community can be obtained from FEMA's Community Status Book (CSB). The CSB is available at *https://* www.fema.gov/national-floodinsurance-program-community-statusbook.

DATES: The effective date of each community's scheduled suspension is the third date ("Susp.") listed in the third column of the following tables.

FOR FURTHER INFORMATION CONTACT: If you want to determine whether a particular community was suspended on the suspension date or for further information, contact Adrienne L. Sheldon, PE, CFM, Federal Insurance and Mitigation Administration, Federal Emergency Management Agency, 400 C Street SW, Washington, DC 20472, (202) 212–3966.

SUPPLEMENTARY INFORMATION: The NFIP enables property owners to purchase Federal flood insurance that is not otherwise generally available from private insurers. In return, communities agree to adopt and administer local floodplain management measures aimed at protecting lives and new construction from future flooding. Section 1315 of the National Flood Insurance Act of 1968, as amended, 42 U.S.C. 4022, prohibits the sale of NFIP flood insurance unless an appropriate public body adopts adequate floodplain management measures with effective enforcement measures. The communities listed in this document no longer meet that statutory requirement for compliance with program regulations, 44 CFR part 59. Accordingly, the communities will be suspended on the effective date in the third column. As of that date, flood insurance will no longer be available in the community. We recognize that some of these communities may adopt and submit the required documentation of legally enforceable floodplain

management measures after this rule is published but prior to the actual suspension date. These communities will not be suspended and will continue to be eligible for the sale of NFIP flood insurance. A notice withdrawing the suspension of such communities will be published in the **Federal Register**.

In addition, FEMA publishes a Flood Insurance Rate Map (FIRM) that identifies the Special Flood Hazard Areas (SFHAs) in these communities. The date of the FIRM, if one has been published, is indicated in the fourth column of the table. No direct Federal financial assistance (except assistance pursuant to the Robert T. Stafford **Disaster Relief and Emergency** Assistance Act not in connection with a flood) may be provided for construction or acquisition of buildings in identified SFHAs for communities not participating in the NFIP and identified for more than a year on FEMA's initial FIRM for the community as having flood-prone areas (section 202(a) of the Flood Disaster Protection Act of 1973, 42 U.S.C. 4106(a), as amended). This prohibition against certain types of Federal assistance becomes effective for the communities listed on the date shown in the last column. The Administrator finds that notice and public comment procedures under 5 U.S.C. 553(b), are impracticable and unnecessary because communities listed in this final rule have been adequately notified.

Each community receives 6-month, 90-day, and 30-day notification letters addressed to the Chief Executive Officer stating that the community will be suspended unless the required floodplain management measures are met prior to the effective suspension date. Since these notifications were made, this final rule may take effect within less than 30 days.

National Environmental Policy Act. FEMA has determined that the community suspension(s) included in this rule is a non-discretionary action and therefore the National Environmental Policy Act of 1969 (42 U.S.C. 4321 *et seq.*) does not apply. *Regulatory Flexibility Act.* The

Administrator has determined that this rule is exempt from the requirements of the Regulatory Flexibility Act because the National Flood Insurance Act of 1968, as amended, Section 1315, 42 U.S.C. 4022, prohibits flood insurance coverage unless an appropriate public body adopts adequate floodplain management measures with effective enforcement measures. The communities listed no longer comply with the statutory requirements, and after the effective date, flood insurance will no longer be available in the communities unless remedial action takes place.

Regulatory Classification. This final rule is not a significant regulatory action under the criteria of section 3(f) of Executive Order 12866 of September 30, 1993, Regulatory Planning and Review, 58 FR 51735.

Executive Order 13132, Federalism. This rule involves no policies that have federalism implications under Executive Order 13132. *Executive Order 12988, Civil Justice Reform.* This rule meets the applicable standards of Executive Order 12988.

Paperwork Reduction Act. This rule does not involve any collection of information for purposes of the Paperwork Reduction Act, 44 U.S.C. 3501 *et seq.*

List of Subjects in 44 CFR Part 64

Flood insurance, Floodplains. Accordingly, 44 CFR part 64 is amended as follows:

PART 64—[AMENDED]

■ 1. The authority citation for part 64 continues to read as follows:

Authority: 42 U.S.C. 4001 *et seq.;* Reorganization Plan No. 3 of 1978, 3 CFR, 1978 Comp.; p. 329; E.O. 12127, 44 FR 19367, 3 CFR, 1979 Comp.; p. 376.

§64.6 [Amended]

■ 2. The tables published under the authority of § 64.6 are amended as follows:

State and location	Community No.	Effective date authorization/cancellation of sale of flood insurance in community	Current effective map date	Date certain federal assistance no longer available in SFHAs
Region III				
Pennsylvania: Adams, Township of, Butler County	421415	March 28, 1975, Emerg; April 17, 1989, Reg;	August 2, 2018	August 2, 2018.
Allegheny, Township of, Butler County	422341	August 2, 2018, Susp. June 30, 1979, Emerg; May 1, 1985, Reg; August 2, 2018, Susp.	do*	Do.
Brady, Township of, Butler County	422241	July 6, 1979, Emerg; June 19, 1985, Reg; August 2, 2018, Susp.	do	Do.
Bruin, Borough of, Butler County	420211	March 7, 1977, Emerg; May 1, 1985, Reg; August 2, 2018, Susp.	do	Do.
Buffalo, Township of, Butler County	421416	July 7, 1975, Emerg; January 18, 1984, Reg;	do	Do.
Chicora, Borough of, Butler County	420214	August 2, 2018, Susp. July 2, 1975, Emerg; August 10, 1979, Reg; August 2, 2018, Susp.	do	Do.
Clay, Township of, Butler County	422343	November 14, 1979, Emerg; May 1, 1985, Reg;	do	Do.
Concord, Township of, Butler County	422346	August 2, 2018, Susp. December 21, 1978, Emerg; May 1, 1985, Reg;	do	Do.
Connoquenessing, Township of, Butler County.	421418	August 2, 2018, Susp. April 7, 1975, Emerg; September 1, 1986, Reg;	do	Do.
Cranberry, Township of, Butler County	421217	August 2, 2018, Susp. September 16, 1974, Emerg; April 1, 1982, Reg;	do	Do.
Donegal, Township of, Butler County	422347	August 2, 2018, Susp. July 22, 1975, Emerg; February 15, 1985, Reg;	do	Do.
East Butler, Borough of, Butler County	420215	August 2, 2018, Susp. March 7, 1977, Emerg; March 18, 1991, Reg;	do	Do.
Fairview, Township of, Butler County	422603	August 2, 2018, Susp. February 20, 1976, Emerg; September 1, 1986, Reg; August 2, 2018, Susp.	do	Do.
Harmony, Borough of, Butler County	420217	August 2, 2018, Susp. April 21, 1975, Emerg; May 4, 1989, Reg; August 2, 2018, Susp.	do	Do.
Jackson, Township of, Butler County	421420	January 3, 1975, Emerg; September 15, 1989, Reg;	do	Do.
Jefferson, Township of, Butler County	421421	August 2, 2018, Susp. February 25, 1977, Emerg; February 15, 1985, Reg:	August 2, 2018	August 2, 2018.
Karns City, Borough of, Butler County	420218	August 2, 2018, Susp. March 2, 1977, Emerg; February 15, 1985, Reg;	do	Do.
Marion, Township of, Butler County	420219	August 2, 2018, Susp. June 18, 1980, Emerg; June 8, 1984, Reg; August 2, 2018, Susp.	do	Do.
Middlesex, Township of, Butler County	421229	December 10, 1974, Emerg; December 1, 1983, Reg;	do	Do.
	I	August 2, 2018, Susp.	I	I

State and location	Community No.	Effective date authorization/cancellation of sale of flood insurance in community	Current effective map date	Date certain federal assistance no longer available in SFHAs
Parker, Township of, Butler County	421219	July 9, 1979, Emerg; September 1, 1986, Reg;	do	Do.
Petrolia, Borough of, Butler County	420221	August 2, 2018, Susp. March 3, 1977, Emerg; December 5, 1989, Reg;	do	Do.
Summit, Township of, Butler County	422358	August 2, 2018, Susp. May 13, 1976, Emerg; February 15, 1985, Reg;	do	Do.
Valencia, Borough of, Butler County	420223	August 2, 2018, Susp. July 11, 1975, Emerg; May 4, 1989, Reg; August 2, 2018, Susp.	do	Do.
Worth, Township of, Butler County	421425	August 6, 1975, Emerg; September 1, 1986, Reg;	do	Do.
Region IV		August 2, 2018, Susp.		
Alabama: Hillsboro, Town of, Lawrence County.	010305	December 21, 1978, Emerg; April 2, 1986, Reg;	do	Do.
Lauderdale County, Unincorporated Areas.	010323	August 2, 2018, Susp. June 14, 1979, Emerg; February 4, 1981, Reg;	do	Do.
Lawrence County, Unincorporated Areas.	010324	August 2, 2018, Susp. N/A, Emerg; March 14, 1991, Reg; August 2, 2018, Susp.	do	Do.
Marshall County, Unincorporated Areas	010275	N/A, Emerg; June 4, 1991, Reg;	do	Do.
Moulton, City of, Lawrence County	010142	August 2, 2018, Susp. April 1, 1974, Emerg; October 16, 1979, Reg;	do	Do.
Rogersville, Town of, Lauderdale Coun- ty.	010339	August 2, 2018, Susp. October 30, 2006, Emerg; September 11, 2009, Reg; August 2, 2018, Susp.	do	Do.
Region V Michigan: Butman, Township of, Gladwin County.	261024	July 30, 1999, Emerg; N/A, Reg; August 2, 2018, Susp.	August 2, 2018	August 2, 2018.
Hay, Township of, Gladwin County	260984	January 29, 1997, Emerg; December 31,	do	Do.
Secord, Township of, Gladwin County	260985	1997, Reg; August 2, 2018, Susp. January 29, 1997, Emerg; N/A, Reg; Au- gust 2, 2018, Susp.	do	Do.

.....do = Ditto.

Code for reading third column: Emerg.-Emergency; Reg.-Regular; Susp.-Suspension.

Dated: July 12, 2018.

Michael M. Grimm,

Assistant Administrator for Mitigation, Federal Insurance and Mitigation Administration, Department of Homeland Security, Federal Emergency Management Agency.

[FR Doc. 2018-15838 Filed 7-24-18; 8:45 am]

BILLING CODE 9110-12-P

DEPARTMENT OF COMMERCE

National Oceanic and Atmospheric Administration

50 CFR Part 679

[Docket No. 170817779-8161-02]

RIN 0648-XG370

Fisheries of the Exclusive Economic Zone Off Alaska; Sablefish in the Aleutian Islands Subarea of the Bering Sea and Aleutian Islands Management Area

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

ACTION: Temporary rule; closure.

SUMMARY: NMFS is prohibiting directed fishing for sablefish by vessels using trawl gear in the Aleutian Islands

subarea of the Bering Sea and Aleutian Islands management area (BSAI). This action is necessary to prevent exceeding the 2018 sablefish initial total allowable catch (ITAC) in the Aleutian Islands subarea of the BSAI.

DATES: Effective 1200 hours, Alaska local time (A.l.t.), July 20, 2018, through 2400 hrs, A.l.t., December 31, 2018.

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

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

The 2018 sablefish trawl ITAC in the Aleutian Islands subarea of the BSAI is 422 metric tons (mt) as established by the final 2018 and 2019 harvest specifications for groundfish in the BSAI (83 FR 8365, February 27, 2018). In accordance with §679.20(d)(1)(i), the Administrator, Alaska Region, NMFS (Regional Administrator), has determined that the 2018 sablefish trawl ITAC in the Aleutian Islands subarea of the BSAI will soon be reached. Therefore, the Regional Administrator is establishing a directed fishing allowance of 80 mt, and is setting aside the remaining 342 mt as incidental catch. In accordance with §679.20(d)(1)(iii), the Regional Administrator finds that this directed fishing allowance has been reached. Consequently, NMFS is prohibiting directed trawl fishing for nonCommunity Development Quota sablefish in the Aleutian Islands subarea of the BSAI. While this closure is effective the maximum retainable amounts at § 679.20(e) and (f) apply at any time during a trip.

Classification

This action responds to the best available information recently obtained from the fishery. The Assistant Administrator for Fisheries, NOAA (AA), finds good cause to waive the requirement to provide prior notice and opportunity for public comment pursuant to the authority set forth at 5 U.S.C. 553(b)(B) as such requirement is impracticable and contrary to the public interest. This requirement is impracticable and contrary to the public interest as it would prevent NMFS from responding to the most recent fisheries data in a timely fashion and would delay the directed fishing closure for sablefish by vessels using trawl gear in

the Aleutian Islands subarea of the BSAI. NMFS was unable to publish a notice providing time for public comment because the most recent, relevant data only became available as of July 19, 2018.

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

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

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

Dated: July 20, 2018.

Jennifer M. Wallace,

Acting Director, Office of Sustainable Fisheries, National Marine Fisheries Service. [FR Doc. 2018–15915 Filed 7–20–18; 4:15 pm] BILLING CODE 3510–22–P _____

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

DEPARTMENT OF AGRICULTURE

Agricultural Marketing Service

7 CFR Part 953

[Doc. No. AMS-SC-18-0037; SC18-953-1 PR]

Irish Potatoes Grown in Southeastern States; Termination of Marketing Order 953

AGENCY: Agricultural Marketing Service, USDA.

ACTION: Proposed rule.

SUMMARY: This proposed rule invites comments on the termination of the Federal marketing order regulating the handling of Irish potatoes grown in Southeastern states (Order). The Order has been suspended, at the industry's recommendation, since 2011. Because the industry has not petitioned to have the Order reactivated, in accordance with the terms of the suspension, the Agricultural Marketing Service (AMS) is proposing termination of the Order.

DATES: Comments must be received by September 24, 2018.

ADDRESSES: Interested persons are invited to submit written comments concerning this rule. Comments must be sent to the Docket Clerk, Marketing Order and Agreement Division, Specialty Crops Program, AMS, USDA, 1400 Independence Avenue SW, STOP 0237, Washington, DC 20250–0237; Fax: (202) 720–8938; or internet: http:// www.regulations.gov. Comments should reference the document number and the date and page number of this issue of the **Federal Register** and will be available for public inspection in the Office of the Docket Clerk during regular business hours or can be viewed at: http://www.regulations.gov. All comments submitted in response to this proposal will be included in the record and will be made available to the public. Please be advised that the identity of the individuals or entities submitting the comments will be made

public on the internet at the address provided above.

FOR FURTHER INFORMATION CONTACT: Debbie Wray, Marketing Specialist, or Julie H. Santoboni, Rulemaking Branch Chief, Marketing Order and Agreement Division, Specialty Crops Program, AMS, USDA; 1400 Independence Avenue SW, Stop 0237, Washington, DC 20250–0237; Telephone: (202) 720– 2491, Fax: (202) 720–8938, or Email: Debbie.Wray@ams.usda.gov or Julie.Santoboni@ams.usda.gov.

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

SUPPLEMENTARY INFORMATION: This proposal is governed by section 608c(16)(A) of the Agricultural Marketing Agreement Act of 1937, as amended (7 U.S.C. 601–674), hereinafter referred to as the "Act," and Marketing Agreement 104 and Marketing Order 953 (7 CFR part 953), referred to as the "Order," effective under the Act.

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

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

The Act provides that administrative proceedings must be exhausted before parties may file suit in court. Under section 608c(15)(A) of the Act, any handler subject to an order may file with USDA a petition stating that the order, any provision of the order, or any obligation imposed in connection with the order is not in accordance with law and request a modification of the order or to be exempted therefrom. A handler is afforded the opportunity for a hearing on the petition. After the hearing, USDA would rule on the petition. The Act provides that the district court of the United States in any district in which the handler is an inhabitant, or has his or her principal place of business, has jurisdiction to review USDA's ruling on the petition, provided an action is filed not later than 20 days after the date of the entry of the ruling.

This proposal invites comments on the termination of the Order. The Order authorizes regulation of the handling of Irish potatoes grown in designated counties of Virginia and North Carolina. The Order has been suspended for approximately seven years, at the industry's recommendation, and the industry has not expressed interest in reactivating the Order.

Section 953.66 provides, in pertinent part, that USDA terminate or suspend any or all provisions of the Order when a finding is made that the Order or any provision thereof does not tend to effectuate the declared policy of the Act. In addition, section 608c(16)(A) of the Act provides that USDA terminate or suspend the operation of any order or any provision thereof whenever the order or any provision thereof obstructs or does not tend to effectuate the declared policy of the Act. Additionally, USDA is required to notify Congress not later than 60 days before the date an order would be terminated.

The Order has been in effect since 1948 and provides for the establishment of grade, size, quality, maturity, and inspection requirements for Irish potatoes grown in Southeastern states. The Order also authorizes reporting and recordkeeping functions required for the operation of the Order. The Order, when in effect, is locally administered by the Southeastern Potato Committee (Committee) and is funded by assessments imposed on handlers.

Based on the Committee's unanimous recommendation in 2011, USDA suspended the Order for a three-year period ending March 1, 2014. The Committee recommended the suspension to eliminate the expense of administering the Order while determining the effects of not having the Order in place. When the Committee

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Proposed Rules

made the recommendation to suspend the Order, it wanted the industry to have the option of reactivating the Order, if deemed appropriate. The final rule adopting an interim rule that implemented that action was published in the **Federal Register** on October 21, 2011 (76 FR 65360). Upon suspension of the Order in 2011, the Committee ceased to function.

In anticipation of the expiration of the suspension on March 1, 2014, in late 2013 USDA sent a letter to members of the industry, most of whom were former Committee members. The letter stated that suspension of the Order would soon be ending and that members of the industry would need to recommend an action to USDA. On December 18, 2013, representatives of the Virginia and North Carolina Irish potato industry met and requested that the suspension of all provisions of the Order be continued through March 1, 2017. The extension of the suspension would allow the industry further opportunity to study changes and evaluate new developments in the industry that could affect the need for the Order. The final rule adopting the interim rule that implemented that action was published in the Federal Register on August 19, 2015 (80 FR 50191).

Under the terms of the suspension, if the industry did not petition USDA to have the Order reactivated by the end of the suspension period, March 1, 2017, AMS would propose termination of the Order. To date, the industry has not filed a petition to have the Order reactivated.

This proposed termination of the Order is intended to solicit input and any additional information available from interested parties regarding whether the Order should be terminated. USDA will evaluate all available information prior to making a final determination on this matter. Termination of the Order would become effective only after a 60-day notification to Congress, as required by law.

Initial Regulatory Flexibility Analysis

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

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

There are approximately ten handlers of Irish potatoes grown in Southeastern states who are subject to regulation under the Order and approximately 20 potato producers in the regulated area. Small agricultural service firms are defined by the Small Business Administration (SBA) as those having annual receipts of less than \$7,500,000, and small agricultural producers are defined as those whose annual receipts are less than \$750,000 (13 CFR 121.201).

Using prices reported by AMS' Market News Service, the average free on board (f.o.b.) price for Southeastern potatoes for the 2017 marketing season was about \$50 per hundredweight. Based on information from the National Agricultural Statistics Service (NASS), estimated total production in Virginia and North Carolina for the 2017 season was 4,666,000 hundredweight of potatoes. Multiplying the f.o.b. price by the estimated production results in an estimated handler value of \$233,300,000. Dividing this figure by the number of handlers (ten) yields an estimated average annual handler receipt of \$23,330,000. Using the average price and shipment information, the number of handlers, and assuming a normal distribution, the majority of handlers have average annual receipts of more than \$7,500,000.

Based on information from NASS, during the 2017 season, there were 19,600 total acres harvested in Virginia and North Carolina with a total value of production at \$59,038,000 for the season. The average producer prices for Virginia and North Carolina Irish potatoes in 2017 were \$16.30 and \$11.40 per hundredweight, respectively, for an average price of \$13.85. Dividing the 2017 total production value by the average of the two states' producer prices and using a normal distribution, the average gross annual revenue for each of the 20 producers would be about \$213,134.

Therefore, based on the above handler and producer revenue estimates, the majority of Southeastern potato handlers may be classified as large entities, while a majority of producers may be classified as small entities.

This proposed rule would terminate the Order for Irish potatoes grown in Southeastern states and the rules and regulations issued thereunder. The Order authorizes regulation of the handling of Irish potatoes grown in designated counties of Virginia and North Carolina. The Order was initially suspended in 2011, at the recommendation of the Committee, to eliminate the expense of administering

the Order while the industry determined the effects of not having regulations in place. In 2013, at the request of the industry, the suspension was extended through March 1, 2017, to provide the industry with more time to consider changes and evaluate new developments in the industry that could affect the future need for the Order. The final rule that extended the suspension through March 1, 2017, stated that AMS would proceed with a notice to propose termination absent an industry recommendation to reactivate the Order. The results of the suspension and the industry's failure to petition USDA to have the Order reactivated by the end of the suspension period support the proposal to terminate the Order.

Section 953.66 provides that USDA terminate or suspend any or all provisions of the Order when a finding is made that the Order does not tend to effectuate the declared policy of the Act. Furthermore, section 608c(16)(A) of the Act provides that USDA terminate or suspend the operation of any order whenever the order or any provision thereof obstructs or does not tend to effectuate the declared policy of the Act. An additional provision requires that Congress be notified not later than 60 days before the date an order would be terminated.

The proposed termination of the Order would reduce costs to both handlers and producers (while marketing order requirements are applied to handlers, the costs of such requirements are often passed on to producers). Furthermore, following a period of over seven years of regulatory suspension, it has been determined that termination of the Order would not adversely impact the Virginia and North Carolina Irish potato industry.

As an alternative to this proposed rule, AMS considered not terminating the Order. In that case, the industry could have recommended further refinements to the Order and the handling regulations to better meet current marketing needs. However, the industry did not petition to have the Order reactivated by the end of the suspension period. Therefore, this alternative was rejected, and AMS proposes that the Order be terminated.

This proposed rule is intended to solicit input and other available information from interested parties on whether the Order should be terminated. USDA will evaluate all available information prior to making a final determination on this matter.

In accordance with the Paperwork Reduction Act of 1995 (44 U.S.C. chapter 35), the information collection requirements that would be terminated were previously approved by OMB and assigned OMB No. 0581–0178, Vegetable and Specialty Crops. Termination of the reporting requirements under the Order would reduce the reporting and recordkeeping burden on Irish potato handlers in Southeastern states and should further reduce industry expenses.

Because handlers would no longer be required to file forms with the Committee, this proposed rule would not impose any additional reporting or recordkeeping requirements on either small or large entities.

In addition, USDA has not identified any relevant Federal rules that duplicate, overlap, or conflict with this rule.

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

Additionally, interested persons are invited to submit information on the regulatory and information collection impacts of this action on small businesses.

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

This proposal invites comments on the termination of Marketing Order No. 953, which regulates the handling of Irish potatoes grown in Southeastern states. All written comments received within the 60-day comment period will be considered before a final determination is made in this matter.

Based on the foregoing, and pursuant to section 608c(16)(A) of the Act and § 953.66 of the Order, USDA is considering termination of the Order. If USDA decides to terminate the Order, trustees would be appointed to conclude and liquidate the affairs of the Committee and would continue in that capacity until discharged by USDA. In addition, USDA would notify Congress 60 days in advance of termination pursuant to section 608c(16)(A) of the Act.

List of Subjects in 7 CFR Part 953

Marketing agreements, Potatoes, Reporting and recordkeeping requirements.

PART 953—[REMOVED]

■ For the reasons set forth in the preamble, under the authority of 7 U.S.C. 601–674, AMS proposes that 7 CFR part 953 be removed.

Dated: July 19, 2018.

Bruce Summers,

Administrator, Agricultural Marketing Service.

[FR Doc. 2018–15890 Filed 7–24–18; 8:45 am] BILLING CODE 3410–02–P

DEPARTMENT OF AGRICULTURE

Agricultural Marketing Service

7 CFR Part 1208

[Document No. AMS-SC-18-0041]

Processed Raspberry Promotion, Research and Information Order; Continuance Referendum

AGENCY: Agricultural Marketing Service, USDA.

ACTION: Notification of referendum order.

SUMMARY: This document directs that a referendum be conducted among eligible producers of raspberries for processing and importers of processed raspberries to determine whether they favor continuance of the Agricultural Marketing Service's (AMS) regulations regarding a national processed raspberry research and promotion program. DATES: The referendum will be conducted from September 10 through October 5, 2018. The Department will provide the option for ballots to be returned electronically. Further details will be provided in the ballot instructions. Mail ballots must be postmarked by October 5. Ballots delivered via express mail or email must show proof of delivery by no later than 11:59 p.m. Eastern Time (ET) on October 5, 2018, to be counted.

ADDRESSES: Copies of the processed raspberry program may be obtained from: Referendum Agent, Promotion and Economics Division, Specialty Crops Program, AMS, USDA, 1400 Independence Avenue SW, Room 1406– S, Stop 0244, Washington, DC 20250– 0244, telephone: (202) 720–9915; facsimile: (202) 205–2800; or contact Hakim Fobia at (202) 720–4835 or via electronic mail: Hakim.Fobia@ ams.usda.gov.

FOR FURTHER INFORMATION CONTACT:

Hakim Fobia, Marketing Specialist, Promotion and Economics Division, Specialty Crops Program, AMS, USDA, 1400 Independence Avenue SW, Room 1406–S, Stop 0244, Washington, DC 20250–0244; telephone: (202) 720–9915, (202) 720–4835 (direct line); facsimile: (202) 205–2800; or electronic mail: *Hakim.Fobia@ams.usda.gov.*

SUPPLEMENTARY INFORMATION: Pursuant to the Commodity Promotion, Research, and Information Act of 1996 (7 U.S.C. 7411–7425) (1996 Act), it is hereby directed that a referendum be conducted to ascertain whether continuance of the Processed Raspberry Promotion, Research and Information Order (7 CFR part 1208) is favored by eligible producers of raspberries for processing and importers of processed raspberries. The program is authorized under the 1996 Act.

The representative period for establishing voter eligibility for the referendum shall be the period from January 1 through December 31, 2017. Persons who produced 20,000 pounds or more of raspberries for processing in the United States or imported 20,000 pounds or more of processed raspberries into the United States during the representative period and were subject to assessment during that period are eligible to vote. Persons who received an exemption from assessments pursuant to § 1208.53 for the entire representative period are ineligible to vote. The referendum will be conducted from September 10 through October 5, 2018. The Department will provide the option for ballots to be returned electronically. Further details will be provided in the ballot instructions.

Section 518 of the 1996 Act (7 U.S.C. 7417) authorizes continuance referenda. Under § 1208.71(b), the U.S. Department of Agriculture (USDA) must conduct a referendum every seven years to determine whether eligible producers of raspberries for processing and importers of processed raspberries favor continuance of the program. A referendum also may be held by a request of 10 percent or more of all the eligible producers and importers, by request of the National Processed Raspberry Council, which administers the program, or by the Secretary of Agriculture. In March 2018, USDA received a petition requesting a referendum from more than the required 10 percent of eligible entities, thus USDA will hold a referendum. The program will continue if it is favored by a majority of eligible producers and importers voting in the referendum.

In accordance with the Paperwork Reduction Act of 1995 (44 U.S.C. chapter 35), the referendum ballot has been approved by the Office of Management and Budget (OMB) and assigned OMB No. 0581–0093. It has been estimated that approximately 200 entities will be eligible to vote in the referendum. It will take an average of 15 minutes for each voter to read the voting instructions and complete the referendum ballot.

Referendum Order

Hakim Fobia, Marketing Specialist, and Heather Pichelman, Director, Promotion and Economics Division, Specialty Crops Program, AMS, USDA, Stop 0244, Room 1406–S, 1400 Independence Avenue SW, Washington, DC 20250–0244, are designated as referendum agents for this referendum. The referendum procedures at 7 CFR 1208.100 through 1208.108, issued pursuant to the 1996 Act, will be used to conduct the referendum.

The referendum agents will mail the ballots to be cast in the referendum and voting instructions to all known, eligible producers and importers prior to the first day of the voting period. Persons who produced 20,000 pounds or more of raspberries for processing in the United States or imported 20,000 pounds or more of processed raspberries into the United States during the representative period and were subject to assessment during that period are eligible to vote. Persons who received an exemption from assessments pursuant to § 1208.53 during the entire representative period are ineligible to vote. Any eligible producer of raspberries for processing or importer of processed raspberries who does not receive a ballot should contact a referendum agent no later than one week before the end of the voting period. Mail ballots must be postmarked by October 5. Ballots delivered via express mail or email must show proof of delivery by no later than 11:59 p.m. ET on October 5, 2018, to be counted.

List of Subjects in 7 CFR Part 1208

Administrative practice and procedure, Advertising, Consumer information, Marketing agreements, Raspberry promotion, Reporting and recordkeeping requirements.

Authority: 7 U.S.C. 7411–7425; 7 U.S.C. 7401.

Dated: July 20, 2018.

Bruce Summers,

Administrator.

[FR Doc. 2018–15894 Filed 7–24–18; 8:45 am] BILLING CODE 3410–02–P

DEPARTMENT OF HEALTH AND HUMAN SERVICES

Food and Drug Administration

21 CFR Part 15

[Docket No. FDA-2018-N-2689]

Facilitating Competition and Innovation in the Biological Products Marketplace; Public Hearing; Request for Comments

AGENCY: Food and Drug Administration, HHS.

ACTION: Notification of public hearing; request for comments.

SUMMARY: The Food and Drug Administration (FDA or the Agency) is announcing a public hearing on FDA's approach to enhancing competition and innovation in the biological products marketplace, including by facilitating greater availability of biosimilar and interchangeable products.

DATES: The public hearing will be held on Tuesday, September 4, 2018, from 9 a.m. to 5 p.m. The public hearing may be extended or may end early, depending on the level of public participation. Persons seeking to attend or to present at the public hearing must register by Tuesday, August 14, 2018. Section III provides attendance and registration information. Electronic or written comments will be accepted after the public hearing until Friday, September 21, 2018.

ADDRESSES: The public hearing will be held at the FDA White Oak Campus, 10903 New Hampshire Ave., Bldg. 31 Conference Center, the Great Room (Rm. 1503A), Silver Spring, MD 20993–0002. Entrance for public hearing participants (non-FDA employees) is through Building 1, where routine security check procedures will be performed. For parking and security information, please refer to https://www.fda.gov/AboutFDA/ WorkingatFDA/BuildingsandFacilities/ WhiteOakCampusInformation/ ucm241740.htm.

You may submit comments as follows. Please note that late, untimely filed comments will not be considered. Electronic comments must be submitted on or before Friday, September 21, 2018. The *https://www.regulations.gov* electronic filing system will accept comments until midnight Eastern Time at the end of Friday, September 21, 2018. Comments received by mail/hand delivery/courier (for written/paper submissions) will be considered timely if they are postmarked or the delivery service acceptance receipt is on or before that date.

Electronic Submissions

Submit electronic comments in the following way:

• Federal eRulemaking Portal: *https://www.regulations.gov.* Follow the instructions for submitting comments. Comments submitted electronically, including attachments, to https:// www.regulations.gov will be posted to the docket unchanged. Because your comment will be made public, you are solely responsible for ensuring that your comment does not include any confidential information that you or a third party may not wish to be posted, such as medical information, your or anyone else's Social Security number, or confidential business information, such as a manufacturing process. Please note that if you include your name, contact information, or other information that identifies you in the body of your comments, that information will be posted on *https://www.regulations.gov*.

• If you want to submit a comment with confidential information that you do not wish to be made available to the public, submit the comment as a written/paper submission and in the manner detailed (see "Written/Paper Submissions" and "Instructions").

Written/Paper Submissions

Submit written/paper submissions as follows:

• *Mail/Hand delivery/Courier (for written/paper submissions):* Dockets Management Staff (HFA–305), Food and Drug Administration, 5630 Fishers Lane, Rm. 1061, Rockville, MD 20852.

• For written/paper comments submitted to the Dockets Management Staff, FDA will post your comment, as well as any attachments, except for information submitted, marked, and identified as confidential, if submitted as detailed in "Instructions."

Instructions: All submissions received must include the Docket No. FDA– 2018–N–2689 for "Facilitating Competition and Innovation in the Biological Products Marketplace; Public Hearing; 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 Division of Dockets Management between 9 a.m. and 4 p.m., Monday through Friday.

• Confidential Submissions—To submit a comment with confidential information that you do not wish to be made publicly available, submit your comments only as a written/paper submission. You should submit two copies total. One copy will include the information you claim to be confidential with a heading or cover note that states "THIS DOCUMENT CONTAINS CONFIDENTIAL INFORMATION." The Agency will review this copy, including the claimed confidential information, in its consideration of comments. The second copy, which will have the claimed confidential information redacted/blacked out, will be available for public viewing and posted on https://www.regulations.gov. Submit both copies to the Dockets Management Staff. If you do not wish your name and contact information to be made publicly available, you can provide this information on the cover sheet and not in the body of your comments and you must identify this information as "confidential." Any information marked as "confidential" will not be disclosed except in accordance with 21 CFR 10.20 and other applicable disclosure law. For more information about FDA's posting of comments to public dockets, see 80 FR 56469, September 18, 2015, or access the information at: https://www.gpo.gov/ fdsys/pkg/FR-2015-09-18/pdf/2015-23389.pdf.

Docket: For access to the docket to read background documents or the electronic and written/paper comments received, go to *https:// www.regulations.gov* and insert the docket number, found in brackets in the heading of this document, into the "Search" box and follow the prompts and/or go to the Dockets Management Staff, 5630 Fishers Lane, Rm. 1061, Rockville, MD 20852.

FOR FURTHER INFORMATION CONTACT:

Allison Hoffman, Food and Drug Administration, 10903 New Hampshire Ave., Bldg. 1, Rm. 1314, Silver Spring, MD 20993, 301–796–9203, *OMPTFeedback@fda.hhs.gov.*

SUPPLEMENTARY INFORMATION:

I. Background

The Biologics Price Competition and Innovation Act of 2009 (BPCI Act) amended the Public Health Service Act (PHS Act) and other statutes to create an abbreviated licensure pathway for biological products shown to be biosimilar to, or interchangeable with, an FDA-licensed biological reference product. The BPCI Act was intended to balance innovation and consumer interests. The abbreviated licensure pathway, in section 351(k) of the PHS Act, allows an applicant (a ''351(k) applicant") to rely, in part, on FDA's previous determination of safety and effectiveness for the reference product for approval. The BPCI Act provides, among other things, exclusivity periods

for certain biological products licensed in "stand alone" applications under section 351(a) of the PHS Act.

As the marketplace of biological products continues to expand and evolve, FDA expects that increased availability of biosimilars and interchangeable products will result in more competition and create savings for patients and the healthcare system. At the same time, we recognize that there are challenges to the rapid growth of this marketplace. For instance, although FDA has approved 11 marketing applications for biosimilars as of July 1, 2018, FDA is aware that the majority of biosimilars licensed by FDA have not vet been marketed and are not available to patients.

Although such delays in the market entry of an approved biosimilar are outside FDA's control, we remain focused on FDA's critical role in increasing the availability of biosimilars and interchangeable products. Recognizing that this is a crucial time in the emergence of the marketplace of biosimilar and interchangeable products, FDA recently developed a Biosimilars Action Plan. This Plan focuses on four key areas: (1) Improving the efficiency of the biosimilar and interchangeable product development and approval process; (2) maximizing scientific and regulatory clarity for the biosimilar product development community; (3) developing effective communications to improve understanding of biosimilars among patients, clinicians, and payors; and (4) supporting market competition by reducing gaming of FDA requirements or other attempts to unfairly delay competition.

FDA's Biosimilars Action Plan builds on the Agency's substantial progress, to date, implementing the approval pathway for biosimilar and interchangeable products. For example, FDA has issued guidance for industry on numerous scientific and regulatory issues related to the development of proposed biosimilar and interchangeable products. FDA also created the Biosimilar Product Development (BPD) Program to facilitate the rapid development of biosimilar and interchangeable products. Through enrollment in this program, FDA provides detailed, product-specific advice to manufacturers. As of July 1, 2018, 68 programs were enrolled in the BPD Program and FDA had received meeting requests to discuss the development of biosimilars for 31 different reference products.

FDA has also prioritized its efforts to provide useful information about licensed biological products to the

public. FDA publishes the Purple Book: Lists of Licensed Biological Products with Reference Product Exclusivity and Biosimilarity or Interchangeability Evaluations¹ to provide information on licensed biological products, including information on exclusivity for reference products and on whether a product has been demonstrated to be biosimilar to, or interchangeable with, a reference product. Another FDA priority is the development of educational materials for patients, healthcare providers, and other stakeholders to increase knowledge about biological products, including biosimilar and interchangeable products. For example, FDA launched an educational campaign in October 2017 to promote understanding by healthcare providers of biosimilar and interchangeable products and how these products can help patients (see, *https://www.fda.gov/* Drugs/DevelopmentApprovalProcess/ HowDrugsareDevelopedandApproved/ ApprovalApplications/Therapeutic BiologicApplications/Biosimilars/ ucm580435.htm).

As FDA continues working to implement the BPCI Act, FDA welcomes input from the public on how the Agency can enhance its efforts to increase access by patients to state-ofthe-art, lifesaving treatment options by encouraging innovation and competition in the biological products marketplace. FDA will hold a public hearing on September 4, 2018, from 9 a.m. to 5 p.m., to provide an opportunity for all interested stakeholders to submit comments.

The format of the hearing involves presentations from the public. The Agency will not be inviting specific presenters; rather, with this document, FDA is soliciting presentations from interested stakeholders. FDA also invites interested persons to submit written comments to the docket on the topics described in section II.

II. Purpose and Scope of the Public Hearing

FDA is soliciting input from the public on how to facilitate greater availability of biosimilar and interchangeable products while retaining the balance between competition and innovation that Congress intended to achieve under the BPCI Act. FDA is holding a public hearing to receive information and comments from a broad group of stakeholders, including patients,

¹https://www.fda.gov/drugs/development approvalprocess/howdrugsaredeveloped andapproved/approvalapplications/ therapeuticbiologicapplications/biosimilars/ ucm411418.htm.

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researchers, healthcare providers, manufacturers, interested industry, professional organizations, and the public. The Agency has determined that a public hearing is the most appropriate way to ensure public engagement.

FDA welcomes any relevant information that stakeholders wish to share. FDA is particularly interested in stakeholder input on how the Agency can achieve the following goals:

• Facilitate the efficient development of biosimilar and interchangeable products using state-of-the-art science;

• Develop information resources, as well as scientific or regulatory tools, to streamline the development of biosimilar and interchangeable products;

• Enhance the efficiency of FDA review of marketing applications for biosimilar and interchangeable products;

• Provide additional scientific or regulatory clarity regarding FDA's regulation of biological products, including FDA's review and approval of marketing applications for biological products;

• Increase healthcare provider, patient, and payor understanding of biological products, including biosimilar and interchangeable products; and

• Support market competition by addressing attempts to game FDA requirements or otherwise delay market entry of competing biological products.

FDA is also interested in stakeholder input on the following questions about additional steps FDA can take, within its statutory authority, related to the Agency's regulation of biological products:

1. FDA is aware that many of the biosimilar products that have been licensed by FDA are not yet marketed and available to patients. What can FDA do to help biosimilars and interchangeable products reach patients more quickly after these products are licensed?

2. FDA uses the Purple Book to provide information about biological products licensed under section 351 of the PHS Act. What additional information or features could be incorporated into the Purple Book to make it more useful to stakeholders, including patients, healthcare providers, pharmacists, and manufacturers?

3. FDA expects that the number of licensed biosimilar and interchangeable products will continue to increase in the coming years. In many, if not most, cases, FDA anticipates that multiple products will be licensed as biosimilar to, or interchangeable with, a given reference product. What additional steps can FDA take to facilitate the evolution of the biosimilar and interchangeable product marketplace? What can FDA do to ensure that confidence in these products among patients, healthcare providers, pharmacists, and other stakeholders will continue to grow?

4. Extensive analytical characterization of the proposed biosimilar product and the reference product serves as the foundation for a demonstration of biosimilarity. FDA recognizes that obtaining and testing multiple lots of the reference product adds to the costs of developing a biosimilar product. What can FDA do to help reduce development costs arising from analytical studies of the reference product without compromising FDA's robust scientific standards for licensure of products under section 351(k) of the PHS Act? FDA is particularly interested in stakeholder comments on (1) the number of lots of each product (the proposed biosimilar product and the reference product) that should be used in analytical studies submitted to support licensure of a proposed biosimilar product; and (2) how a 351(k)applicant should account for and evaluate any observed variability in analytical attributes among lots of the reference product or the proposed biosimilar product.

5. A 351(k) applicant may, with adequate scientific justification, use a non-U.S.-licensed comparator product in certain studies submitted to support licensure of a proposed biosimilar product. What additional steps can FDA take to facilitate multinational development programs that may include non-U.S.-licensed comparators, to help support development of biosimilar products?

6. FDA expects continued innovation in the biological product marketplace, including innovation during the lifecycle of reference products licensed under section 351(a) of the PHS Act. What can FDA do to ensure that product changes during the lifecycle of reference products (*e.g.*, changes in product presentation) are adequately incentivized without inappropriately deterring competition from biosimilar and interchangeable products, with the overall goal of balancing of innovation and competition?

7. Patents or exclusivity may protect one or more conditions of use (*e.g.*, indications) of the reference product. As a result, 351(k) applicants may seek licensure of the proposed biosimilar product for fewer than all of the conditions of use for which the reference product is licensed. Once a condition of use is no longer protected by patents or exclusivity, FDA anticipates that 351(k) applicants often will seek licensure of their product for this condition of use. What challenges do 351(k) applicants face in this context and what should FDA do to achieve the appropriate balance between innovation and competition when one or more conditions of use of the reference product are protected by exclusivity or patents?

8. The scope of exclusivity under section 351(k)(7) of the PHS Act may also affect biological product innovation and market entry of biosimilars. Accordingly, FDA seeks comment on the potential application of "umbrella exclusivity" under section 351(k)(7). If umbrella exclusivity were to apply in this context, a biological product that would not be eligible for a new period of exclusivity under section 351(k)(7)(C) would nevertheless be protected for the duration of the exclusivity period for a previously approved reference product. See, for example, 54 FR 28872 at 28897 (July 10, 1989) for an explanation of how umbrella exclusivity functions under the Hatch-Waxman scheme, a related and potentially instructive context (available at: https:// cdn.loc.gov/service/ll/fedreg/fr054/ fr054130/fr054130.pdf). Thus, umbrella exclusivity could help shield certain biological products that would otherwise not be eligible for their own period of exclusivity under section 351(k)(7)(C) from biosimilar competition. What considerations support recognition of umbrella exclusivity under section 351(k)(7), and what considerations disfavor recognizing umbrella exclusivity? How would umbrella exclusivity promote biological product innovation, and what effect would it have on market entry of biosimilars? What is the relevance and significance, if any, of the patent scheme in considering this issue?

9. What other challenges have the potential to disrupt the balance between innovation and competition in the biological product marketplace and how can FDA or other stakeholders address these challenges?

III. Participating in the Public Hearing

Registration and Requests for Oral Presentations: The FDA Conference Center at the White Oak location is a Federal facility with security procedures and limited seating. Attendance will be free and on a first-come, first-served basis. If you wish to attend (either in person or by webcast (see Streaming Webcast of the Public Hearing)) and/or present at the hearing, please register for the hearing and, if appropriate, request an oral presentation or participation in the open public hearing by sending an email to OMPTfeedback@fda.hhs.gov by Tuesday, August 14, 2018. Requests for participation in the open public hearing are accepted until 9 a.m. on Tuesday September 4, 2018, and will be accepted as long as time allows. The email should contain complete contact information for each attendee (name, title, degree(s), affiliation, address, email address, and telephone number). For those wishing to present at the hearing, the email should also include a presentation title. Those without email access can register by contacting Allison Hoffman at 301-796-9203 by Tuesday, August 14, 2018 (see FOR FURTHER INFORMATION CONTACT). An agenda for the hearing and any other background materials will be made available 5 days before the hearing at https://www.fda.gov/NewsEvents/ MeetingsConferencesWorkshops/ UCM610692.htm.

FDA will try to accommodate all persons who wish to make a presentation. Individuals wishing to present should identify the number of the specific question, or questions, they wish to address. This will help FDA organize the presentations. Individuals and organizations with common interests should consolidate or coordinate their presentations and request time for a joint presentation. FDA will notify registered presenters of their scheduled presentation times. The time allotted for each presenter will depend on the number of individuals who wish to speak. Presenters are encouraged to submit an electronic copy of their presentation (PowerPoint or PDF) to OMPTfeedback@fda.hhs.gov on or before Thursday, August 16, 2018. Those who are not giving electronic presentations are encouraged to submit a single slide (PowerPoint or PDF) with their name, affiliation, and topic. Persons registered to make either an oral presentation or participate as part of the open public hearing are encouraged to arrive at the hearing room early and check in at the onsite registration table to confirm their designated presentation time. An agenda for the hearing and any other background materials will be made available 5 days before the hearing at https://www.fda.gov/NewsEvents/ MeetingsConferencesWorkshops/ ucm580561.htm.

If you need special accommodations because of a disability, please contact OMPTFeedback@fda.hhs.gov (see FOR FURTHER INFORMATION CONTACT) no later than Friday, August 17, 2018, at 12 noon Eastern Time.

Streaming Webcast of the Public *Hearing:* For those unable to attend in person, FDA will provide a live webcast of the hearing. To join the hearing via

the webcast, please go to https:// collaboration.fda.gov/biosimilarspart15.

Transcripts: Please be advised that as soon as a transcript is available, it will be accessible at https:// www.regulations.gov. It may be viewed at the Dockets Management Staff (see ADDRESSES).

IV. Notification of Hearing Under 21 CFR Part 15

The Commissioner of Food and Drugs is announcing that the public hearing will be held in accordance with part 15 (21 CFR part 15). The hearing will be conducted by a presiding officer, who will be accompanied by FDA senior management from the Office of the Commissioner, the Center for Drug Evaluation and Research, and the Center for Biologics Evaluation and Research. Under § 15.30(f) (21 CFR 15.30(f)), the hearing is informal and the rules of evidence do not apply. No participant may interrupt the presentation of another participant. Only the presiding officer and panel members can pose questions; they can question any person during or at the conclusion of each presentation. Public hearings under part 15 are subject to FDA's policy and procedures for electronic media coverage of FDA's public administrative proceedings (21 CFR part 10, subpart C). Under 21 CFR 10.205, representatives of the media may be permitted, subject to certain limitations, to videotape, film, or otherwise record FDA's public administrative proceedings, including presentations by participants. The hearing will be transcribed as stipulated in § 15.30(b) (see Transcripts). To the extent that the conditions for the hearing, as described in this notification, conflict with any provisions set out in part 15, this notification acts as a waiver of those provisions as specified in § 15.30(h).

Dated: July 19, 2018.

Leslie Kux.

Associate Commissioner for Policy. [FR Doc. 2018–15859 Filed 7–24–18; 8:45 am] BILLING CODE 4164-01-P

DEPARTMENT OF LABOR

Mine Safety and Health Administration

30 CFR 56 and 75

[Docket No. MSHA-2018-0016]

RIN 1219-AB91

Safety Improvement Technologies for Mobile Equipment at Surface Mines, and for Belt Conveyors at Surface and **Underground Mines**

AGENCY: Mine Safety and Health Administration, Labor.

ACTION: Announcement of public stakeholder meetings.

SUMMARY: The Mine Safety and Health Administration (MSHA) is announcing the dates and locations of public stakeholder meetings on the Agency's **Request for Information on Safety** Improvement Technologies for Mobile Equipment at Surface Mines, and for Belt Conveyors at Surface and Underground Mines.

DATES: Comments must be received or postmarked by midnight Eastern Standard Time on December 24, 2018. The meeting dates and locations are listed in the SUPPLEMENTARY **INFORMATION** section of this document.

ADDRESSES: Federal Register Publications: Access documents electronically at *http://www.msha.gov/* regsinfo.htm or http:// www.regulations.gov [Docket No. MSHA-2018-0016].

FOR FURTHER INFORMATION CONTACT:

Sheila A. McConnell, Director, Office of Standards, Regulations, and Variances, MSHA, at *mcconnell.sheila.a*@dol.gov (email), 202-693-9440 (voice), or 202-693–9441 (fax). These are not toll-free numbers.

SUPPLEMENTARY INFORMATION:

I. Stakeholder Meetings

MSHA will hold six public stakeholder meetings and one webinar on the Agency's Request for Information (RFI) addressing Safety Improvement Technologies for Mobile Equipment at Surface Mines, and for Belt Conveyors at Surface and Underground Mines. The meetings will be conducted in an informal manner. Presenters and attendees may provide written information to the court reporter for inclusion in the record. MSHA will make transcripts of the meetings available at http://www.regulations.gov and on MSHA's website at: https:// arlweb.msha.gov/currentcomments.asp.

Interested parties may attend these stakeholder meetings either in-person or by participating by webinar (See table below).

1. To attend the stakeholder meeting in Arlington, Virginia:

• Address—201 12th Street South, Arlington, Virginia 22202.

• When you enter the building, take the East elevators to your right, up to the 4th Floor reception area, 4E401, to check in. You will then be escorted to the conference room.

• Nearest metro stations: Pentagon City, and Crystal City. Parking is available on the street and in the building.

2. To participate at the Webinar by Phone or WebEx:

By Phone—

• Dial the toll-free conference number (Verizon): 1–866–718–1874.

• Attendee access code: 242 716 6. By WebEx—

• To log into the Webinar, go to: *https://dol.webex.com*.

- Enter Meeting number: 642 399 450.
- Meeting password: M!ne2018.

A. Stakeholder Meetings

SAFETY IMPROVEMENT TECHNOLOGIES FOR MOBILE EQUIPMENT AT SURFACE MINES, AND FOR BELT CONVEYORS AT SURFACE AND UNDERGROUND MINES STAKEHOLDER MEETINGS

[Dates, times, and locations]

Date/time	Location	Contact No.
August 7, 2018, 9 a.m. Central Time	Sheraton Birmingham Hotel, 2101 Richard Arrington Jr. Blvd. N, Birmingham, Alabama 35203.	205–324–5000
August 9, 2018, 9 a.m. Central Time	DoubleTree by Hilton Hotel, Dallas-Market Center, 2015 Market Center Blvd., Dallas, Texas 75207.	214–741–7481
August 16, 2018, 11 a.m. Eastern Time	Webinar	202-693-9440
August 21, 2018, 9 a.m. Pacific Time	Renaissance Reno Downtown Hotel, One South Lake Street, Reno, Nevada 89501.	775–682–3900
September 11, 2018, 9 a.m. Eastern Time.	National Mine Health and Safety Academy, 1301 Airport Road, Beckley, West Virginia 25813 (Auditorium).	304–256–3100
September 20, 2018, 9 a.m. Eastern Time.	Hilton Albany, 40 Lodge Street, Albany, New York 12207	518-462-6611
September 25, 2018, 9 a.m. Eastern Time.	Mine Safety and Health Administration (Headquarters), 201 12th Street South, 4E401, Arlington, Virginia 22202.	202–693–9440

II. Background

On June 26, 2018, (83 FR 29716), MSHA published an RFI on Safety Improvement Technologies for Mobile Equipment at Surface Mines, and for Belt Conveyors at Surface and Underground Mines. MSHA is soliciting stakeholder comments, data and information on technologies that can reduce accidents involving mobile equipment at surface mines and belt convevors at surface and underground mines. Specifically, the Agency is requesting information from the mining community regarding the types of engineering controls available, how to implement such engineering controls, and how these controls could be used in mobile equipment and belt conveyors to reduce accidents, fatalities and injuries. MSHA is also seeking suggestions from stakeholders on best practices, training materials, policies and procedures, innovative technologies, and any other information that stakeholders may have available to improve safety in and around mobile equipment, and working near and around belt conveyors. The meetings will provide the mining community an opportunity to discuss and share information about the issues raised in the RFI. Comments must be received or postmarked by midnight

Eastern Standard Time on December 24, 2018.

David G. Zatezalo,

Assistant Secretary of Labor for Mine Safety and Health. [FR Doc. 2018–15808 Filed 7–24–18; 8:45 am] BILLING CODE 4520–43–P

FEDERAL COMMUNICATIONS COMMISSION

47 CFR Part 73

[MB Docket Nos. 18–202, 17–105; FCC 18– 93]

Children's Television Programming Rules; Modernization of Media Regulation Initiative

AGENCY: Federal Communications Commission.

ACTION: Proposed rule.

SUMMARY: In this document, the Commission proposes to revise the children's television programming rules to modify outdated requirements and give broadcasters greater flexibility in serving the educational and informational needs of children. The proposed revisions reflect the dramatic changes in the video programming marketplace since the children's television programming rules were first adopted more than 20 years ago. **DATES:** Comments for this proceeding are due on or before September 24, 2018; reply comments are due on or before October 23, 2018.

ADDRESSES: You may submit comments, identified by MB Docket Nos. 18–202 and 17–105, by any of the following methods:

• Federal Communications Commission's Website: http:// www.fcc.gov/cgb/ecfs/. Follow the instructions for submitting comments.

• *Mail:* Filings can be sent by hand or messenger delivery, by commercial overnight courier, or by first-class or overnight U.S. Postal Service mail (although the Commission continues to experience delays in receiving U.S. Postal Service mail). All filings must be addressed to the Commission's Secretary, Office of the Secretary, Federal Communications Commission.

• *People with Disabilities:* Contact the FCC to request reasonable accommodations (accessible format documents, sign language interpreters, CART, etc.) by email: *FCC504@fcc.gov* or phone: (202) 418–0530 or TTY: (202) 418–0432.

For detailed instructions for submitting comments and additional information on the rulemaking process, see the **SUPPLEMENTARY INFORMATION** section of this document.

FOR FURTHER INFORMATION CONTACT: For additional information, contact Kathy Berthot, *Kathy.Berthot@fcc.gov*, of the Media Bureau, Policy Division, (202) 418–7454.

SUPPLEMENTARY INFORMATION: This is a summary of the Commission's Notice of Proposed Rulemaking (NPRM), FCC 18-93, adopted on July 12, 2018 and released on July 13, 2018. The full text of this document is available for public inspection and copying during regular business hours in the FCC Reference Center, Federal Communications Commission, 445 12th Street SW, CY-A257, Washington, DC 20554. The full text of this document will also be available via ECFS (http://www.fcc.gov/ cgb/ecfs/). Documents will be available electronically in ASCII, Word 97, and/ or Adobe Acrobat. Alternative formats are available for people with disabilities (Braille, large print, electronic files, audio format), by sending an email to fcc504@fcc.gov or calling the Commission's Consumer and Governmental Affairs Bureau at (202) 418-0530 (voice), (202) 418-0432 (TTY).

The NPRM may result in new or revised information collection requirements. If the Commission adopts any new or revised information collection requirements, the Commission will publish a notice in the Federal Register inviting the public to comment on such requirements, as required by the Paperwork Reduction Act of 1995. In addition, pursuant to the Small Business Paperwork Relief Act of 2002, the Commission will seek specific comment on how it might "further reduce the information collection burden for small business concerns with fewer than 25 employees.'

Synopsis

I. Introduction

1. In the NPRM, we propose to revise the children's television programming rules to modify outdated requirements and to give broadcasters greater flexibility in serving the educational and informational needs of children. In the more than two decades since the Commission adopted the children's programming rules, there have been dramatic changes in the way television viewers, including younger viewers, consume video programming. Appointment viewing—watching the same program on the same channel at the same time every week-has significantly declined, while timeshifted viewing has risen. At the same time, the amount of programming for children available via non-broadcast platforms, including children's cable networks, over-the-top providers, and the internet, has proliferated. Moreover, with the transition to digital television, broadcasters are able to carry more than one programming stream on their 6 MHz

spectrum blocks. Thus, if given more flexibility, broadcasters can now provide a host of alternative children's programming options outside of the primary stream, giving over-the-air (OTA) viewers access to additional free children's programming. In light of these changes, and based on comments we have received in response to the Commission's Modernization of Media Regulation Initiative proceeding, we think the time is ripe to modernize the children's programming rules to improve broadcasters' ability to serve the educational and informational needs of today's young viewers. Our proposals are guided by the directives of the Children's Television Act of 1990 (CTA), which requires the Commission to consider, in its review of television license renewals, the extent to which the licensee "has served the educational and informational needs of children through the licensee's overall programming, including programming specifically designed to serve such needs." (47 U.S.C. 303b(a)(2))

2. Among other matters, we seek input on the Core Programming definition, the Commission's processing guidelines, and updated rules on multicasting stations. In addition to the specific issues and proposals discussed in this *NPRM*, we also seek comment on whether there are any other changes to the existing children's programming rules that we should consider.

II. Background

3. The CTA requires that the Commission consider, in reviewing television license renewals, the extent to which the licensee "has served the educational and informational needs of children through the licensee's overall programming, including programming specifically designed to serve such needs." The CTA provides that, in addition to considering the licensee's programming, the Commission may consider in its review of television license renewals (1) any special nonbroadcast efforts by the licensee which enhance the educational and informational value of such programming to children; and (2) any special efforts by the licensee to produce or support programming broadcast by another station in the licensee's marketplace which is specifically designed to serve the educational and informational needs of children.

4. Initial Children's Programming Rules. In 1991, the Commission adopted rules implementing the CTA. Specifically, the Commission defined "educational and informational programming" as "any television

programming which furthers the positive development of children 16 years of age and under in any respect, including the child's intellectual/ cognitive or social/emotional needs." The Commission declined at that time to adopt specific requirements as to the number of hours of educational and informational programming that commercial stations must broadcast or the time of day during which such programming must be aired. Instead, the Commission simply required that commercial stations air some amount of educational and informational programming specifically designed for children 16 years of age and under. The Commission also adopted recordkeeping and reporting requirements for commercial stations. Specifically, it required commercial licensees to maintain records on their children's programming efforts, including a summary of the licensee's programming, non-broadcast efforts, and support for other stations' programming directed to the educational and informational needs of children, and to place these records in their public inspection files. In addition, it required commercial licensees to submit with their license renewal applications the summary of the programming and other efforts directed to the educational and informational needs of children.

5. The Commission initially declined to impose any children's programming requirements on noncommercial stations. The Commission noted that the legislative history of the CTA "portrays public broadcasting as a model for educational and informational programming which commercial broadcasters should emulate" and concluded that application of the CTA's programming provisions to noncommercial stations is not required by the statute, its legislative history, or the public interest. On reconsideration, the Commission reversed course, concluding that the statutory obligation to meet children's educational and informational needs applies to all broadcasters, including noncommercial broadcasters. However, the Commission continued to exempt noncommercial stations from the recordkeeping and reporting requirements applicable to commercial stations, finding such requirements unnecessary given the commitment that noncommercial stations had demonstrated to serving children. The Commission instead required noncommercial stations to maintain documentation sufficient to show compliance at renewal time with the CTA's programming obligations in

response to a challenge or to specific complaints.

6. 1996 "Core Programming" Rules and Processing Guidelines. The Commission revised the children's programming rules in 1996, concluding that its initial regulations implementing the CTA "have not been fully effective in prompting broadcasters 'to increase the amount of educational and informational broadcast television programming available to children.'" In order to provide broadcasters with clear guidance regarding their children's programming obligations, the Commission adopted a more particularized definition of programming "specifically designed" to serve children's educational and informational needs. The Commission labeled such programming as "Core Programming," which it defined as programming that, among other things, has serving the educational and informational needs of children ages 16 and under as a significant purpose, is at least 30 minutes in length, is aired between the hours of 7:00 a.m. and 10:00 p.m., and is a regularly scheduled weekly program. The Commission stated that although a program must be regularly scheduled on a weekly basis to qualify as Core, it would leave it to the staff to determine, with guidance from the full Commission as necessary, what constitutes regularly scheduled programming and what level of preemption is allowable.

7. The Commission also adopted several public information initiatives designed to facilitate access to information about the shows broadcasters air to fulfill their obligation to air educational and informational programming under the CTA. The Commission reasoned that enhancing parents' knowledge of children's educational programming could result in larger audiences for such programs, which in turn could increase the incentives for broadcasters to air more educational programming. The Commission further concluded that access to programming information could facilitate viewer campaigns and other community-based efforts to influence stations to air more and better educational programming. These public information initiatives require licensees to provide publishers of program guides and listings information identifying core programs and the target age group for the programs; to submit children's programming reports on a quarterly basis on a standardized reporting form, the Children's Television Programming Report (FCC Form 398); to publicize the existence and location of their children's programming reports; to

provide a brief explanation in their children's programming reports of how particular programs meet the definition of "Core Programming"; and to designate a liaison for children's programming and to include the name and method of contacting that individual in the station's children's programming reports. The Commission also required licensees to provide on-air identification of core educational programs, in a manner and form at the sole discretion of the licensee, at the beginning of the program. The Commission continued to exempt noncommercial licensees from the reporting requirements and also exempted them from the other new public information initiatives.

8. Additionally, the Commission adopted a three-hour per week safe harbor processing guideline for determining compliance with the children's programming rules. The Commission concluded that a processing guideline would provide broadcasters clarity about their programming obligations under the CTA and would minimize the inequities created by stations that air little Core Programming by subjecting all broadcasters to the same scrutiny for CTA compliance at renewal time. Under the processing guideline, the Media Bureau staff is authorized to approve the children's programming portion of a licensee's renewal application where the licensee has aired approximately three hours per week (as averaged over a six month period) of Core Programming. Renewal applications are divided into two categories for purposes of staff-level CTA review. Under Category A, a licensee can demonstrate compliance with the processing guideline by checking a box on its renewal application and providing supporting information indicating that it has aired three hours per week of Core Programming. Under Category B, the Bureau staff will approve the children's programming portion of a licensee's renewal application where the licensee makes a showing that it has aired a package of different types of educational and informational programming that, while containing somewhat less than three hours per week of Core Programming, demonstrates a level of commitment to educating and informing children that is at least equivalent to airing three hours per week of Core Programming. Specials, public service announcements (PSAs), short-form programs, and regularly scheduled nonweekly programs with a significant purpose of educating and informing children can count toward the

processing guideline under Category B. Licensees have rarely attempted to demonstrate compliance under Category B due to uncertainty as to how much Core Programming must be provided.

The Commission stated that licensees whose showings do not fall within Category A or B of the processing guideline will have their renewal applications referred to the full Commission, where they will have the opportunity to demonstrate compliance with the CTA by relying in part on special non-broadcast efforts which enhance the value of children's educational and informational programming and/or special efforts by the licensee to produce or support programming broadcast by another station in the licensee's marketplace which is specifically designed to serve the educational and informational needs of children. The Commission explained that to receive credit for special nonbroadcast efforts, a licensee must show that it has engaged in substantial community activity and that there is a close relationship between its Core Programming and its non-broadcast efforts. To receive credit for special sponsorship efforts, a licensee must demonstrate that its production or support of Core Programming aired on another station in its market increased the amount of Core Programming on the station airing the sponsored Core Programming. The Commission stated that relying on special non-broadcast efforts or special sponsorship efforts does not relieve a licensee of the obligation to air Core Programming, noting that the CTA permits the Commission to consider such special efforts only "in addition to consideration of the licensee's [educational] programming." The Commission declined to define the minimum amount of Core Programming that a station must air on its own station to receive credit for special efforts or to establish specific program sponsorship guidelines, concluding that these matters are best addressed on a case-bycase basis. Use of this option to demonstrate compliance with the CTA is even rarer than use of Category B because of the uncertainty as to how much Core Programming must be provided and how special nonbroadcast efforts and special sponsorship efforts will be weighed.

10. 2004 Digital Broadcasting, Preemption, and "E/I" Symbol Requirements. In 2004, the Commission revised the processing guideline to address how the children's programming requirements apply to digital broadcasters that multicast. Under the revised guideline, in addition to the requirement that stations air an average of three hours of Core Programming on their main program stream, digital broadcasters that choose to provide supplemental streams of free video programming have an increased Core Programming benchmark that is proportional to the additional amount of free video programming they choose to provide via such multicast streams. Specifically, digital broadcasters must provide one-half hour per week of additional Core Programming for every increment of one to 28 hours of free video programming provided in addition to that provided on the main program stream. Broadcasters are permitted to air all of their additional digital Core Programming on either one free digital video channel or distribute it across multiple free digital video channels, at their discretion, as long as the stream on which the Core Programming is aired has comparable carriage on MVPDs as the stream triggering the additional Core Programming obligation. To ensure that digital broadcasters do not simply replay the same Core Programming to meet the revised processing guideline, the Commission required that at least 50 percent of Core Programming on multicast streams not be repeated during the same week to qualify as core. The Commission exempted from the additional Core Programming guideline any program stream that merely time shifts the entire programming line-up of another program stream.

11. The Commission also revised its policies regarding when a station can count preempted Core Programming toward meeting the three-hour per week safe harbor processing guideline. The Commission determined that a preempted core program must be rescheduled in order to be considered Core Programming. Additionally, the Commission stated that it would consider, in determining whether the rescheduled program counts as a core educational program, the reason for the preemption, the licensee's efforts to promote the rescheduled program, the time when the rescheduled program is broadcast, and the station's level of preemption of Core Programming. The Commission exempted core programs preempted for breaking news from the requirement that core programs be rescheduled. With respect to digital broadcasters that multicast, the Commission stated that it would not consider a core program moved to the same time slot on another of the station's digital program streams to be preempted as long as the alternate program stream receives MVPD carriage

comparable to the stream from which the program is being moved and the station provides adequate on-screen information about the move, including when and where the program will air, on both the original and the alternate program stream. Further, the Commission limited the number of preemptions under the processing guideline to no more than ten percent of core programs in each calendar quarter, explaining that each preemption beyond the ten percent limit would cause that program not to count as core under the processing guideline, even if the program is rescheduled. The Commission exempted from this ten percent limit preemptions for breaking news.

12. Moreover, the Commission amended its rules regarding on-air identification of Core Programming to require broadcasters to identify Core Programming with the symbol "E/I" and to display this symbol throughout the program in order for the program to qualify as Core. The Commission found that this amendment was warranted because studies of the effectiveness of the children's programming requirements showed a continued lack of awareness on the part of parents regarding the availability of Core Programming and the use of different identifiers by different broadcasters was confusing parents and impairing their ability to choose Core Programming for their children. The Commission applied the revised on-air identification requirement to both commercial and noncommercial licensees. Although the Commission previously had exempted noncommercial licensees from the onair identification requirement, it found that requiring all licensees to use the E/I symbol throughout the program to identify Core Programming would help "reinforce viewer awareness of the meaning of this symbol." The Commission also revised the definition of "Core Programming" to include this on-air identification requirement.

13. 2006 Reconsideration Order and Joint Proposal. In 2006, the Commission modified the children's programming rules in response to petitions for reconsideration of the 2004 Report and Order and a Joint Proposal negotiated by a group of cable and broadcast industry representatives and children's television advocates to resolve their concerns with the rules adopted in 2004. The Commission clarified that at least 50 percent of the Core Programming counted toward meeting the revised programming guideline for multicasting stations cannot consist of program episodes that had already aired within the previous seven days on either the

station's main program stream or on another of the station's free digital program streams. In addition, the Commission adopted the Joint Proposal recommendation to amend the Children's Television Programming Report, FCC Form 398, to collect the information necessary to enforce the limit on repeats under the revised guideline. Licensees are permitted to certify on Form 398 that they have complied with the repeat restriction and are not required to identify each repeated program episode on Form 398, but must retain records sufficient to document the accuracy of their certification, including records of actual program episodes aired, and to make such documentation available to the public upon request.

14. The Commission also accepted the Joint Proposal recommendation to repeal the ten percent cap on preemptions adopted in the 2004 Report and Order and instead institute a procedure similar to that previously used by the Media Bureau, whereby broadcast networks sought informal approval of their preemption plans each year. Under this procedure, a program counts as preempted only if it was not aired in a fixed substitute time slot of the station's choice (known as a "second home") with an on-air notification of the schedule change occurring at the time of preemption during the previously scheduled time slot. The onair notification must announce the alternate date and time when the preempted show will air. All networks requesting preemption flexibility must file a request with the Bureau by August 1 of each year stating the number of preemptions the network expects, when the program will be rescheduled, whether the rescheduled time is the program's second home, and the network's plan to notify viewers of the schedule change. Non-network stations are presumed to be complying with the Core Programming guideline and do not need to request preemption relief.

III. Discussion

15. As discussed above, the CTA requires the Commission to take into account the extent to which a broadcast television licensee "has served the educational and informational needs of children through its overall programming, including programming specifically designed to serve such needs" when evaluating its license renewal application. In addition to considering a licensee's programming, the Commission is also permitted under the CTA to consider any special nonbroadcast efforts by the licensee which enhance the educational and informational value of such programming to children and any special efforts by the licensee to sponsor educational and informational programming for children aired on another in-market station. While the CTA does not mandate a particular quantitative standard for children's programming, the statute makes clear that all television broadcast stations must air some amount of programming specifically designed to serve children's educational and informational needs.

16. The video programming landscape has changed dramatically since the Commission first adopted rules implementing the CTA more than 20 years ago. There has been a major shift in the way in which viewers, including children, consume video programming. Appointment viewing has declined sharply as viewers increasingly access video programming using time-shifting technology (e.g., DVRs and video on demand). Recent Nielsen data indicate that live TV viewing has been declining between 2% and 6% each year for the last four years in the U.S. Moreover, there is a vast array of children's programming available on nonbroadcast platforms today. As NAB observes, myriad full-time children's cable channels are flourishing, including Nickelodeon, Nick Jr., Teen Nick, Disney Channel, Disney Junior, and Disney XD, as are other channels, such as Discovery, Discovery Family, National Geographic, National Geographic Wild, Animal Planet, History Channel, and Smithsonian Channel, that provide educational and informational programming intended for viewers of all ages. In addition, overthe-top providers such as Netflix, Amazon, and Hulu offer a host of original and previously-aired children's programming. There are also numerous online sites which provide educational content for children for free or via subscription, including LeapFrog, National Geographic Kids, PBS Kids, Scholastic Kids, Smithsonian Kids, Time for Kids, Funbrain, Coolmath, YouTube, and Apple iTunes U. Further, as part of their educational mission, PBS member stations, which make up 89 percent of all noncommercial television stations, are required by the terms of their membership to air at least seven hours of educational children's programming each weekday, far in excess of what is required under our safe harbor processing guideline.

17. Furthermore, with the transition of broadcast television from analog to digital, broadcasters are now able to offer multiple free, OTA digital streams or channels of programming simultaneously, using the same amount

of spectrum previously required for one stream of analog programming. As of February 2016, broadcast television stations were offering more than 5,900 digital multicast channels. Multicasting allows broadcasters to offer additional programming choices to consumers, particularly consumers in smaller, rural markets, by expanding access to the four major broadcast networks (i.e., ABC, CBS, Fox, or NBC), other established networks (e.g., The CW, myNetworkTV, and Telemundo), and newer networks (e.g., MeTV, This-TV, and Grit). Programming content offered on multicast channels includes increased local news and public affairs coverage, sports and entertainment programming, foreign-language programming, religious programming, and children's programming. We also note that in January 2017, PBS launched a 24/7 educational children's multicast channel that reaches 95 percent of households and "that is re-doubling the efforts of local stations to serve all children with curriculum-driven children's programing." And, Qubo, Ion Television's 24/7 broadcast network for kids on one of its multicast streams, allows Ion to provide over 500 percent more children's programming than what is required in our rules. The additional programming choices afforded by multicast channels today are particularly beneficial to households that rely exclusively on OTA programming.

18. Given these developments, we believe that it is appropriate at this time to take a fresh look at the children's programming rules, with an eye toward updating our rules to reflect the current media landscape in a manner that will ensure that the objectives of the CTA continue to be fulfilled. Our proposals set forth below are intended to provide broadcasters more flexibility in fulfilling their obligations under the CTA, while at the same time recognizing that particularized guidance may provide them greater regulatory certainty.

A. "Core Programming" Definition and Requirements

19. We seek comment on possible modifications to the definition of "Core Programming" to remove outdated requirements and provide broadcasters more flexibility in fulfilling their children's programming obligations. As noted above, "Core Programming" is defined as programming that satisfies the following criteria: (1) It has serving the educational and informational needs of children ages 16 and under as a significant purpose; (2) it is at least 30 minutes in length; (3) it is aired between the hours of 7:00 a.m. and 10:00 p.m.;

(4) it is a regularly scheduled weekly program; (5) the program is identified as specifically designed to educate and inform children by the display on the television screen throughout the program of the symbol E/I; (6) instructions for listing the program as educational/informational, including an indication of the intended age group, are provided to publishers of program guides; and (7) the educational and informational objective and the target child audience are specified in writing in the licensee's children's programming report. This definition has remained largely unchanged since its adoption in 1996. Given the evolution in the way Americans, including children, consume video now, we seek comment on potential changes to the Core Programming definition.

1. Requirement That Core Programming Be at Least 30 Minutes in Length

20. We tentatively conclude that we should eliminate the requirement that educational and informational programming be at least 30 minutes in length to be considered Core Programming. Elimination of this requirement would enable broadcasters to receive Core Programming credit for PSAs, interstitials (*i.e.*, programming of brief duration that is used as a bridge between two longer programs), and other short segments. The Commission recognized that short segments can serve the educational and informational needs of children when it initially implemented the CTA in 1991 and again when it revised the children's programming rules in 1996. NAB asserts, however, that the Commission's decision to count only programs 30 minutes or longer as core has effectively driven popular short segment programming such as "Schoolhouse Rock" and "In the News" from the air and that this reduction in the variety of children's educational programming does not promote the public interest. We agree with NAB that short segments can be used effectively to educate and inform children. We seek comment on our tentative decision to eliminate the requirement that educational and informational programming be of a minimum length to be considered Core Programming. Are there additional studies or other data showing the benefits to children of educational and informational short segments? Are there any recent studies that evaluate the utility of short form programming relative to long form programming?

21. Furthermore, if we eliminate the requirement that educational and informational programming be at least 30 minutes in length to be counted as

Core Programming, can we address concerns that short segments may be difficult to locate by requiring broadcasters to promote such segments? Moreover, if we eliminate the requirement that educational and information programming be at least 30 minutes in length to be counted as Core Programming, we seek comment on whether we should count short segment programming on a minute-for-minute basis (*e.g.*, 30 minutes of short segment programming would be equivalent to 30 minutes of Core Programming) or in some other manner.

2. Core Programming Hours

22. We seek comment on whether the existing 7:00 a.m. to 10:00 p.m. time frame should be expanded and if so, what the expanded Core Programming hours should be. NAB suggests that we should expand the Core Programming hours to 6:00 a.m. to 11:00 p.m. We seek comment on this suggestion. Is there data showing that a substantial number of children ages 16 and under watch television programming or view video content earlier than 7:00 a.m. and/or later than 10:00 p.m.? Commenters that propose alternative expanded Core Programming hours should provide support or justification for their proposed hours. What are the costs of the Core Programming hours requirement and what savings or other benefits would viewers receive if we expanded the Core Programming hours? For example, to what extent does the current Core Programming hours requirement limit broadcasters' flexibility to air other desired programming, such as weekend local news and live sports programming?

23. Alternatively, we seek comment on whether it is still necessary to define the time frame in which educational and informational programming for children must be aired to be considered Core Programming. The Commission adopted the current 7:00 a.m. to 10:00 p.m. Core Programming time frame in 1996 because then data showed that there was a relatively small percentage of children in the audience prior to 7:00 a.m. and that the number of children watching television dropped off considerably after 10:00 p.m. Commenters assert that the 7:00 a.m. to 10:00 p.m. Core Programming time frame has become unduly narrow given the decline in "appointment viewing" by viewers, especially young viewers, and the increased ability of viewers to access children's programming using time-shifting technology. We seek comment on this view. We ask commenters to present studies or other data indicating the extent of

appointment viewing by children ages 16 and under. Is it reasonable to expect that the decline in appointment viewing by viewers over 18 extends to children 16 and under? Do these studies or other data demonstrate that appointment viewing by children ages 16 and under has declined to the extent that there is no longer any need or that there is a significantly reduced need to require that Core Programming air during a prescribed time period to be counted as Core Programming? We note that DVRs that record OTA television are now available at a relatively low cost. Have such devices led to a decrease in appointment viewing of children's programming for families that rely on OTA television?

3. Regularly Scheduled Weekly Programming Requirement

24. We tentatively conclude that we should eliminate the requirement that educational and informational programming be "regularly scheduled weekly programming'' to be counted as Core Programming. The Commission adopted the regularly scheduled weekly programming requirement because it found that such programming "is more likely to be anticipated by parents and children, to develop audience loyalty, and to build successfully upon and reinforce educational and informational messages, thereby better serving the educational and informational needs of children." We seek comment on whether, given the overall decline in appointment viewing noted above, the regularly scheduled weekly programming requirement is no longer needed to serve its intended purposes and whether it may in fact undermine broadcasters' incentives to air a wider variety of children's programming. If we eliminate this requirement, broadcasters could receive Core Programming credit for airing more types of children's programming, such as educational specials that are not regularly scheduled and non-weekly children's programming. We note, for example, that the "ABC Afterschool Specials" aired between 1972 and 1997 and the "CBS Schoolbreak Specials" aired between 1980 and 1996 were popular and highly acclaimed. We seek comment on our tentative conclusion that the regularly scheduled programming requirement should be eliminated. Would elimination of the regularly scheduled weekly programming requirement likely incentivize broadcasters to invest in high quality educational specials and non-weekly programming? Is it reasonable to expect that broadcasters would be motivated to promote

educational specials and non-weekly children's programming to promote viewership? Do the costs of the regularly scheduled weekly programming requirement outweigh the benefits and, if so, how?

4. On-Air Notification Requirement

25. We tentatively conclude that noncommercial stations should no longer be required to identify Core Programming with the E/I symbol at the beginning of the program or to display this symbol throughout the program. As discussed above, the Commission adopted this requirement for both commercial and noncommercial broadcasters in 2004 to address concerns that there was a continued lack of awareness on the part of parents regarding the availability of Core Programming, finding that use of the E/I symbol could greatly improve the public's ability to recognize and locate core programs at minimal cost to broadcasters. Although noncommercial stations previously had been exempted from the on-air identification requirement, the Commission concluded that requiring all stations to display the E/I symbol throughout the program would help "reinforce viewer awareness of the meaning of this symbol." Public Broadcasting urges the Commission to eliminate this requirement for noncommercial stations, asserting that since the E/I symbol is intended to facilitate the children's programming requirements that apply only to commercial stations, it is not rational to continue to apply this mandate to noncommercial stations. We think that the E/I symbol is sufficiently familiar to parents today that there is little benefit to requiring noncommercial stations-which are not otherwise subject to the reporting requirements and other public information initiatives applicable to commercial stations-to display the E/I symbol. We seek comment on our tentative conclusion to eliminate this requirement for noncommercial stations. If we eliminate the requirement that noncommercial stations display the E/I symbol, how will parents distinguish programming aired on noncommercial stations that is specifically designed to educate and inform children from programming that may be educational or informative but is intended for general audiences?

26. Public Broadcasting also asserts that displaying the E/I symbol "creates technical and viewability challenges for PBS as it works to innovate by streaming across a wide range of platforms" and "is particularly disruptive on smaller screens." In order to more fully understand this concern as a basis for eliminating the E/I symbol requirement, we request additional information on exactly what technical and viewability challenges are created for noncommercial stations when displaying the E/I symbol on children's programming. Is the symbol generally added to programming prior to delivery to the station, or is it added at the time of broadcast by the station? How does the answer impact a broadcaster's ability to remove the E/I symbol? Do stations send their signals to smaller devices, such as smartphones and tablets, through the same transmission that is used to send the signals to television set receivers or through a separate transmission? If separate transmissions are used, does that impact a broadcaster's ability to remove the E/I symbol? Do these challenges arise when the E/I symbol is displayed in programming transmitted OTA to devices with smaller screens or do the challenges arise only when programming containing the E/I symbol is streamed online? If we do not eliminate the requirement that noncommercial stations include the E/I symbol on Core Programming displayed on television sets, should we nonetheless eliminate the requirement when the programming is transmitted OTA to and received by smaller devices, such as smartphones and tablets?

27. We also request comment on whether we should continue to require commercial stations to identify Core Programming with the E/I symbol and display this symbol throughout the program in order for the program to qualify as Core Programming. To what extent do parents today use the E/I symbol to locate and choose Core Programming on commercial stations for their children? Do the costs to commercial licensees of the requirement to display the E/I symbol outweigh the benefits to parents? Does the current E/I symbol requirement cause undue technical difficulties for commercial stations or limit their flexibility to air programming on a variety of devices, including those with small screens? We seek comment from commercial broadcasters on the technical issues raised in the previous paragraph. If we retain the on-air identification requirement for commercial stations, should we afford commercial licensees greater flexibility to address any such technical difficulties by not requiring them to display the E/I symbol when consumers are viewing Core Programming transmitted OTA to and received by devices with smaller screens?

5. Program Guides

28. We seek comment on whether we should retain or eliminate the requirement that broadcasters provide information identifying programming specifically designed to educate and inform children, including an indication of the intended age group, to publishers of program guides. This requirement was intended to improve the information available to parents regarding programming specifically designed for children's educational and informational needs and to make broadcasters more accountable in classifying programming as specifically designed to educate and inform. We request comment on whether this requirement continues to serve its intended purposes. Do program guides publish the information provided by stations? If not, why not? If so, do parents use program guide information today to identify educational and information programming for their children? If not, how do parents identify such programming? Is program guide information used by interested parties to ensure that broadcasters are properly classifying programming as specifically designed to educate and inform? How is the information provided to publishers of program guides made available for use by OTA viewers? Is this information only available in print form, such as in the newspaper or *TV Guide*? Is the information also passed along to interactive guides available on internet connected television sets or other devices capable of receiving an OTA signal? Do stations include information on their websites to identify their Core Programming as educational and informational?

6. Reporting Requirements

29. We seek comment on ways to streamline the children's television reporting requirements to eliminate unnecessary burdens and redundancies. Currently, commercial television broadcasters are required to file a Children's Television Programming Report on FCC Form 398 on a quarterly basis reflecting efforts made during the preceding quarter, and efforts planned for the next quarter, to serve the educational and informational needs of children. The report requires licensees to provide the average weekly number of hours of Core Programming aired by the station on its main program stream and any multicast streams over the quarter and to provide detailed information on each core and non-core program that is specifically designed to serve the educational and informational needs of children. The report also

requires licensees to certify that at least 50 percent of Core Programming aired on its multicast streams was not repeated during the same week, identify the program guide publishers to which information regarding the licensee's educational and informational programming was provided, as required by our rules, list each core program that was preempted during the preceding quarter, and provide information about whether each such program was rescheduled in accordance with the Commission's preemption policy. Licensees are required to place a copy of each quarterly report in the station's online public file and to publicize the existence and location of the reports.

30. We tentatively conclude that the Children's Television Programming Report should be filed on an annual rather than quarterly basis, as proposed by NAB and other commenters. NAB asserts that the extraordinary detail required by the quarterly reports places undue burdens on television stations. NAB indicates that the reports of a single station that provides three program streams (one main and two multicast) generally range from 30-40 pages per quarter and that a station whose reports average 40 pages per quarter will file 160 pages of programming details every year and approximately 1,280 pages during the station's eight-year license term. NAB maintains that the quarterly reports are also redundant, as stations must identify every quarter the programs they expect to air in the next quarter and then in the following quarter must report on the programs actually aired. We seek comment on our tentative conclusion that these reports should be filed on an annual basis. We note that the quarterly reporting requirement was intended to "provide[] more current information about station performance and encourage[] more consistent focus on educational programming efforts." It does not appear, however, that requiring broadcasters to file these reports on a quarterly basis serves any useful purpose today. Does broadcasters' educational and informational programming change significantly from quarter to quarter so as to justify the burden of quarterly reports? To what extent does the public use the quarterly reports to monitor station performance in complying with the CTA? Do the burdens to broadcasters of preparing these reports on a quarterly basis outweigh the benefits to the public of having this information on a quarterly basis? If we adopt an annual reporting requirement, we seek comment on when licensees should be required to file their

annual reports. Should they be required to file within 10 days of the end of the calendar year, or is a longer filing deadline, such as within 30 days of the end of the calendar year, more appropriate? We also seek comment on whether we should revise our rules to require broadcasters and cable operators to place in their public files on an annual basis, instead of on quarterly basis as is currently required, records demonstrating compliance with the limits on commercial matter in children's programming. Would such modification of the recordkeeping requirements result in any loss of accountability or transparency?

31. Whether we adopt an annual reporting requirement or retain the quarterly reports, we tentatively conclude that the reports should only require broadcasters to provide information on the programs that they aired to meet their Core Programming requirement and not on the programs they plan to air in the future. There is no evidence that such duplicative reporting serves any useful purpose today. We seek comment on this tentative conclusion.

32. In addition, we seek comment on whether the requirement that broadcasters specify the educational and informational purpose and the target age group of Core Programming in their Children's Television Programming Reports continues to serve the objectives underlying its adoption. The Commission previously found that requiring a statement of educational and informational purpose will ensure that licensees devote attention to the educational and informational goals of Core Programming and how those goals may be achieved, assist licensees in distinguishing programs specifically designed to serve children's educational and informational needs from programs whose primary purpose is to entertain children, and allow parents and other interested parties to participate more actively in monitoring licensee compliance with the CTA. Requiring licensees to specify the target age group of a core program was intended to encourage licensees to consider whether the content of the program is suited to the interests, knowledge, vocabulary, and other abilities of that age group, was specifically designed to meet the informational and educational needs for children under 16, and to provide information to parents regarding the appropriate age for core programs, thereby facilitating increased program audience and ratings. We request comment on whether the requirement that licensees specify the educational and informational purpose and target

age group of Core Programming in their reports is still needed to serve these goals. Do parents rely on this information to plan their children's viewing or do they use program guides or some other source of information? Do parents and other interested parties use this information to monitor licensee compliance with the CTA? To what extent does the E/I symbol obviate the need for this requirement? Do the costs of providing this information outweigh the benefits?

33. We also seek comment on whether to streamline the report and permit broadcasters to certify their compliance with the children's programming requirements, instead of providing detailed information documenting their compliance, as proposed by several commenters. For example, with regard to a station's Core Programming, the streamlined report could require a licensee to certify that it aired the required number of Core Programming hours and that the programming complied with all applicable Core Programming criteria. To the extent that a station does not fully comply, the report would require the licensee to provide details concerning its noncompliance. We request comment on whether the detailed program information required by the current report is still needed for any useful purpose or whether certifications of compliance with the various children's programming requirements would be sufficient. If we streamline the reports and eliminate the requirement to provide detailed program information, how would the Media Bureau staff and the public verify broadcasters' compliance with the children's programming rules? Similar to how the Commission addresses noncommercial stations, should we require commercial stations to maintain documentation sufficient to show compliance at renewal time in response to a challenge or to specific complaints? How has this process worked for noncommercial stations?

34. What other certifications should be included in a streamlined children's programming report? What information should the reports continue to require in more detail? For example, if a station relies in part on special sponsorship efforts and/or special non-broadcast efforts, should the report continue to require the licensee to provide details on these efforts? While we expect that the rule changes we are proposing should largely eliminate the need for preemptions of Core Programming, to the extent that a station does preempt Core Programming, should the report continue to require the station to

provide detailed information on preemptions and any necessary rescheduling, or should a station be permitted to certify compliance with any preemption policies?

35. We tentatively conclude that we should eliminate the requirement that licensees publicize their Form 398s. We note that licensees currently are required to place their Form 398s in their public files and we are not proposing to change this requirement. The additional requirement that licensees publicize their Form 398s was originally intended to "heighten awareness of the CTA and invite members of the public to take an active role in monitoring compliance." We tentatively conclude that it no longer serves this purpose. We seek comment on our tentative conclusion. Does the requirement that licensees publicize their Form 398s encourage members of the public to seek out stations' Form 398s or to take an active role in monitoring stations' compliance with the CTA?

B. Processing Guideline

36. We seek comment on whether we should modify the three-hour per week safe harbor processing guideline for determining compliance with the children's programming rules. Under the Commission's children's programming processing guideline, Media Bureau staff is authorized to approve the children's programming portion of a broadcaster's license renewal application if the broadcaster has aired three hours per week (averaged over a six-month period) of Core Programming on its primary stream, and an additional three hours per week for each free 24-hour multicast stream. How has this requirement affected the delivery of broadcast content to consumers? What have been the costs and benefits of this requirement? What programming would broadcasters air if they were not constrained by our processing guideline? Commenters are encouraged to provide real world examples of the scheduling challenges associated with our current processing guideline.

37. If we modify our requirement to carry children's programming on the primary stream, how does this equation change? For example, if broadcasters were able to meet our processing guideline by delivering educational and informational programming on one of their multicast streams, would the scheduling burdens associated with this quantitative requirement diminish? What benefits could arise from such an arrangement? Could this additional flexibility incentivize broadcasters to air more children's programming?

38. Alternatively, if we maintain the processing guideline on the broadcaster's primary stream, is more flexibility needed to address scheduling demands? For example, should the safe harbor processing guideline be based on the number of hours aired annually, instead of weekly? Under this modification, Media Bureau staff would be authorized to approve the children's programming portion of a broadcaster's license renewal application where the broadcaster has aired 156 hours per calendar year as opposed to three hours per week of Core Programming as averaged over six months.

39. We seek comment on the merits of evaluating broadcasters' compliance based on programming aired over the course of a year. Would an annual processing guideline provide benefits to broadcasters over the weekly guideline? What impact, if any, would an annual processing guideline have on viewers? If we adopt an annual processing guideline, should we nevertheless require that broadcasters air some minimum number or percentage of their Core Programming hours throughout the year, to ensure that they do not attempt to "stack" Core Programming by airing it all within a single week, month, or quarter and that children have access to educational and informational programming year-round? In addition, we seek comment on whether there are other adjustments to the current processing guideline we should consider and what the justification would be for any such changes.

40. We also seek comment on the impact of our proposals in this NPRM on Category B of the processing guideline. Under Category B, a licensee can demonstrate compliance with the three-hour per week processing guideline by showing that it has aired a package of different types of educational and informational programming that, while containing somewhat less than three hours per week of Core Programming, demonstrates a level of commitment to educating and informing children that is at least equivalent to airing three hours per week of Core Programming. Specials, PSAs, shortform programs, and regularly scheduled non-weekly programs with a significant purpose of educating and informing children can count toward the processing guideline under Category B. For example, Media Bureau staff might approve the children's programming portion of a renewal application based upon a showing that, while a station fell two hours short of meeting its Core Processing Guideline during a sixmonth period (*i.e.* an average of 2.92 hours of Core Programming over the sixmonth period), it aired one hour of interstitial programming and an hourlong special. If we determine that the definition of "Core Programming" should be revised as proposed above to eliminate the requirements that Core Programming be at least 30 minutes in length and regularly scheduled (i.e., allow broadcasters to count specials, PSAs, short segments, and non-weekly programming towards their Core Programming hours), we seek comment on whether there is still a need for Category B. Are there other factors that should continue to be considered under Category B even if we eliminate the requirements that Core Programming be at least 30 minutes in length and regularly scheduled? For example, the Commission stated in 1996 that airing Core Programming or non-Core Programming during primetime and investing a substantial amount of money in developing Core Programming aired on the broadcaster's channel would be relevant factors under Category B. Should these Category B factors still be considered if a licensee does not air the required number of Core Programming hours? If so, how much weight should we give these factors?

41. In the event we decide to retain Category B, we seek comment on how to clarify or revise Category B to increase its certainty and predictability, as requested by commenters. According to NAB, Category B's vague "somewhat less than three hours per week' requirement creates uncertainty as to how much Core Programming a licensee is expected to provide. For example, should we require that licensees utilizing the Category B option provide some minimum number of hours of Core Programming and if so, how many hours (under the existing three-hours per week processing guideline, as well as under the annual guideline option discussed above)? Are there other clarifications or revisions that could be made to make the Category B option a more viable alternative for broadcasters? As noted above, it is our intent in this proceeding to provide broadcasters greater flexibility, while at the same time ensuring that they have sufficient guidance on how to comply with the children's programming rules.

42. Additionally, we seek comment on whether there is still a need at all for a quantitative processing guideline for determining compliance of television licensees with the children's programming rules. As discussed above, the CTA does not require the Commission to prescribe specific requirements as to the number of hours

of educational and informational programming that television stations must broadcast. Rather, it simply requires that the Commission consider, in its review of television license renewals, the extent to which the licensee "has served the educational and informational needs of children through its overall programming, including programming specifically designed to serve such needs." The three-hour weekly processing guideline was intended to provide licensees clear and timely notice of what they can do to ensure they meet their obligations under the CTA. Nevertheless, given the abundance of children's programming available today from various sources, including PBS, cable networks, overthe-top video providers, internet sites, and video on demand, is a quantitative processing guideline for television stations still needed? We seek comment on the extent to which children's programming available on noncommercial broadcast stations, cable networks, and other non-broadcast platforms is programming that is 'specifically designed to meet the educational and informational needs of children" and thus an adequate substitute for commercial broadcasters' educational and informational programming. How has the availability of programming for children via nonbroadcast platforms changed since the CTA was enacted in 1990? Considering that Congress prescribed only a very general children's programming requirement and gave the Commission the discretion in how to implement this requirement, is the amount of children's programming available today on noncommercial broadcast stations, cable networks, and other sources relevant to a determination as to whether a quantitative processing guideline is still needed? We also seek comment on how the increase in other sources of children's programming, changes in relevant viewing patterns, and other developments since the enactment of the CTA in 1990 may affect the First Amendment considerations applicable to the Commission's prescription of broadcast television programming requirements in this manner.

43. We also seek comment on what effect the elimination of the quantitative processing guideline would have on the amount of educational and informational programming available to children. What percentage of parents rely on OTA commercial television to provide programming serving the educational and informational needs of their children? Does OTA commercial television continue to be an important source of video programming, including educational and informational programming, for children of low income families? Are there current studies or data showing how much educational and informational programming children watch overall and on OTA commercial stations in particular? If we determine that there is no need for a quantitative processing guideline, how should the Commission evaluate a television licensee's compliance with the children's programming requirement under the CTA during the license renewal process?

C. Special Sponsorship Efforts and Special Non-Broadcast Efforts

We seek comment on the creation of a framework under which broadcasters could satisfy their children's programming obligations by relying in part on special efforts to produce or support Core Programming aired on other stations in the market and/or special non-broadcast efforts which enhance the value of children's educational and informational programming. The CTA permits the Commission to consider special sponsorship and special non-broadcast efforts, in addition to consideration of a licensee's programming, in evaluating whether a licensee has served the educational and informational needs of children. However, few, if any, broadcasters have taken advantage of this opportunity to date. Broadcasters explain that this is because of the additional regulatory hurdles and uncertainty built into our existing rules for broadcasters that choose this option. Specifically, broadcasters note that our rules require the full Commission to approve the children's programming portion of renewal applications relying on such special efforts and claim that there is insufficient guidance on how such special efforts will be counted. Thus, we seek to establish a framework that will make the use of special sponsorship efforts and special nonbroadcast efforts a more viable option for broadcasters in fulfilling their children's programming obligations.

45. The CTA states that special sponsorship and special non-broadcast efforts may be considered only "in addition to considering the licensee's [educational] programming." We seek comment on how much Core Programming a licensee should be required to air when it is relying in part on special sponsorship and/or special non-broadcast efforts. Should we require a minimum amount of Core Programming and if so, how much should we require? Alternatively, should we give broadcasters the flexibility to decide how much Core Programming to air, provided that their Core Programming hours when combined with their special sponsorship and/or special nonbroadcast efforts are the equivalent of the required Core Programming hours? As we have previously stated, we wish to give broadcasters flexibility in fulfilling their children's programming obligations, but we also recognize that particularized guidance may provide them more regulatory certainty.

46. In addition, we seek comment on how we should count a licensee's sponsorship of Core Programming on another in-market station. NAB proposes that we count the sponsorship of Core Programming on another inmarket station on a straightforward "minute-for-minute" basis (i.e., count each minute of a sponsored program as the equivalent of a minute of Core Programming). We request comment on this proposal and encourage commenters to suggest alternative proposals for quantifying sponsorship efforts. Should the size of the sponsoring broadcast station be taken into account in our analysis? For example, should we require larger broadcast stations to undertake more substantial sponsorship efforts (e.g., by sponsoring a greater number of minutes of Core Programming) than small broadcast stations in order to receive sponsorship credit? If so, how much more? How should we define "large broadcast station" and "small broadcast station" for purposes of such a requirement-based on annual revenues, market size, or some other measure? The Commission previously has stated that to receive credit for a special sponsorship effort, a broadcaster must demonstrate that its production or support of Core Programming aired on another station in its market increased the amount of Core Programming on the station airing the sponsored Core Programming. We tentatively agree that a licensee should not receive credit where its sponsorship results in no net increase in the amount of Core Programming on the other in-market station; rather, the licensee should be required to demonstrate that its sponsorship resulted in the creation of new Core Programming or expanded the hours of an existing core program. We seek comment on this view.

47. We also seek comment on how to define "special non-broadcast efforts." Under the CTA, special non-broadcast efforts must "enhance the educational and informational value" of a licensee's programming to children. We request comment on the types of special non-

broadcast efforts that should receive credit under this provision. We note that PBS stations currently engage in a variety of non-broadcast activities to supplement their educational and informational programming for children, such as hosting educational events for kids at libraries, bookstores, children's museums, science centers, theaters, and other locations in their local communities; partnering with local organizations, including schools, libraries, and summer camps, to keep kids reading and learning during the summer months; and providing free books and learning materials to children from low-income families in their communities. Are these the types of activities that should be credited as special non-broadcast efforts? Should a broadcaster receive credit for hosting or participating in an educational website for children that reinforces the themes or lessons in the broadcaster's Core Programming? Under non-broadcast efforts, should the Commission take into consideration the availability of children's programming that is aired on internet streaming platforms? For example, PBS has a dedicated website and app for its children's programming. Are there similar on-demand outlets for children's programming aired by commercial stations? Should it matter whether such content is accessible for free or on a paid or subscription basis? How should we count or weigh special non-broadcast efforts? For example, should we count each special nonbroadcast effort in which the broadcaster participates as the equivalent of a specified number of required Core Programming hours? Should some special non-broadcast efforts be assigned greater weight than others?

48. Finally, we propose to allow Media Bureau staff, rather than the full Commission, to approve the children's programming portion of renewal applications of licensees relying in part on special sponsorship and/or special non-broadcast efforts. The Bureau staff has substantial experience in evaluating the children's programming efforts of license renewal applicants. Further, we note NAB's comment that broadcasters would be unlikely to take advantage of this option if they are required to subject their license renewal to a nonroutine review by the full Commission. We seek comment on this proposal.

D. Multicasting Stations

49. We propose to allow broadcasters the flexibility to choose on which of their free OTA streams to air any Core Programming (or non-Core Programming, to the extent that a broadcaster relies on non-Core Programming to meet its children's programming obligation). Under this proposal, broadcasters would not be required to air their Core Programming on their main program stream or on a stream that has comparable MVPD carriage as the main program stream. This approach would provide broadcasters with more flexibility to air Core Programming during hours when children are most likely to be watching TV and alleviate the need for broadcasters to preempt Core Programming when it conflicts with content such as public affairs programming and live sports. We seek comment on this proposal. NAB asserts that under the current rules, "[e]ven if a station devotes a significant portion or the entirety of another stream to children's educational programming, it must still air E/I programming on its main stream. Such a requirement appears overly burdensome and unnecessarily restrictive, if not irrational." Do our current rules disincentivize more broadcasters from airing additional children's programming on their multicast streams, outside of our requirements? How would increased flexibility enhance the scheduling and delivery of broadcast content to viewers, both adults and children?

50. We tentatively conclude that neither section 336 or the CTA mandates that a station fulfill its obligation to serve the educational and informational needs of children through its primary programming stream. In establishing the statutory framework for the transition to DTV, Congress stated in section 336(d) that "[n]othing in this section shall be construed as relieving a television broadcasting station from its obligation to serve the public interest, convenience, and necessity." We tentatively conclude that a station can continue to serve the public interest by providing children's educational and informational programming on a multicast channel. Indeed, this is consistent with the CTA, which requires that we consider at renewal whether a television licensee has served the educational and informational needs of children through its "programming," but does not dictate that such programming must be provided on the primary stream. We believe that this meets the statutory obligation as outlined by Congress while continuing to serve OTA-only households and children that do not have access to alternative non-broadcast content. As Members of Congress recently stressed to the Commission, "Kid Vid' rules

remain important today, especially for the many underserved families who rely on free broadcast stations for educational content. Many families cannot access or afford the broadband speeds necessary for streaming online video and have trouble paying for monthly pay-TV subscription services. The 'Kid Vid' rules (and especially the mandatory programming hours requirement) make sure that these children have access to quality content to help them learn and thrive in school." We believe that permitting broadcasters to air their Core Programming on a multicast stream would be the surest way to provide needed flexibility while at the same time allow broadcasters to continue serving this important segment of the population. We seek comment on this tentative conclusion.

51. We also tentatively conclude that we should eliminate the additional Core Programming processing guideline applicable to digital stations that multicast. Under this guideline, broadcasters providing streams of free video programming in addition to their main program stream must air additional Core Programming based on the amount of programming that is aired on their multicast streams. Multicasting stations are permitted to air all of their additional Core Programming on one free video channel, or distribute it across multiple free video channels, at their discretion, as long as the stream on which the Core Programming is aired has comparable MVPD carriage as the stream whose programming generates the Core Programming obligation. Commenters note that when the Commission adopted this processing guideline in 2004, it stated that it intended to revisit the issues addressed in that proceeding within the next three years and consider whether its determinations should be changed in light of technological developments. In 2018, we finally revisit this issue.

52. Given the changes in how consumers access video programming and the growth in the amount and sources of educational and information programming available for children since the rule's adoption in 2004, we tentatively conclude that the additional Core Programming processing guideline for multicasting stations is no longer needed. We also tentatively find that neither the CTA nor section 336 of the Act mandates that the Commission impose children's educational and informational programming requirements on multicast streams. The CTA requires that we consider at renewal whether a television licensee has served the educational and

informational needs of children through its "programming," but does not dictate that such programming be assessed on a stream-by-stream basis. In addition, in establishing the statutory framework for the transition to DTV, Congress stated in section 336(b)(5) that the Commission "shall prescribe such other regulations as may be necessary for the protection of the public interest, convenience, and necessity." We tentatively conclude that children's educational and informational programming requirements for multicast streams are not necessary for the protection of the public interest, convenience, and necessity. We seek comment on our tentative conclusions and ask commenters to provide input on the relative costs and benefits of the current requirements for multicasting stations. To what extent do consumers benefit from the additional Core Programming hours that currently must be provided on multicast channels under the existing processing guideline? Is this programming well-known to or frequently watched by children? To what extent does the current processing guideline increase programming costs for stations or require them to forego other programming options?

53. We also seek comment on how to ensure that the current viewership of children's programming is not reduced. Should the flexibility to choose on which free OTA stream to air required Core Programming hours come with additional public interest obligations? For example, if a broadcaster decides to air its Core Programming on a multicast stream rather than its primary stream, should it be required to air additional hours of children's programming or provide some other service to its community? What other, if any, additional safeguards should apply?

54. To the extent that we adopt our proposal to allow broadcasters to choose on which of their free OTA streams to air any Core Programming, we seek comment on how to apply our children's programming rules to stations broadcasting in ATSC 3.0. In the recent order authorizing television broadcasters to use the Next Generation or ATSC 3.0 broadcast television transmission standard on a voluntary, market-driven basis, the Commission concluded that the ATSC 1.0 and ATSC 3.0 signals of a Next Gen TV broadcaster will be two separately authorized companion channels under the broadcaster's single, unified license. It further required Next Gen TV broadcasters to simulcast the primary video programming stream of their ATSC 3.0 channels in an ATSC 1.0 format, so that viewers will continue to

receive ATSC 1.0 service. The programming aired on the ATSC 1.0 simulcast channel must be "substantially similar" to the programming aired on the 3.0 channel. This means that the programming must be the same, except for programming features that are based on the enhanced capabilities of ATSC 3.0, advertisements, and promotions for upcoming programs. Although the Commission "encourage[d] those Next Gen TV broadcasters that elect to air multiple streams of ATSC 3.0 programming to also simulcast more than a single programming stream," it only required Next Gen TV broadcasters to simulcast their primary stream in ATSC 1.0 format. The Commission also concluded that each 1.0 and 3.0 stream is subject to children's programming obligations. Accordingly, based on the rules adopted in the Next Gen TV Report and Order, if we adopt our proposal to allow broadcasters to choose on which of their free OTA streams to air any Core Programming, a Next Gen TV broadcaster that chooses to air its Core Programming on its primary 3.0 video stream would be required to simulcast "substantially similar" programming, including any Core Programming, in 1.0 format. If, however, a Next Gen TV broadcaster chooses to air its Core Programming on a multicast 3.0 stream, there is no current requirement that this programming be simulcast on a 1.0 stream—although the broadcaster would still have the obligation to air Core Programming in 1.0 format. Given this, we seek comment on whether the flexibility of our children's programming proposal requires us to modify our recent ATSC 3.0 rules. For example, a Next Gen TV broadcaster may wish to air its Core Programming on its primary 3.0 video stream, but instead of simulcasting that Core Programming in 1.0 format, air unique Core programming on a 1.0 multicast stream. Should we permit such flexibility? How would this flexibility impact the children's programming available to 1.0 viewers? Similarly, how would it impact the other, non-children's programming offered to viewers via the 1.0 stream? Should broadcasters be required to simulcast the Core Programming aired on the 3.0 multicast video stream on a 1.0 multicast video stream? Are there other issues related to compliance with the proposed revisions to our children's programming rules, as they relate to the ATSC 3.0 rules, that we should consider? We invite specific comment on what modifications to our ATSC 3.0 rules, if any, may be necessary in light

of the contemplated changes to our children's programming rules.

55. We acknowledge that MVPDs are not required to carry stations' multicast streams, so it is possible that the stream on which a station chooses to air its required Core Programming would not be available to those viewing broadcast stations only through MVPDs. Nevertheless, the stream would still be available over the air and therefore should be available to children in households that do not subscribe, and therefore do not have access to, the myriad of children's programming options available on cable or satellite. We note that the Commission has allowed multicasting stations to air all of their additional Core Programming (beyond the three-hour weekly baseline) on any free OTA stream only where the stream has MVPD carriage comparable to the stream whose programming generates the Core Programming obligation. We tentatively conclude that the comparable MVPD carriage requirement is no longer necessary. We believe that the MVPD comparable carriage requirement is less important today, given that viewers with MVPD service have access to cable children's networks and likely also have access to children's programming on over-the-top services and internet sites. We seek comment on this tentative conclusion. If we allow broadcasters to move all of their Core Programming off of their main program stream to a stream that does not receive MVPD carriage, do broadcasters have business incentives to ensure that the programming attracts as many viewers as possible? How do such incentives operate in connection with the broadcast of children's educational and informational programming? Would the statutory purpose of 47 U.S.C. 303b continue to be fulfilled if we were to permit Core Programming to be moved off of the stream that is carried by the MVPD?

56. If we adopt this proposal and broadcasters choose to move their required Core Programming from their main program stream to another free OTA stream, would there be a need to ensure that parents are able to locate the Core Programming? We note that for OTA viewers the multicast stream is located next to the main stream in the channel lineup. Nevertheless, should we require broadcasters to provide onair notifications to consumers that they intend to move the Core Programming from the main program stream to another channel? If we require them, how often and when should such notifications air? Should they be aired only on those days on which the Core Programming is broadcast or

immediately before or during the broadcast of the Core Programming, to ensure that the notifications are seen by the programming's existing audience? Should we also require broadcasters to post information about the move on their websites or allow broadcasters to use websites to notify viewers in lieu of on-air notifications? Alternatively, are there more relevant ways to educate viewers today? Should we give broadcasters flexibility in determining the best way to inform their viewers? Even after initially moving Core Programming to a secondary stream, should stations be required to publicize the availability of children's programming on their secondary stream?

E. Preemption of Children's Programming

57. We seek comment on whether we should revise our policies regarding the preemption of children's programming or whether the added flexibility afforded to broadcasters by the other rule changes proposed in this NPRM, if adopted, would largely eliminate the need for preemptions. Under our existing policies, if a station preempts an episode of a core program for any reason other than breaking news, the station generally must air the rescheduled program in a previously selected "second home" and provide an on-air notification of the schedule change in order for the rescheduled program to count toward compliance with the processing guideline. Commenters complain that the restrictive "second home" policy unnecessarily burdens local stationsespecially those stations that air live network sports programming and network and local newscasts on weekend mornings-and impairs their ability to reschedule preempted programs. We seek comment on whether the potential rule changes discussed above would provide broadcasters sufficient flexibility to schedule their Core Programming so as to avoid the need for preemptions. To the extent that commenters believe that these other rule changes would not fully address their concerns with the preemption policies, or if we do not adopt all of those proposals, we request comment on how to provide broadcasters greater flexibility in rescheduling preempted Core Programming. NAB proposes that we eliminate the "second home" policy and instead permit stations to air preempted core programs on the day, time, and OTA stream of their choice, provided that the broadcaster gives adequate notice of the rescheduled time. We seek comment on this proposal and

invite commenters to suggest alternative proposals to address their concerns with preemption issues.

IV. Procedural Matters

A. Initial Regulatory Flexibility Act Analysis

1. As required by the Regulatory Flexibility Act of 1980, as amended (RFA), the Commission has prepared this Initial Regulatory Flexibility Act Analysis (IRFA) of the possible significant economic impact on a substantial number of small entities by the policies and rules proposed in the NPRM. Written public comments are requested on this IRFA. Comments must be identified as responses to the IRFA and must be filed by the deadlines for comments provided on the first page of the NPRM. The Commission will send a copy of the NPRM, including this IRFA, to the Chief Counsel for Advocacy of the Small Business Administration (SBA). In addition, the NPRM and IRFA (or summaries thereof) will be published in the Federal Register.

B. Need for, and Objectives of, the Proposed Rules

2. The Children's Television Act of 1990 (CTA) requires that the Commission consider, in its review of television license renewals, the extent to which the licensee "has served the educational and informational needs of children through its overall programming, including programming specifically designed to serve such needs." The CTA provides that, in addition to considering the licensee's programming, the Commission also may consider in its review of television license renewals (1) any special nonbroadcast efforts by the licensee which enhance the educational and informational value of such programming to children; and (2) any special efforts by the licensee to produce or support programming broadcast by another station in the licensee's marketplace which is specifically designed to serve the educational and informational needs of children. The Commission adopted rules implementing the CTA in 1991, and revised these rules in 1996, 2004, and 2006.

3. The existing children's programming rules include a three-hour per week safe harbor processing guideline for determining a renewal applicant's compliance with the rules. Under the processing guideline, the Media Bureau staff is authorized to approve the children's programming portion of a licensee's renewal application where the licensee has aired three hours per week (averaged over a six-month period) of "Core Programming" (*i.e.*, programming that is specifically designed to serve children's educational and informational needs and meets certain defined criteria). A licensee can demonstrate compliance with the processing guideline by (1) checking a box on its renewal application and providing supporting information indicating that it has aired three hours per week of Core Programming; or (2) showing that it has aired a package of different types of educational and informational programming that, while containing somewhat less than three hours per week of Core Programming, demonstrates a level of commitment to educating and informing children that is at least equivalent to airing three hours per week of Core Programming. Stations that multicast must provide an additional three hours per week of Core Programming for each full-time multicast stream that airs free programming. Licensees that do not satisfy the processing guideline have their renewal applications referred to the full Commission, where they have the opportunity to demonstrate compliance with the CTA by relying in part on special non-broadcast efforts which enhance the value of children's educational and informational programming and/or special efforts by the licensee to produce or support programming broadcast by another station in the licensee's marketplace which is specifically designed to serve the educational and informational needs of children. The children's programming rules also include, among other requirements, procedures governing the preemption of Core Programming; quarterly reporting requirements; program guide requirements; a requirement to publicize the existing and location of children's programming reports; and a requirement to identify Core Programming on-air with the E/I symbol and display this symbol throughout the program.

4. In the *NPRM*, the Commission proposes to revise the children's television programming rules to modify outdated requirements and to give broadcasters greater flexibility in serving the educational and informational needs of children. Many of the proposed revisions are based on comments received in response to the Commission's Modernization of Media Regulation Initiative proceeding. These proposed revisions reflect the dramatic changes in the video landscape in the two decades since the children's programming rules were adopted, including changes in the way television viewers, including younger viewers, consume video programming, the increase in the amount of programming for children available via non-broadcast platforms, such as children's cable networks, over-the-top providers, and the internet, and the availability today of multicast channels which provide additional programming options for households that rely exclusively on over-the-air television. Among other matters, the *NPRM* seeks input on the following issues and proposals:

• Requirement that Core Programming Be At Least 30 Minutes in Length. The NPRM tentatively concludes that the requirement that educational and informational programming be at least 30 minutes in length to be counted as Core Programming should be eliminated, which would allow public service announcements, interstitials (*i.e.*, programming of brief duration that is used as a bridge between two longer programs), and other short segments to be counted as Core Programming.

• *Core Programming Hours.* The *NPRM* seeks comment on whether it is still necessary to define the hours in which educational and informational programming must be aired to be considered Core Programming, and if so, whether to expand the Core Programming hours from 7:00 a.m. to 10:00 p.m. to 6:00 a.m. to 11:00 p.m.

• Regularly Scheduled Weekly Programming Requirement. The NPRM tentatively concludes that the requirement that educational and informational programming be regularly scheduled weekly programming should be eliminated, which would allow educational specials and non-weekly programming to be counted as Core Programming.

• On-Air Identification. The NPRM tentatively concludes that noncommercial stations should no longer be required to identify Core Programming with the "E/I" symbol or to display this symbol throughout the program. The NPRM also seeks comment on whether to continue to require commercial stations to display the E/I symbol throughout Core Programming.

• *Program Guides.* The *NPRM* seeks comment on whether to retain or eliminate the requirement that broadcasters provide information identifying programming specifically designed to educate and inform children, including an indication of the intended age group, to publishers of program guides.

• Reporting and Recordkeeping Requirements. The NPRM tentatively concludes that the Children's Television Programming Report, FCC Form 398, should be filed on an annual rather than quarterly basis and seek comment on ways to streamline this report. The NPRM also seeks comment on whether the rules should be revised to require broadcasters and cable operators to place in their public files on an annual basis, instead of on quarterly basis as is currently required, records demonstrating compliance with the limits on commercial matter in children's programming. Additionally, the NPRM tentatively concludes that the requirement that broadcasters publicize the existence and location of their Children's Television Programming Reports should be eliminated.

• Processing Guideline. The NPRM seeks comment on whether to modify the three-hour per week safe harbor processing guideline for determining compliance with the children's programming rules to make it an annual guideline, which would give broadcasters greater flexibility to air Core Programming based on scheduling demands.

• Special Sponsorship Efforts and Special Non-Broadcast Efforts. The NPRM seeks comment on the creation of a framework under which broadcasters could satisfy their children's programming obligations by relying in part on special sponsorship efforts and/ or special non-broadcast effort. In particular, the NPRM seeks comment on how much Core Programming a licensee should be required to air when it is relying in part on special sponsorship and/or special non-broadcast efforts; whether to count the sponsorship of Core Programming on another in-market station on a straightforward "minutefor-minute" basis or on some other basis; and on the types of activities that should be credited as special nonbroadcast efforts. The *NPRM* also proposes to allow Media Bureau staff, rather than the full Commission, to approve the children's programming portion of renewal applications of licensees relying in part on such special efforts.

• Multicasting Stations. The NPRM proposes to allow broadcasters that multicast the flexibility to choose on which of their free over-the-air streams to air their required Core Programming hours without regard to carriage by multichannel video programming distributors. Moreover, the NPRM tentatively concludes that the additional Core Programming guideline applicable to broadcasters providing streams of free over-the-air programming in addition to their main program stream (*i.e.*, multicasting stations) should be eliminated.

• Preemption Policies. The NPRM seeks comment on whether the policies regarding the preemption of children's programming should be revised or whether other rules changes proposed in the NPRM, including elimination of the regularly scheduled weekly programming requirement and the requirement that Core Programming be at least 30 minutes in length, making the three-hour per week processing guideline an annual processing guideline, and allowing broadcasters to choose on which of their free OTA streams to air their required Core Programming hours, would provide broadcasters sufficient flexibility to schedule their Core Programming so as to avoid the need for preemptions. To the extent that commenters believe that these other rule changes would not fully address their concerns with the preemption policies, or some or all of these other rules changes are not adopted, the NPRM seeks comment on NAB's proposal to eliminate the "second home" policy and instead permit stations to air preempted core programs on the day, time, and OTA channel of their choice, provided that the broadcaster gives adequate notice of the rescheduled time.

C. Legal Basis

5. The proposed action is authorized pursuant to sections 303, 303b, 307, and 336 of the Communications Act of 1934, as amended, 47 U.S.C. 303, 303b, 307, and 336.

D. Description and Estimates of the Number of Small Entities To Which the Proposed Rules Will Apply

6. The RFA directs agencies to provide a description of and, where feasible, an estimate of the number of small entities that may be affected by the proposed rules, if adopted. The RFA generally defines the term "small entity" as having the same meaning as the terms "small business," "small organization," and "small governmental jurisdiction." In addition, the term "small business" has the same meaning as the term "small business concern' under the Small Business Act. A small business concern is one which: (1) Is independently owned and operated; (2) is not dominant in its field of operation; and (3) satisfies any additional criteria established by the SBA.

7. The rules proposed herein will directly affect small television broadcast stations. Below, we provide a description of these small entities, as well as an estimate of the number of such small entities, where feasible.

8. Television Broadcasting. This Economic Census category "comprises establishments primarily engaged in broadcasting images together with sound." These establishments operate television broadcast studios and facilities for the programming and transmission of programs to the public. These establishments also produce or transmit visual programming to affiliated broadcast television stations, which in turn broadcast the programs to the public on a predetermined schedule. Programming may originate in their own studio, from an affiliated network, or from external sources. The SBA has created the following small business size standard for such businesses: those having \$38.5 million or less in annual receipts. The 2012 Economic Census reports that 751 firms in this category operated in that year. Of this number, 656 had annual receipts of \$25 million or less. Based on this data we therefore estimate that the majority of commercial television broadcasters are small entities under the applicable SBA size standard.

9. The Commission has estimated the number of licensed commercial television stations to be 1,377. Of this total, 1,257 stations had revenues of \$38.5 million or less, according to Commission staff review of the BIA Kelsev Inc. Media Access Pro Television Database (BIA) on January 8, 2018, and therefore these licensees qualify as small entities under the SBA definition. In addition, the Commission has estimated the number of licensed noncommercial educational (NCE) television stations to be 390. Notwithstanding, the Commission does not compile and otherwise does not have access to information on the revenue of NCE stations that would permit it to determine how many such stations would qualify as small entities.

10. We note, however, that in assessing whether a business concern qualifies as "small" under the above definition, business (control) affiliations must be included. Our estimate. therefore, likely overstates the number of small entities that might be affected by our action, because the revenue figure on which it is based does not include or aggregate revenues from affiliated companies. In addition, another element of the definition of "small business" requires that an entity not be dominant in its field of operation. We are unable at this time to define or quantify the criteria that would establish whether a specific television broadcast station is dominant in its field of operation. Accordingly, the estimate of small businesses to which rules may

apply does not exclude any television station from the definition of a small business on this basis and is therefore possibly over-inclusive. Also, as noted above, an additional element of the definition of "small business" is that the entity must be independently owned and operated. The Commission notes that it is difficult at times to assess these criteria in the context of media entities and its estimates of small businesses to which they apply may be over-inclusive to this extent.

11. Cable Companies and Systems (Rate Regulation). The Commission has developed its own small business size standards for the purpose of cable rate regulation. Under the Commission's rules, a "small cable company" is one serving 400,000 or fewer subscribers nationwide. Industry data indicate that there are currently 4,600 active cable systems in the United States. Of this total, all but nine cable operators nationwide are small under the 400,000subscriber size standard. In addition, under the Commission's rate regulation rules, a ''small system'' is a cable system serving 15,000 or fewer subscribers. Current Commission records show 4,600 cable systems nationwide. Of this total, 3,900 cable systems have fewer than 15,000 subscribers, and 700 systems have 15,000 or more subscribers, based on the same records. Thus, under this standard as well, we estimate that most cable systems are small entities.

12. Cable System Operators (Telecom Act Standard). The Communications Act of 1934, as amended, also contains a size standard for small cable system operators, which is "a cable operator that, directly or through an affiliate, serves in the aggregate fewer than one percent of all subscribers in the United States and is not affiliated with any entity or entities whose gross annual revenues in the aggregate exceed \$250,000,000." There are approximately 52,403,705 cable video subscribers in the United States today. Accordingly, an operator serving fewer than 524,037 subscribers shall be deemed a small operator if its annual revenues, when combined with the total annual revenues of all its affiliates, do not exceed \$250 million in the aggregate. Based on available data, we find that all but nine incumbent cable operators are small entities under this size standard. We note that the Commission neither requests nor collects information on whether cable system operators are affiliated with entities whose gross annual revenues exceed \$250 million. Although it seems certain that some of these cable system operators are affiliated with entities whose gross annual revenues exceed \$250,000,000,

we are unable at this time to estimate with greater precision the number of cable system operators that would qualify as small cable operators under the definition in the Communications Act.

E. Description of Projected Reporting, Recordkeeping, and Other Compliance Requirements

13. Reporting Requirements. The NPRM tentatively concludes that the Children's Television Programming Report, FCC Form 398, should be filed on an annual rather than quarterly basis. The NPRM also seeks comment whether the requirement that broadcasters specify the educational and informational purpose and the target child audience of Core Programming in their Children's Television Programming Reports continues to serve the objectives underlying its adoption. In addition, the NPRM seeks comment on whether to streamline the Children's **Television Programming Report and** allow broadcasters to certify their compliance with the children's programming requirements, rather than provide detailed information in the report documenting their compliance.

14. Recordkeeping Requirements. The NPRM seeks comment on whether the rules should be revised to require broadcasters and cable operators to place in their public files on an annual basis, instead of on quarterly basis as is currently required, records demonstrating compliance with the limits on commercial matter in children's programming.

15. Other Compliance Requirements. The NPRM seeks comment on whether it is still necessary to define the hours in which educational and informational programming must be aired to be considered "Core Programming" and if so, whether to expand the Core Programming hours from 7:00 a.m. to 10:00 p.m. to 6:00 a.m. to 11:00 p.m. Additionally, the NPRM tentatively concludes that the requirement that educational and informational programming be "regularly scheduled weekly programming, which would allow educational specials and non-weekly programming to be counted as Core Programming. The NPRM also tentatively concludes that the requirement that educational and informational programming be at least 30 minutes in length to be considered Core Programming should be eliminated, which would enable broadcasters to receive Core Programming credit for public service announcements, interstitials (i.e., programming of brief duration that is

used as a bridge between two longer programs), and other short segments.

16. The NPRM seeks comment on whether to provide broadcasters greater flexibility in scheduling their Core Programming by modifying the threehour per week safe harbor processing guideline for determining compliance with the children's programming rules to make it an annual guideline. The NPRM also seeks comment on the creation of a framework under which broadcasters could satisfy their children's programming obligations by relying in part on special sponsorship efforts and/or special non-broadcast efforts. The NPRM tentatively concludes that the additional Core Programming requirement applicable to multicasting stations should be eliminated. Further, the NPRM seeks comment on whether to allow broadcasters to choose on which of their free over-the-air streams to air their required Core Programming hours.

17. Finally, the NPRM tentatively concludes that the requirement that broadcasters publicize the existence and location of their Children's Television Programming Reports should be eliminated; tentatively concludes that noncommercial stations should no longer be required to identify Core Programming with the "E/I" symbol or to display this symbol throughout the program and seeks comment on whether commercial stations should be required to do so; and seeks comment on whether to retain or eliminate the requirement that broadcasters provide information identifying programming specifically designed to educate and inform children, including an indication of the intended age group, to publishers of program guides.

F. Steps Taken To Minimize Significant Economic Impact on Small Entities, and Significant Alternatives Considered

18. The RFA requires an agency to describe any significant, specifically small business, alternatives that it has considered in reaching its proposed approach, which may include the following four alternatives (among others): (1) The establishment of differing compliance or reporting requirements or timetables that take into account the resources available to small entities: (2) the clarification. consolidation, or simplification of compliance and reporting requirements under the rule for such small entities; (3) the use of performance, rather than design, standards; and (4) an exemption from coverage of the rule, or any part thereof, for small entities.

19. The revisions proposed in the *NPRM* are intended to modernize the children's programming rules by

modifying outdated requirements, reducing recordkeeping burdens on broadcasters and cable operators, and giving broadcasters greater flexibility in fulfilling their children's programming obligations. Thus, we expect that the proposed revisions, if adopted, will only benefit affected small entities.

G. Federal Rules That May Duplicate, Overlap, or Conflict With the Proposed Rule

20. None

H. Initial Paperwork Reduction Act of 1995 Analysis

21. This document contains proposed modified information collection requirements. The Commission, as part of its continuing effort to reduce paperwork burdens, invites the general public and the Office of Management and Budget (OMB) to comment on the information collection requirements contained in this document, as required by the Paperwork Reduction Act of 1995. In addition, pursuant to the Small Business Paperwork Relief Act of 2002, the Commission will seek specific comment on how we might further reduce the information collection burden for small business concerns with fewer than 25 employees.

I. Ex Parte Rules

22. Permit-But-Disclose. This proceeding shall be treated as a "permitbut-disclose" proceeding in accordance with the Commission's ex parte rules. Persons making ex parte presentations must file a copy of any written presentation or a memorandum summarizing any oral presentation within two business days after the presentation (unless a different deadline applicable to the Sunshine period applies). Persons making oral ex parte presentations are reminded that memoranda summarizing the presentation must (1) list all persons attending or otherwise participating in the meeting at which the ex parte presentation was made, and (2) summarize all data presented and arguments made during the presentation. If the presentation consisted in whole or in part of the presentation of data or arguments already reflected in the presenter's written comments, memoranda, or other filings in the proceeding, the presenter may provide citations to such data or arguments in his or her prior comments, memoranda, or other filings (specifying the relevant page and/or paragraph numbers where such data or arguments can be found) in lieu of summarizing them in the memorandum. Documents shown or given to Commission staff

during ex parte meetings are deemed to be written ex parte presentations and must be filed consistent with section 1.1206(b) of the rules. In proceedings governed by section 1.49(f) of the rules or for which the Commission has made available a method of electronic filing, written ex parte presentations and memoranda summarizing oral ex parte presentations, and all attachments thereto, must be filed through the electronic comment filing system available for that proceeding, and must be filed in their native format (e.g., .doc, .xml, .ppt, searchable .pdf). Participants in this proceeding should familiarize themselves with the Commission's ex parte rules.

J. Filing Procedures

23. Pursuant to §§ 1.415 and 1.419 of the Commission's rules, 47 CFR 1.415, 1.419, interested parties may file comments and reply comments on or before the dates indicated on the first page of this document. Comments may be filed using the Commission's Electronic Comment Filing System (ECFS).

• *Electronic Filers:* Comments may be filed electronically using the internet by accessing the ECFS: *http://apps.fcc.gov/ecfs/.*

• *Paper Filers:* Parties who choose to file by paper must file an original and one copy of each filing. If more than one docket or rulemaking number appears in the caption of this proceeding, filers must submit two additional copies for each additional docket or rulemaking number.

Filings can be sent by hand or messenger delivery, by commercial overnight courier, or by first-class or overnight U.S. Postal Service mail. All filings must be addressed to the Commission's Secretary, Office of the Secretary, Federal Communications Commission.

• All hand-delivered or messengerdelivered paper filings for the Commission's Secretary must be delivered to FCC Headquarters at 445 12th Street SW, TW-A325, Washington, DC 20554. The filing hours are 8:00 a.m. to 7:00 p.m. All hand deliveries must be held together with rubber bands or fasteners. Any envelopes and boxes must be disposed of *before* entering the building.

• Commercial overnight mail (other than U.S. Postal Service Express Mail and Priority Mail) must be sent to 9050 Junction Drive, Annapolis Junction, MD 20701.

• U.S. Postal Service first-class, Express, and Priority mail must be addressed to 445 12th Street SW, Washington, DC 20554. 24. Availability of Documents. Comments, reply comments, and ex parte submissions will be available for public inspection during regular business hours in the FCC Reference Center, Federal Communications Commission, 445 12th Street SW, CY– A257, Washington, DC 20554. These documents will also be available via ECFS. Documents will be available electronically in ASCII, Microsoft Word, and/or Adobe Acrobat.

25. *People with Disabilities.* 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 FCC's Consumer and Governmental Affairs Bureau at (202) 418–0530 (voice), (202) 418–0432 (TTY).

V. Ordering Clauses

26. Accordingly, *it is ordered* that, pursuant to the authority found in sections 303, 303b, 307, and 336 of the Communications Act of 1934, as amended, 47 U.S.C. 303, 303b, 307, and 336 this Notice of Proposed Rulemaking *is adopted*.

27. *It is further ordered* that the Commission's Consumer and Governmental Affairs Bureau, Reference Information Center, *shall send* a copy of this Notice of Proposed Rulemaking, including the Initial Regulatory Flexibility Analysis, to the Chief Counsel for Advocacy of the Small Business Administration.

List of Subjects in 47 CFR Parts 73 and 76

Reporting and recordkeeping requirements, Television, Cable television.

Federal Communications Commission. Marlene Dortch,

Secretary.

Proposed Rules

For the reasons discussed in the preamble, the Federal Communications Commission proposes to amend 47 CFR part 73 as follows:

PART 73—Radio Broadcast Services

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

Authority: 47 U.S.C. 154, 303, 334, 336, and 339.

■ 2. Amend § 73.671 by removing paragraphs (c)(3) and (4), redesignating paragraphs (c)(5) through (7) as paragraphs (c)(3) through (5), and revising redesignated paragraph (c)(3) to read as follows: §73.671 Educational and informational programming for children.

(c) * * *

*

*

(3) For commercial broadcast stations only, the program is identified as specifically designed to educate and inform children by the display on the television screen throughout the program of the symbol E/I; * *

■ 3. Amend § 73.671 by removing paragraph (d), redesignating paragraph (e) as paragraph (d), and revising redesignated paragraph (d) to read as follows:

§73.671 Educational and informational programming for children. *

(d) The Commission will apply the following processing guideline to digital stations in assessing whether a television broadcast licensee has complied with the Children's Television Act of 1990 ("CTA") on its digital channel(s). A digital television licensee that has aired at least three hours per week of Core Programming (as defined in paragraph (c) of this section and as averaged over a six month period) on its main program stream will be deemed to have satisfied its obligation to air such programming and shall have the CTA portion of its license renewal application approved by the Commission staff. The licensee may air all of the Core Programing on its main program stream or on another free program stream, or may distribute it across multiple free program streams, at its discretion. Licensees that do not meet this processing guidelines will have full opportunity to demonstrate compliance with the CTA and be eligible for such staff approval by relying in part on sponsorship of Core educational/informational programs on other stations in the market that increases the amount of Core educational and informational programming on the station airing the sponsored program and/or on special nonbroadcast efforts which enhance the value of children's educational and informational television programming. ■ 4. Amend 73.3526 by revising paragraph (e)(11)(iii) to read as follows:

§73.3526 Local public inspection file of commercial stations.

- (e) * * *
- (11) * * *
- (iii) Children's television

programming reports. For commercial TV broadcast stations on an annual basis, a completed Children's Television Programming Report ("Report"), on FCC Form 398, reflecting efforts made by the

licensee during the preceding year to serve the educational and informational needs of children. The Report is to be placed in the public inspection file by the tenth day of the succeeding calendar year. By this date, a copy of the Report is also to be filed electronically with the FCC. The Report shall identify the licensee's educational and informational programming efforts, including programs aired by the station that are specifically designed to serve the educational and informational needs of children, and it shall explain how programs identified as Core Programming meet the definition set forth in § 73.671(c). The Report shall include the name of the individual at the station responsible for collecting comments on the station's compliance with the Children's Television Act, and it shall be separated from other materials in the public inspection file. The Report shall also identify the program guide publishers to which information regarding the licensee's educational and informational programming was provided as required in §73.673, as well as the station's license renewal date. These Reports shall be retained in the public inspection file until final action has been taken on the station's next license renewal application. * * * *

[FR Doc. 2018-15819 Filed 7-24-18; 8:45 am] BILLING CODE 6712-01-P

DEPARTMENT OF THE INTERIOR

Fish and Wildlife Service

50 CFR Part 17

[Docket No. FWS-HQ-ES-2018-0007; 4500030113]

RIN 1018-BC97

Endangered and Threatened Wildlife and Plants; Revision of the **Regulations for Prohibitions to** Threatened Wildlife and Plants

AGENCY: Fish and Wildlife Service, Interior.

ACTION: Proposed rule.

SUMMARY: We, the U.S. Fish and Wildlife Service, propose to revise our regulations extending most of the prohibitions for activities involving endangered species to threatened species. For species already listed as a threatened species, the proposed regulations would not alter the applicable prohibitions. The proposed regulations would require the Service, pursuant to section 4(d) of the

Endangered Species Act, to determine what, if any, protective regulations are appropriate for species that the Service in the future determines to be threatened.

DATES: We will accept comments received or postmarked on or before September 24, 2018. Comments submitted electronically using the Federal eRulemaking Portal (see ADDRESSES below) must be received by 11:59 p.m. Eastern Time on the closing date.

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

(1) Electronically: Go to the Federal eRulemaking Portal: http:// www.regulations.gov. In the Search box, enter FWS-HQ-ES-2018-0007, which is the docket number for this rulemaking. Then, in the Search panel on the left side of the screen, under the Document Type heading, click on the Proposed Rules link to locate this document. You may submit a comment by clicking on "Comment Now!"

(2) By hard copy: Submit by U.S. mail or hand-delivery to: Public Comments Processing, Attn: FWS-HQ-ES-2018-0007; U.S. Fish and Wildlife Service, MS: BPHC, 5275 Leesburg Pike, Falls Church, VA 22041-3803.

We request that you send comments only by the methods described above. We will post all comments on http:// *www.regulations.gov.* This generally means that we will post any personal information you provide us (see Request for Information, below, for more information).

FOR FURTHER INFORMATION CONTACT:

Bridget Fahey, U.S. Fish and Wildlife Service, Division of Conservation and Classification, 5275 Leesburg Pike, Falls Church, VA 22041-3803, telephone 703/358–2171. If you use a telecommunications device for the deaf (TDD), call the Federal Relay Service at 800/877-8339.

SUPPLEMENTARY INFORMATION:

Background

The Endangered Species Act of 1973, as amended ("ESA" or "Act"; 16 U.S.C. 1531 *et seq.*), states that the purposes of the Act are to provide a means to conserve the ecosystems upon which listed species depend, to develop a program for the conservation of listed species, and to achieve the purposes of certain treaties and conventions. Moreover, the Act states that it is the policy of Congress that the Federal Government will seek to conserve threatened and endangered species and use its authorities to further the purposes of the Act. This proposed rulemaking action pertains primarily to

sections 4 and 9 of the Act: Section 9 sets forth prohibitions for activities pertaining to species listed under the Act, and section 4(d) pertains to protective regulations for threatened species.

This proposed rule is one of three related proposed rules that are publishing in today's **Federal Register**. All of these documents propose revisions to various regulations that implement the ESA.

In carrying out Executive Order 13777, "Enforcing the Regulatory Reform Agenda," the Department of the Interior (DOI) published a document with the title "Regulatory Reform" in the Federal Register of June 22, 2017 (82 FR 28429). The document requested public comment on how DOI can improve implementation of regulatory reform initiatives and policies and identify regulations for repeal, replacement, or modification. This proposed rule and the two related proposed rules in today's Federal **Register** address some of the comments that DOI has received in response to the regulatory reform docket.

Proposed Changes to Part 17

The regulations that implement the ESA are located in title 50 of the Code of Federal Regulations. This proposed rule would revise regulations found in part 17 of title 50, particularly in subpart D, which pertains to threatened wildlife, and subpart G, which pertains to threatened plants.

We propose to amend §§ 17.31 and 17.71, along with conforming amendments to other sections of title 50. Among other changes, the proposal would add language in both sections to paragraph (a) to specify that its provisions apply only to species listed as threatened species on or before the effective date of this rule. Species listed or reclassified as a threatened species after the effective date of this rule, if finalized, would have protective regulations only if the Service promulgates a species-specific rule (also referred to as a special rule). In those cases, we intend to finalize the speciesspecific rule concurrent with the final listing or reclassification determination. Notwithstanding our intention, we have discretion to revise or promulgate species-specific rules at any time after the final listing or reclassification determination. However, we specifically request comments on our stated intention of finalizing species-specific rules concurrent with final listing rules, including whether we should include any binding requirement in the regulatory text to do so, such as setting a timeframe for finalizing speciesspecific rules after a final listing or reclassification determination.

This change would make our regulatory approach for threatened species parallel with the approach that the National Marine Fisheries Service (NMFS) has taken since Congress added section 4(d) to the Act, as discussed below. The protective regulations that currently apply to threatened species would not change, unless the Service adopts a species-specific rule in the future. As of the date of this proposal, there are species-specific protective regulations for threatened wildlife in subpart D of part 17, but the Service has not adopted any species-specific protective regulations for plants. The proposed regulations would not affect the consultation obligations of Federal agencies pursuant to section 7 of the Act. The proposed regulations would not change permitting pursuant to 50 CFR 17.32.

The prohibitions set forth in ESA Section 9 expressly apply only to species listed as endangered under the Act, as opposed to threatened. 16 U.S.C. 1538(a). ESA Section 4(d), however, provides that the Secretaries may by regulation extend some or all of the Section 9 prohibitions to any species listed as threatened. Id. § 1533(d). 16 U.S.C. 1533(d). See, also S. Rep. 93-307 (July 1, 1973) (in amending the ESA to include the protection of threatened species and creating "two levels of protection" for endangered species and threatened species, "regulatory mechanisms may more easily be tailored to the needs of the" species). Our existing regulations in §§ 17.31 and 17.71, extending most of the prohibitions for endangered species to threatened species unless altered by a specific regulation, is one reasonable approach to exercising the discretion granted to the Service by section 4(d) of the Act. See Sweet Home Chapter of Communities for a Great Or. v. Babbitt, 1 F.3d 1, 7 (D.C. Cir. 1993) ("regardless of the ESA's overall design, § 1533(d) arguably grants the FWS the discretion to extend the maximum protection to all threatened species at once, if guided by its expertise in the field of wildlife protection, it finds it expeditious to do so"), altered on other grounds in rehearing, 17 F.3d 1463 (D.C. Cir. 1994).

Another reasonable approach is the one that the Department of Commerce, through NMFS, has taken in regard to the species under its purview. NMFS did not adopt regulations that extended most of the prohibitions for endangered species to threatened species as we did. Rather, for each species that they list as threatened, NMFS promulgates the appropriate regulations to put in place prohibitions, protections, or restrictions tailored specifically to that species. In more than 40 years of implementing the Act, NMFS has successfully implemented the provisions of the Act using this approach.

Moreover, we have gained considerable experience in developing species-specific rules over the years. Where we have developed speciesspecific 4(d) rules, we have seen many benefits, including removing redundant permitting requirements, facilitating implementation of beneficial conservation actions, and making better use of our limited personnel and fiscal resources by focusing prohibitions on the stressors contributing to the threatened status of the species. This revision allows us to capitalize on these benefits in tailoring the regulations to the conservation needs of the species.

For example, we finalized a speciesspecific 4(d) rule for the coastal California gnatcatcher (*Polioptila* californica californica) on December 10, 1993 (58 FR 65088). In that 4(d) rule, we determined that activities that met the requirements of the State of California's Natural Communities Conservation Plan for the protection of coastal sage scrub habitat would not constitute violations of section 9 of the Act. Similarly, in 2016, we finalized the listing of the Kentucky arrow darter (Etheostoma *spilotum*) with a species-specific 4(d) rule that exempts take as a result of beneficial in-stream habitat enhancement projects, bridge and culvert replacement, and maintenance of stream crossings on lands managed by the U.S. Forest Service in habitats occupied by the species (81 FR 68963, October 5, 2016). As with both of these examples, if the proposed rule is finalized, we would continue our practice of explaining in the preamble the rationale for the species-specific prohibitions included in each 4(d) rule.

Upon reviewing the approach NMFS has taken and in light of the benefits we have noted in developing speciesspecific rules, we now conclude these proposed changes will align our practices with those of NMFS regarding threatened species under Department of Commerce purview, but also that they will better tailor protections to the needs of the threatened species while still providing meaning to the statutory distinction between "endangered species" and "threatened species."

The proposed regulations would remove the references to subpart A in § 17.31 and § 17.71. In § 17.31, we propose to specify which sections apply to wildlife, to be more transparent as to which provisions contain exceptions to the prohibitions. In § 17.71, we propose 35176

to remove all reference to subpart A, because none of those exceptions apply to plants.

In proposing the specific changes to the regulations that follow, and setting out the accompanying clarifying discussion in this preamble, the Service is establishing prospective standards only. Nothing in these proposed revised regulations is intended to require (now or at such time as these regulations may become final) that any previous listing, delisting, or reclassification determinations or species-specific protective regulations be reevaluated on the basis of any final regulations. The existing protections for currently-listed threatened species are within the discretion expressly delegated to the Secretary by Congress.

Pursuant to section 10(j) of the Act, members of experimental populations are generally treated as threatened species and, pursuant to 50 CFR 17.81, populations are designated through population-specific regulation found in §§ 17.84–17.86. As under our existing practice, each such population-specific regulation will contain all of the applicable prohibitions, along with any exceptions to prohibitions, for that experimental population. None of the changes associated with this rulemaking will change existing special rules for experimental populations. Any 10(j) special rules promulgated after the effective date of this rule which make applicable to a non-essential experimental population some or all of the prohibitions that statutorily apply to endangered species will not refer to 50 CFR 17.31(a); rather, they will instead independently articulate those prohibitions or refer to 50 CFR 17.21.

Request for Information

Any final rule based on this proposal will consider information and recommendations timely submitted from all interested parties. We solicit comments, information, and recommendations from governmental agencies, Native American tribes, the scientific community, industry groups, environmental interest groups, and any other interested parties on this proposed rule. All comments and materials received by the date listed in **DATES**, above, will be considered prior to the approval of a final rule.

You may submit your information concerning this proposed rule by one of the methods listed in **ADDRESSES**. If you submit information via *http:// www.regulations.gov*, your entire submission—including any personal identifying information—will be posted on the website. If your submission is made via a hardcopy that includes personal identifying information, you may request at the top of your document that we withhold this personal identifying information from public review. However, we cannot guarantee that we will be able to do so. We will post all hardcopy submissions on *http:// www.regulations.gov.*

Information and supporting documentation that we receive in response to this proposed rule will be available for you to review at *http:// www.regulations.gov* in Docket No. FWS-HQ-ES-2018-0007.

Required Determinations

Regulatory Planning and Review (Executive Orders 12866 and 13563)

Executive Order 12866 provides that the Office of Management and Budget's Office of Information and Regulatory Affairs (OIRA) will review all significant rules. OIRA has determined that this rule is significant.

Executive Order 13563 reaffirms the principles of E.O. 12866 while calling for improvements in the nation's regulatory system to promote predictability, to reduce uncertainty, and to use the best, most innovative, and least burdensome tools for achieving regulatory ends. The executive order directs agencies to consider regulatory approaches that reduce burdens and maintain flexibility and freedom of choice for the public where these approaches are relevant, feasible, and consistent with regulatory objectives. E.O. 13563 emphasizes further that regulations must be based on the best available science and that the rulemaking process must allow for public participation and an open exchange of ideas. We have developed this rule in a manner consistent with these requirements. This proposed rule is consistent with Executive Order 13563, and in particular with the requirement of retrospective analysis of existing rules, designed "to make the agency's regulatory program more effective or less burdensome in achieving the regulatory objectives."

Executive Order 13771

This proposed rule is expected to be an Executive Order 13771 deregulatory action.

Regulatory Flexibility Act

Under the Regulatory Flexibility Act (as amended by the Small Business Regulatory Enforcement Fairness Act (SBREFA) of 1996; 5 U.S.C. 601 *et seq.*), whenever a Federal agency is required to publish a notice of rulemaking for any proposed or final rule, it must prepare, and make available for public

comment, a regulatory flexibility analysis that describes the effect of the rule on small entities (*i.e.*, small businesses, small organizations, and small government jurisdictions). However, no regulatory flexibility analysis is required if the head of an agency, or his designee, certifies that the rule will not have a significant economic impact on a substantial number of small entities. SBREFA amended the Regulatory Flexibility Act to require Federal agencies to provide a statement of the factual basis for certifying that a rule will not have a significant economic impact on a substantial number of small entities. We certify that, if adopted as proposed, this proposed rule would not have a significant economic effect on a substantial number of small entities. The following discussion explains our rationale.

This rulemaking revises the regulations for 4(d) rules for species determined to meet the definition of a "threatened species" under the Act. The changes in this proposed rule are instructive regulations and do not affect small entities.

The Service is the only entity that is directly affected by this proposed regulation change at 50 CFR part 17 because we are the only entity that is affected by changes to this section of the Code of Federal Regulations. No external entities, including any small businesses, small organizations, or small governments, will experience any economic impacts from this rule. Consequently, this proposed rulemaking action is not a major rule under SBREFA.

Unfunded Mandates Reform Act (2 U.S.C. 1501 et seq.)

In accordance with the Unfunded Mandates Reform Act (2 U.S.C. 1501 *et seq.*):

(a) On the basis of information contained in the Regulatory Flexibility Act section above, this proposed rule would not "significantly or uniquely" affect small governments. We have determined and certify pursuant to the Unfunded Mandates Reform Act, 2 U.S.C. 1502, that this rule would not impose a cost of \$100 million or more in any given year on local or State governments or private entities. A Small Government Agency Plan is not required. As explained above, small governments would not be affected because the proposed rule would not place additional requirements on any city, county, or other local municipalities.

(b) This proposed rule would not produce a Federal mandate on State,

local, or tribal governments or the private sector of \$100 million or greater in any year; that is, this proposed rule is not a "significant regulatory action" under the Unfunded Mandates Reform Act. This proposed rule would impose no obligations on State, local, or tribal governments.

Takings (E.O. 12630)

In accordance with Executive Order 12630, this proposed rule would not have significant takings implications. This proposed rule would not pertain to "taking" of private property interests, nor would it directly affect private property. A takings implication assessment is not required because this proposed rule (1) would not effectively compel a property owner to suffer a physical invasion of property and (2) would not deny all economically beneficial or productive use of the land or aquatic resources. This proposed rule would substantially advance a legitimate government interest (conservation and recovery of endangered and threatened species) and would not present a barrier to all reasonable and expected beneficial use of private property.

Federalism (E.O. 13132)

In accordance with Executive Order 13132, we have considered whether this proposed rule would have significant Federalism effects and have determined that a federalism summary impact statement is not required. This proposed rule pertains only to prohibitions for activities pertaining to threatened species under the Endangered Species Act and would not have substantial direct effects on the States, on the relationship between the Federal Government and the States, or on the distribution of power and responsibilities among the various levels of government.

Civil Justice Reform (E.O. 12988)

This proposed rule does not unduly burden the judicial system and meets the applicable standards provided in sections 3(a) and 3(b)(2) of Executive Order 12988. This proposed rule would clarify the prohibitions to threatened species under the Endangered Species Act.

Government-to-Government Relationship With Tribes

In accordance with the President's memorandum of April 29, 1994, "Government-to-Government Relations with Native American Tribal Governments" (59 FR 22951), Executive Order 13175, and the Department of the Interior's manual at 512 DM 2, we readily acknowledge our responsibility to communicate meaningfully with recognized Federal Tribes on a government-to-government basis.

Paperwork Reduction Act

This rule does not contain information collection requirements, and a submission to the Office of Management and Budget (OMB) under the Paperwork Reduction Act of 1995 (44 U.S.C. 3501–3520) is not required. 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.

National Environmental Policy Act

We are analyzing this proposed regulation in accordance with the criteria of the National Environmental Policy Act (NEPA), the Department of the Interior regulations on Implementation of the National Environmental Policy Act (43 CFR 46.10–46.450), and the Department of the Interior Manual (516 DM 8).

We anticipate that the categorical exclusion found at 43 CFR 46.210(i) likely applies to these proposed regulation changes. At 43 CFR 46.210(i), the Department of the Interior has found that the following category of actions would not individually or cumulatively have a significant effect on the human environment and are, therefore, categorically excluded from the requirement for completion of an environmental assessment or environmental impact statement: "Policies, directives, regulations, and guidelines: that are of an administrative, financial, legal, technical, or procedural nature."

We invite the public to comment on the extent to which this proposed regulation may have a significant impact on the human environment, or fall within one of the categorical exclusions for actions that have no individual or cumulative effect on the quality of the human environment. We will complete our analysis, in compliance with NEPA, before finalizing this proposed rule.

Energy Supply, Distribution or Use (E.O. 13211)

Executive Order 13211 requires agencies to prepare Statements of Energy Effects when undertaking certain actions. This proposed rule, if made final, is not expected to affect energy supplies, distribution, and use. Therefore, this action is not a significant energy action, and no Statement of Energy Effects is required.

Clarity of the Rule

We are required by Executive Orders 12866 and 12988 and by the Presidential Memorandum of June 1, 1998, to write all rules in plain language. This means that each rule we publish must:

(1) Be logically organized;

(2) Use the active voice to address readers directly;

(3) Use clear language rather than jargon;

(4) Be divided into short sections and sentences; and

(5) Use lists and tables wherever possible.

If you feel that we have not met these requirements, send us comments by one of the methods listed in **ADDRESSES**. To better help us revise the rule, your comments should be as specific as possible. For example, you should tell us the numbers of the sections or paragraphs that are unclearly written, which sections or sentences are too long, the sections where you feel lists or tables would be useful, etc.

List of Subjects in 50 CFR Part 17

Endangered and threatened species, Exports, Imports, Reporting and recordkeeping requirements, Transportation.

Proposed Regulation Promulgation

Accordingly, we hereby propose to amend part 17, subchapter B of chapter I, title 50 of the Code of Federal Regulations, as set forth below:

PART 17—ENDANGERED AND THREATENED WILDLIFE AND PLANTS

• . 1. The authority citation for part 17 continues to read as follows:

Authority: 16 U.S.C. 1361–1407; 1531– 1544; and 4201–4245, unless otherwise noted.

■ . 2. Revise § 17.31 to read as follows:

§17.31 Prohibitions.

(a) Except as provided in §§ 17.4 through 17.8, or in a permit issued under this subpart, all of the provisions of § 17.21, except § 17.21(c)(5), shall apply to threatened species of wildlife that were added to the List of Endangered and Threatened Wildlife in § 17.11(h) on or prior to [EFFECTIVE DATE OF THE FINAL RULE], unless the Secretary has promulgated species-specific provisions (see paragraph (c) of this section).

(b) In addition to any other provisions of this part 17, any employee or agent of the Service, of the National Marine Fisheries Service, or of a State conservation agency that is operating a conservation program pursuant to the terms of a cooperative agreement with the Service in accordance with section 6(c) of the Act, who is designated by that agency for such purposes, may, when acting in the course of official duties, take those threatened species of wildlife that are covered by an approved cooperative agreement to carry out conservation programs.

(c) Whenever a species-specific rule in §§ 17.40 through 17.48 applies to a threatened species, none of the provisions of paragraphs (a) and (b) of this section will apply. The speciesspecific rule will contain all the applicable prohibitions and exceptions.

■ 3. Revise § 17.71 to read as follows:

§17.71 Prohibitions.

(a) Except as provided in a permit issued under this subpart, all of the provisions of § 17.61 shall apply to threatened species of plants that were added to the List of Endangered and Threatened Plants in § 17.12(h) on or prior to [EFFECTIVE DATE OF THE FINAL **RULE**], with the following exception: Seeds of cultivated specimens of species treated as threatened shall be exempt from all the provisions of § 17.61, provided that a statement that the seeds are of "cultivated origin" accompanies the seeds or their container during the course of any activity otherwise subject to these regulations.

(b) In addition to any provisions of this part 17, any employee or agent of the Service or of a State conservation agency that is operating a conservation program pursuant to the terms of a cooperative agreement with the Service in accordance with section 6(c) of the Act, who is designated by that agency for such purposes, may, when acting in the course of official duties, remove and reduce to possession from areas under Federal jurisdiction those threatened species of plants that are covered by an approved cooperative agreement to carry out conservation programs.

(c) Whenever a species-specific rule in §§ 17.73 through 17.78 applies to a threatened species, the species-specific rule will contain all the applicable prohibitions and exceptions.

Dated: July 18, 2018.

Ryan K. Zinke,

Secretary, Department of the Interior. [FR Doc. 2018–15811 Filed 7–24–18; 8:45 am] BILLING CODE 4333–15–P

DEPARTMENT OF THE INTERIOR

Fish and Wildlife Service

DEPARTMENT OF COMMERCE

National Oceanic and Atmospheric Administration

50 CFR Part 402

[Docket No. FWS-HQ-ES-2018-0009; FXES11140900000-189-FF09E300000; Docket No. 180207140-8140-01; 4500090023]

RIN 1018-BC87; 0648-BH41

Endangered and Threatened Wildlife and Plants; Revision of Regulations for Interagency Cooperation

AGENCY: U.S. Fish and Wildlife Service (FWS), Interior; National Marine Fisheries Service (NMFS), National Oceanic and Atmospheric Administration (NOAA), Commerce. **ACTION:** Proposed rule.

SUMMARY: We, FWS and NMFS (collectively referred to as the "Services" or "we"), propose to amend portions of our regulations that implement section 7 of the Endangered Species Act of 1973, as amended. The Services are proposing these changes to improve and clarify the interagency consultation processes and make them more efficient and consistent.

DATES: We will accept comments from all interested parties until September 24, 2018. Please note that if you are using the Federal eRulemaking Portal (see **ADDRESSES** below), the deadline for submitting an electronic comment is 11:59 p.m. Eastern Standard Time on this date.

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

(1) *Electronically*: Go to the Federal eRulemaking Portal: *http:// www.regulations.gov*. In the Search box, enter FWS-HQ-ES-2018-0009, which is the docket number for this rulemaking. Then, in the Search panel on the left side of the screen, under the Document Type heading, click on the Proposed Rules link to locate this document. You may submit a comment by clicking on "Comment Now!"

(2) *By hard copy:* Submit by U.S. mail or hand-delivery to: Public Comments Processing, Attn: FWS–HQ–ES–2018– 0009; U.S. Fish and Wildlife Service, MS: BPHC, 5275 Leesburg Pike, Falls Church, VA 22041–3803 or National Marine Fisheries Service, Office of Protected Resources, 1315 East-West Highway, Silver Spring, MD 20910.

We request that you send comments only by the methods described above. We will post all comments on *http://www.regulations.gov*. This generally means that we will post any personal information you provide us (see Request for Information below for more information).

FOR FURTHER INFORMATION CONTACT:

Craig Aubrey, U.S. Fish and Wildlife Service, Division of Environmental Review, 5275 Leesburg Pike, Falls Church, VA 22041–3803, telephone 703/358–2442; or Cathy Tortorici, ESA Interagency Cooperation Division, Office of Protected Resources, 1315 East-West Highway, Silver Spring, MD 20910, telephone 301/427–8495. If you use a telecommunications device for the deaf (TDD), call the Federal Relay Service at 800–877–8339.

SUPPLEMENTARY INFORMATION:

Background

The purposes of the Endangered Species Act of 1973, as amended ("ESA" or "Act"; 16 U.S.C. 1531 *et seq.*) are to provide a means to conserve the ecosystems upon which listed species depend, to develop a program for the conservation of listed species, and to achieve the purposes of certain treaties and conventions. Moreover, the Act states that it is the policy of Congress that the Federal Government will seek to conserve threatened and endangered species, and use its authorities in furtherance of the purposes of the Act.

The Secretaries of the Interior and Commerce share responsibilities for implementing most of the provisions of the Act. Generally, marine species are under the jurisdiction of the Secretary of Commerce, and all other species are under the jurisdiction of the Secretary of the Interior. Authority to administer the Act has been delegated by the Secretary of the Interior to the Director of the U.S. Fish and Wildlife Service (FWS) and by the Secretary of Commerce to the Assistant Administrator for the National Marine Fisheries Service (NMFS). References in this document to "the Services" mean FWS and NMFS.

There have been no comprehensive amendments to the Act since 1988, and no comprehensive revisions to the implementing regulations since 1986. In the years since those changes took place, much has happened: The Services have gained considerable experience in implementing the Act, as have other Federal agencies, States, and property owners; there have been numerous court decisions regarding almost every provision of the Act and its implementing regulations; the Government Accountability Office has completed reviews of the Act's implementation; there have been many

scientific reviews, including review by the National Research Council; multiple administrations have adopted various policy initiatives; and nongovernmental entities have issued reports and recommendations.

Title 50, part 402, of the Code of Federal Regulations establishes the procedural regulations governing interagency cooperation under section 7 of the Act, which requires Federal agencies, in consultation with and with the assistance of the Secretaries of the Interior and Commerce (the "Secretaries"), to insure that any action authorized, funded, or carried out by such agencies is not likely to jeopardize the continued existence of endangered or threatened species or result in the destruction or adverse modification of critical habitat of such species. These proposed regulatory amendments are intended to address the Services' collective experience of more than 40 years implementing the Act and several court decisions.

In carrying out Executive Order 13777, "Enforcing the Regulatory Reform Agenda," the Department of the Interior (DOI) published a document with the title "Regulatory Reform" in the Federal Register of June 22, 2017 (82 FR 28429). The document requested public comment on how DOI can improve implementation of regulatory reform initiatives and policies and identify regulations for repeal, replacement, or modification. This proposed rule addresses some of the comments that DOI has received in response to the regulatory reform docket.

As part of implementing E.O. 13777, NOAA published a notice entitled, "Streamlining Regulatory Processes and Reducing Regulatory Burden" (82 FR 31576, July 7, 2017). The notice requested public comments on how NOAA could continue to improve the efficiency and effectiveness of current regulations and regulatory processes. This proposed rule addresses some of the comments NOAA received from the public.

This proposed rule is one of three related proposed rules that are publishing in today's **Federal Register**. All of these documents propose revisions to various regulations that implement the Act. Beyond the specific revisions to the regulations highlighted in this proposed rule, the Services are comprehensively reconsidering the processes and interpretations of statutory language set out in part 402. Thus, this rulemaking should be considered as applying to all of part 402, and as part of the rulemaking initiated today, the Services will

consider whether additional modifications to the interagency cooperation regulations would improve, clarify, or streamline the administration of the Act. We seek public comments recommending, opposing, or providing feedback on specific changes to any provisions in part 402 of the regulations, including but not limited to revising or adopting as regulations existing practices or policies, or interpreting terms or phrases from the Act. Based on comments received and on our experience in administering the Act, the final rule may include revisions to any provisions in part 402 that are a logical outgrowth of this proposed rule, consistent with the Administrative Procedure Act.

In proposing the specific changes to the regulations in this rule, and setting out the accompanying clarifying discussion in this preamble, the Services are proposing prospective standards only. Nothing in these proposed revisions to the regulations is intended to require that any previous consultations under section 7(a)(2) of the Act be reevaluated on the basis of the final rule at such time that the final rule becomes effective.

The Services anticipate that the proposed changes, if finalized, will improve and clarify interagency consultation, and make it more efficient and consistent, without compromising conservation of listed species. Many of the changes should help reduce the costs of consultation. For example, clarifying the definition of "effects of the action" should decrease consultation timeframes (and costs) by eliminating confusion regarding application of terms in the existing definition, which has resulted in time being spent determining how to categorize an effect, rather than simply determining what the effects are regardless of category. As another example, codifying alternative consultation methods and the ability to adopt portions of Federal agencies' documents should reduce overall consultation times and costs. Increased use of programmatic consultations will reduce the number of single, project-byproject consultations, streamline the consultation process, and increase predictability and consistency for action agencies. Eliminating the need to reinitiate consultation in certain situations will avoid impractical and disruptive burdens (and costs), without compromising conservation of listed species. We seek comment on (1) the extent to which the changes outlined in this proposed rule will affect timeframes and resources needed to conduct

consultation and (2) anticipated cost savings resulting from the changes.

While not reflected in any proposed changes to our regulations at this time, we also seek comment on the merit, authority, and means for the Services to conduct a single consultation, resulting in a single biological opinion, for Federal agency actions affecting species that are under the jurisdiction of both FWS and NMFS.

Proposed Changes to 50 CFR Part 402

Section 402.02 Definitions

This section sets out definitions of terms that are used throughout these proposed regulations. Some of these terms are further discussed as they pertain to the consultation procedures in appropriate, subsequent sections. Below we discuss those definitions that would be revised or added by these proposed regulations.

Definition of Destruction or Adverse Modification

We propose to revise the definition of "destruction or adverse modification" by adding the phrase "as a whole" to the first sentence and removing the second sentence of the current definition. The Act requires Federal agencies, in consultation with and with the assistance of the Secretaries, to insure that their actions are not likely to jeopardize the continued existence of endangered or threatened species or result in the destruction or adverse modification of critical habitat of such species. In 1986, the Services established a definition for "destruction or adverse modification" (§ 402.02) that was found to be invalid by the U.S. Court of Appeals for the Fifth (2001) and Ninth (2004) Circuits. In 2016, we revised the definition, in part in response to these court rulings. We now propose to further clarify the definition, removing language that is redundant and has caused confusion about the meaning of the regulation.

Background of the Definition of "Destruction or Adverse Modification"

In 1978, the Services promulgated regulations governing interagency cooperation under section 7 of the Act. (50 CFR part 402) (43 FR 870; Jan. 4, 1978). These regulations provided a definition for "destruction or adverse modification" of critical habitat, which was later updated in 1986 to conform with amendments made to the Act. The 1986 regulations defined "destruction or adverse modification" as: "a direct or indirect alteration that appreciably diminishes the value of critical habitat for both the survival and recovery of a listed species. Such alterations include, but are not limited to, alterations adversely modifying any of those physical or biological features that were the basis for determining the habitat to be critical." (50 CFR 402.02) (51 FR 19926; June 3, 1986). The preamble to the 1986 regulation contained relatively little discussion on the concept of "destruction or adverse modification of critical habitat."

In 2001, the Fifth Circuit Court of Appeals reviewed the 1986 regulatory definition of destruction or adverse modification and found it exceeded the Service's discretion. Sierra Club v. U.S. Fish and Wildlife Service, 245 F.3d 434 (5th Cir. 2001). Specifically, the court found the regulatory definition to be invalid on its face and inconsistent with the Act. The court reasoned that the regulatory definition set too high a threshold for triggering adverse modification by its requirement that the value of critical habitat for both survival and recovery be appreciably diminished before adverse modification would be the appropriate conclusion. The court determined that the regulatory definition actually established a standard that would only trigger an adverse modification determination if the "survival" of the species was appreciably diminished, while ignoring the role critical habitat plays in the recovery of species. Citing legislative history and the Act itself, the court was persuaded that Congress intended the Act to "enable listed species not merely to survive, but to recover from their endangered or threatened status." Sierra Club, 245 F.3d at 438. Noting the Act defines critical habitat as areas that are "essential to the conservation" of listed species, the court determined that "conservation" is a "much broader concept than mere survival." Sierra Club, 245 F.3d at 441. The court concluded that the Act's definition of conservation "speaks to the recovery" of listed species.

In 2004, the Ninth Circuit Court of Appeals also reviewed the 1986 regulatory definition of destruction or adverse modification. Gifford Pinchot Task Force v. U.S. Fish and Wildlife Service, 378 F.3d 1059 (9th Cir. 2004). That court agreed with the Fifth Circuit's determination that the regulation was facially invalid. The Ninth Circuit, following similar reasoning set out in Sierra Club, determined that Congress viewed conservation and survival as "distinct, though complementary, goals and the requirement to preserve critical habitat is designed to promote both conservation and survival." Specifically, the court found that "the

purpose of establishing 'critical habitat' is for the government to [designate habitat] that is not only necessary for the species' survival but also essential for the species' recovery." *Gifford Pinchot Task Force*, 378 F.3d at 1070.

After the Ninth Circuit's decision, the Services each issued guidance to discontinue the use of the 1986 adverse modification regulation (FWS Acting Director Marshall Jones Memorandum to Regional Directors, "Application of the 'Destruction or Adverse Modification' Standard under Section 7(a)(2) of the Endangered Species Act 2004" (FWS 2004); NMFS Assistant Administrator William T. Hogarth Memorandum to Regional Administrators, "Application of the 'Destruction or Adverse Modification' Standard under Section 7(a)(2) of the Endangered Species Act, 2005" (NMFS 2005)). Specifically, in evaluating a proposed action's effects on critical habitat as part of interagency consultation, the Services began applying the definition of "conservation" as set out in the Act, which defines conservation (and conserve and conserving) to mean "to use and the use of all methods and procedures which are necessary to bring any endangered species or threatened species to the point at which the measures provided pursuant to this [Act] are no longer necessary." (16 U.S.C. 1532(3)) (*i.e.*, the species is recovered). See 50 CFR 424.02. Accordingly, after examining the status of critical habitat, the environmental baseline, and the effects of the proposed action, the Services began analyzing whether the implementation of the proposed action, together with any cumulative effects, would result in the critical habitat remaining "functional (or retain the current ability for the primary constituent elements to be functionally established) to serve the intended conservation role for the species." See FWS 2004; NMFS 2005.

In 2016, we promulgated regulations to revise the regulatory definition of "destruction or adverse modification." We adopted the following definition: "Destruction or adverse modification means a direct or indirect alteration that appreciably diminishes the value of critical habitat for the conservation of a listed species. Such alterations may include, but are not limited to, those that alter the physical or biological features essential to the conservation of a species or that preclude or significantly delay development of such features." (81 FR 7214, February 11, 2016).

We explained in the 2016 rule that we did not intend for it to alter the section

7(a)(2) consultation process from existing practice and noted that previously completed biological opinions did not need to be reevaluated in light of that rule. The 2016 definition, particularly the first sentence, sought to clarify and preserve the existing distinction between the definitions of "destruction or adverse modification" and "jeopardize the continued existence of" by focusing the analysis for "destruction or adverse modification" on how the effects of a proposed action affect the value of critical habitat as a whole for the conservation of threatened or endangered species. The focus of the "jeopardize the continued existence of" definition, on the other hand, is whether a proposed action appreciably reduces the likelihood of survival and recovery by reducing a species' reproduction, numbers, and distribution.

The 2016 final rule's definition reflected several changes from what the Services proposed in 2014. The changes to the first sentence were relatively minor. In the 2014 proposed rule, the first sentence read: "Destruction or adverse modification' means a direct or indirect alteration that appreciably diminishes the conservation value of critical habitat for listed species." (79 FR 27060, 27066; May 12, 2014). In the final rule, we made a minor clarification of the first sentence, by changing "conservation value of critical habitat for listed species" to "the value of critical habitat for the conservation of a listed species." (81 FR at 7226, February 11. 2016).

Many commenters of the 2014 proposed rule expressed confusion or concern regarding the scale at which the determination of destruction or adverse modification of critical habitat is made. Some of these commenters thought that the language, "critical habitat, as a whole," should be included in the definition and not just the preamble. While the Services declined to include the phrase "as a whole" in the 2016 final definition, we explained in the preamble that we make our determination on the value of the critical habitat and its role in the conservation of the species, and that the existing consultation process already ensures that the determination is made at the appropriate scale. We also explained that, while an action may result in adverse effects to critical habitat within the action area, those effects may not necessarily rise to the level of destruction or adverse modification to the designated critical habitat. In adding the phrase "as a whole" to the proposed revised definition, we intend to clearly indicate that the final destruction or adverse

modification determination is made at the scale of the entire critical habitat designation. Smaller scales can be very important analysis tools in determining how the impacts may translate to the entire designated critical habitat, but the final determination is not made at the action area, critical habitat unit, or other less extensive scale.

The analysis thus places an emphasis on the value of the designated critical habitat as a whole for the conservation of a species, in light of the role the action area serves with regard to the function of the overall designation. Just as the determination of jeopardy under section 7(a)(2) of the Act is made at the scale of the entire listed entity, a determination of destruction or adverse modification is made at the scale of the entire critical habitat designation. Even if a particular project would cause adverse effects to a portion of critical habitat, the Services must place those impacts in context of the designation to determine if the overall value of the critical habitat is likely to be reduced. This could occur where, for example, a smaller affected area of habitat is particularly important in its ability to support the conservation of a species (e.g., a primary breeding site). Thus, the size or proportion of the affected area is not determinative; impacts to a smaller area may in some cases result in a determination of destruction or adverse modification, while impacts to a large geographic area will not always result in such a finding. Therefore, we are proposing to revise the first sentence of the definition by adding the phrase "as a whole" to clarify the appropriate scale of the destruction or adverse modification determination.

The second sentence proved more controversial. As proposed, the second sentence of the definition read: "Such alterations may include, but are not limited to, effects that preclude or significantly delay the development of the physical or biological features that support the life-history needs of the species for recovery." (79 FR at 27066, May 12, 2014). Many commenters argued that the proposed second sentence established a significant change in practice by appearing to focus the definition on the preclusion or delay of the development of physical or biological features, to the exclusion of the alteration of existing features. A number of commenters believed these concepts were vague, undefined, and allowed for arbitrary determinations. One commenter asserted that focusing on effects that preclude or significantly delay development of features was an expansion of authority that conflicted with E.O. 13604 (Improving

Performance of Federal Permitting and Review of Infrastructure Projects).

In an attempt to clarify our intent, in finalizing the rule, we revised the proposed second sentence to add reference to alterations affecting the physical or biological features essential to the conservation of a species, as well as those that preclude or significantly delay development of such features: "Such alterations may include, but are not limited to, those that alter the physical or biological features essential to the conservation of a species or that preclude or significantly delay development of such features." (81 FR at 7226, February 11, 2016).

The intended purpose of the language about precluding or delaying "development of such features" was to acknowledge "that some important physical or biological features may not be present or are present in a suboptimal quantity or quality. This could occur where, for example, the habitat has been degraded by human activity or is part of an ecosystem adapted to a particular natural disturbance (e.g., fire or flooding), which does not constantly occur but is likely to recur." (79 FR at 27061, May 12, 2014). Our intent was for such determinations not to be based upon speculation.

However, the second sentence of the definition in the 2016 final rule has continued to cause controversy among the public and many stakeholders.

In this proposed rule, we seek to streamline and simplify the definition of "destruction or adverse modification" by removing the second sentence because the second sentence is unnecessary and has caused confusion. The second sentence of the definition attempted to elaborate upon meanings that are included within the first sentence, without attempting to exhaust them (hence, the use of the phrase "may include, but are not limited to"). In all cases, the analysis of destruction or adverse modification must address whether the proposed action will result in an "alteration that appreciably diminishes the value of critical habitat as a whole for the conservation of a listed species."

Application of the Revised Definition

As with the 2016 rule, we do not intend our proposed change to alter existing section 7(a)(2) consultation practice. The bar for whether a proposed action is likely to result in destruction or adverse modification of critical habitat is neither raised nor lowered by this proposed rule, nor is the scope of analysis altered with respect to evaluating the effects of a proposed action on critical habitat. This proposed definition retains the key, operative first sentence of the 2016 regulation while adding the clarifying additional phrase of "as a whole" (as discussed above). Further guidance on how to apply the language in that sentence can be found in the 2016 rule.

It is not necessary, nor possible, for a concise regulatory definition to list every way in which alterations may affect the value of critical habitat for the conservation of a species. The value of critical habitat for the conservation of a listed species is described primarily through the critical habitat designation itself. That designation, in accordance with the Act, will identify, in occupied habitat, "the specific areas within the geographical area occupied by the species . . . on which are found those physical or biological features (I) essential to the conservation of the species and (II) which may require special management considerations or protection." (16 U.S.C. 1532(5)(a)(i)). Accordingly, the Act already makes clear that, in occupied habitat, the value of critical habitat for the conservation of the species is directly associated with designated physical or biological features. Thus, destruction or adverse modification determinations may be based on alterations that affect such features, without needing to specify that fact in the regulatory definition. The Act and regulations also already state that unoccupied areas may be designated to the extent the Service determines they are "essential for the conservation of the species." (16 U.S.C. 1532(5)(a)(ii)). Determining whether alterations in unoccupied critical habitat may constitute destruction or adverse modification will therefore need to consider the reasons for which the Service determined that such unoccupied habitat is "essential to the conservation of the species."

The Services have not changed their underlying view that it may be necessary and consistent with the Act in some circumstances for the destruction and adverse modification analysis to consider how alterations to critical habitat could affect the ability of the habitat to develop or support features essential to the conservation of the species. For example, in some circumstances, recovery of the species may depend upon retaining the ability of a designated area to maintain or recreate the essential features, for instance through ecological succession, fluvial processes, active management, or other dynamic processes. This is a longstanding interpretation and agency practice, as reflected in the 2016 rule and in the 2004 and 2005 FWS and NMFS guidance documents regarding

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application of the destruction or adverse modification standard. This longstanding interpretation has never been meant to assert authority beyond that provided by the Act, nor to allow the Services to designate critical habitat or make adverse modification findings based merely on speculation or desire about future changes to the critical habitat. As required by the Act, such determinations must rely on the best scientific and commercial data available. (16 U.S.C. 1536(a)(2)).

In the proposed definition, "appreciably diminish" remains a key concept. This phrase has been part of the regulatory definition of "destruction or adverse modification" since 1978, and neither it nor its interpretation would be altered by this proposed rule. As we noted in the 2016 rule, with respect to "diminish," the inquiry begins with whether the relevant effects will reduce, lessen, or weaken the value of the critical habitat for the conservation of the species. If so, then the inquiry is whether that reduction or diminishment will be "appreciable" to the value of the critical habitat for the conservation of the species.

As we also noted in 2016, the determination of "appreciably diminish" is made based upon the proposed action's effect on the value of the entire critical habitat to the conservation of the species. That is, the question is whether the "effects of the action" will appreciably diminish the value of the critical habitat as a whole to the conservation of the species, not just in the area where the proposed action takes place. In this respect, "appreciably diminish" is analogous to "appreciably reduce" in the context of determining whether an action will "jeopardize the continued existence" of a species, since that inquiry is similarly not merely addressing the effects within the action area, but rather is concerned with whether the effects "appreciably reduce" the likelihood of survival and recovery of the listed entity, the species.

The 2016 rule discussed the reasons we concluded, and here continue to conclude, that the phrase "appreciably diminish" does not need to be modified. As we noted in 2016, the Services' joint Consultation Handbook (FWS and NMFS, March 1998) uses the word "considerably" to interpret this phrase. In the 2016 rule, we clarified that the phrase "appreciably diminish," like the Consultation Handbook's term "considerably," means " worthy of consideration' and is another way of stating that we can recognize or grasp the quality, significance, magnitude, or worth of the reduction in the value of

critical habitat." (81 FR 7218, February 11, 2016).

We also explained in 2016 that it is not correct to conclude that every diminishment, however small, should constitute destruction or adverse modification. It was necessary to qualify the word "diminish" to exclude those adverse effects on critical habitat that are so minor in nature that they do not appreciably impact the value of designated critical habitat to the conservation of a listed species.

We also note that the word "appreciably" is used in both the Services' definition of "jeopardize the continued existence of" ("appreciably reduce") and "destruction or adverse modification" ("appreciably diminish"). The meaning of the word "appreciably" is similar in either context. In both contexts, it is appropriate for the Services to consider the biological significance of effects when conducting a section 7(a)(2) consultation. As required by the ESA, we conduct formal consultation, and evaluate in detail the potential for destruction or adverse modification of critical habitat (and/or whether a proposed action is likely to jeopardize the continued existence of a species) whenever there are likely to be adverse effects to critical habitat or a listed species. In each of these analyses, we must evaluate, based on the totality of the circumstances and the best available scientific information. the nature and magnitude of the proposed action's effects, to determine whether such effects of the proposed action are consequential enough to rise to the level of "appreciably diminish" or "appreciably reduce." See, e.g., Oceana, Inc. v. Pritzker, 75 F. Supp. 3d 469, 483 (D.D.C. 2014) (discussing and affirming a jeopardy analysis that considered whether a given reduction was "meaningful from a biological perspective"). Reductions in the reproduction, numbers, or distribution of a species that are inconsequential at the species level, or alterations to the features or the extent of designated critical habitat that constitute only an inconsequential impact on the conservation value of designated critical habitat as a whole, would not be considered to rise to the level of "reduce appreciably" or "appreciably diminish" within the meaning of the regulations. Nor do we interpret section 7(a)(2) and the regulations thereunder to require that each proposed action improve or increase the likelihood of survival and recovery of the species, or improve the conservation value of critical habitat. Section 7(a)(2) focuses on the "continued existence" of the species

and the "adverse" modification of critical habitat.

It should also be noted that the analysis must always consider whether such impacts are "appreciable," even where a species already faces severe threats prior to the action. It is sometimes mistakenly asserted that a species may already be in a status of being "in jeopardy," "in peril," or "jeopardized" by baseline conditions, such that any additional adverse impacts must be found to meet the regulatory standards for "jeopardize the continued existence of" or "destruction or adverse modification." See, e.g., Nat'l Wildlife Fed'n v. Nat'l Marine Fisheries Serv., 524 F.3d 917, 930 (9th Cir. 2008) (asserting that "where baseline conditions already jeopardize a species, an agency may not take action that deepens the jeopardy by causing additional harm"); Turtle Island Restoration Network v. United States Dep't of Commerce, 878 F.3d 725, 735 (9th Cir. 2017) ("Where a species is already in peril, an agency may not take an action that will cause an 'active change of status' for the worse.") (quoting Nat'l Wildlife Fed'n, 524 F.3d at 930). That approach is inconsistent with the statute and our regulations.

The terms "jeopardize the continued existence of" and "destruction or adverse modification" are, in the plain language of section 7(a)(2), determinations that are made about the effects of Federal agency actions. They are not determinations made about the environmental baseline or about the preaction condition of the species. Under the ESA, a listed species will have the status of "threatened" or "endangered," and all threatened and endangered species by definition face threats to their continued existence. See 16 U.S.C. §§ 1532(6), (20), 1533(a). But the ESA and our regulations do not use the terms "in jeopardy," "in peril," or "jeopardized" to describe the environmental baseline or the pre-action condition of a species; nor do the terms "appreciably reduce" or "appreciably diminish" have a different meaning where a species already faces very serious threats. In each biological opinion, the determination regarding destruction or adverse modification is made by evaluating the effects of the proposed action on the species in light of the overall status of the species, the baseline conditions within the action area and any cumulative effects occurring within the action area. While we acknowledge that for a species with a particularly dire status, a smaller impact could cause an alteration that appreciably diminishes the conservation value of critical habitat or appreciably

reduces the likelihood of survival and recovery of the species, there is no "baseline jeopardy" status even for the most imperiled species.

A related question that has arisen is whether the Services are required to identify a "tipping point" beyond which the species cannot recover in making section 7(a)(2) determinations. For example, the Ninth Circuit Court of Appeals has said that "when a proposed action will have significant negative effects on the species' population or habitat, the duty to consider the recovery of the species necessarily includes the calculation of the species' approximate tipping point." Oceana, Inc. v. Nat'l Marine Fisheries Serv., 705 F. App'x 577, 580 (9th Cir. 2017) (citing Nat'l Wildlife Fed'n v. Nat'l Marine Fisheries Serv., 524 F.3d 917 (9th Cir. 2008)); see also Wild Fish Conservancy v. Salazar, 628 F.3d 513, 527 (9th Cir. 2010) (overturning jeopardy analysis based on purported NMFS failure to determine "when the tipping point precluding recovery . . . is likely to be reached"). Neither the Act nor our regulations state any requirement for the Services to identify a "tipping point" as a necessary prerequisite for making section 7(a)(2) determinations. Section 7(a)(2) provides the Services with discretion as to how it will determine whether the statutory prohibition is exceeded. We have not interpreted that statutory language as requiring the identification of a tipping point. This interpretation is further supported by the fact that the state of science often does not allow the Services to identify a "tipping point" for many species. The Services have had success in the recovery of several listed species which, despite very low abundance, did not reach a "tipping point."

Definition of Director

We propose to amend the current definition of "Director" to clarify and simplify it, in accordance with the Act and agency practice of FWS and NMFS.

Definition of Effects of the Action

We propose to revise the definition of "effects of the action" in a manner that simplifies the definition. Confusion regarding application of terms has resulted in time being spent determining how to categorize an effect, rather than simply determining what the effects are regardless of category. By providing a simpler definition that applies to the entire range of potential effects, Federal agencies and the Services will be able to focus on better assessing the effects of the proposed action. In addition, we propose to make the definition of environmental baseline a stand-alone definition within § 402.02. Previously, this definition was articulated within the definition of effects of the proposed action. Finally, we have moved the instruction that the effects of the proposed action shall be added to the environmental baseline into the regulations guiding the Services' responsibilities in formal consultation in § 402.14(g).

A few aspects of the revised definition of effects of the action bear further discussion to understand our intent in the proposed revision. We collapsed the various concepts of direct and indirect effects, and the effects of interrelated and interdependent actions, into the new definition that the effects of the action include all effects caused by the proposed action. The revised definition notes that these effects include "the effects of other activities that are caused by the proposed action." It includes a distinction between the word "action" which refers to the action proposed to be authorized, funded, or carried out, in whole or in part, by the Federal agency and brought in for consultation with the Services, and "activity" or "activities," which refer to those activities that are caused by the proposed action but are not included in the proposed action. Under the current definition, these activities would have been considered under either "indirect effects" or "interrelated" or "interdependent" activities. An effect or activity is caused by the proposed action when two tests are satisfied: First, the effect or activity would not occur but for the proposed action, and second, the effect or activity is reasonably certain to occur.

Under the first of these two tests, if an effect or activity would occur regardless of whether the proposed action goes forward, then that effect or activity would not satisfy the "but for" test and would not be considered an effect of the action. The concepts of interrelated and interdependent actions in the existing regulations are now captured by the concept of effects of activities that are caused by the proposed action, but are not part of that proposed action. It has long been our practice that identification of direct and indirect effects as well as interrelated and interdependent activities is governed by the "but for" standard of causation. Our Consultation Handbook states ''In determining whether the proposed action is reasonably likely to be the direct or indirect cause of incidental take, the Services use the simple causation principle: i.e., "but for" the implementation of the proposed action. . . ." (Consultation Handbook, page 4-47). A number of courts have also adopted that position. Sierra Club

v. Bureau of Land Management, 786 F.3d 1219, 1225 (9th Cir. 2015) ("The test for interrelatedness or interdependentness is 'but for' causation") citing Sierra Club v. Marsh, 816 F.2d 1376, 1387 (9th Cir. 1987). This standard, while applicable to analyzing the effects of the action under section 7(a)(2), is not necessarily appropriate for other provisions of the ESA; we therefore do not address in this rulemaking the causation standards applying to other provisions of the Act, such as whether a violation of section 9(a)(1)(B) (the take prohibition) has resulted for purposes of a civil penalty or a criminal violation under the Act.

The second of the two tests speaks to the certainty of whether the effect or activity will occur. The concept of reasonable certainty already exists in our section 7 regulations and currently is explicitly applied in the context of indirect effects, cumulative effects, and incidental take. We propose to increase consistency and avoid confusion and speculation by explicitly applying the concept to all effects of the proposed action (not just indirect) and also to those other activities previously identified as interrelated and interdependent. This concept applies equally to evaluating the beneficial effects of a proposed action (e.g., effects of any components proposed by the Federal agency to avoid, minimize, or offset the effects of the agency action, for example) and adverse effects of the proposed action. Our proposed revision applies the reasonably-certain-to-occur standard to the section 7 process in a consistent manner but does not change past practice on the evaluation of direct and indirect effects of actions. In practice, the Services have evaluated the direct effects of the action using the best available scientific and commercial information about the likelihood of an effect or activity and not on speculation about what effects might occur. As a result, we do not anticipate the revised language will change what types of effects or activities will be considered within our consultations; rather, we expect it to simplify and improve consistency in our effects analyses. For example, our prior discussion in our 2015 rulemaking adopting revisions to the incidental take statement portions of our section 7 regulations is instructive in this regard:

As a practical matter, application of the "reasonable certainty" standard is done in the following sequential manner in light of the best available scientific and commercial data to determine if incidental take is anticipated: (1) A determination is made regarding whether a listed species is present within the area affected by the proposed

Federal action; (2) if so, then a determination is made regarding whether the listed species would be exposed to stressors caused by the proposed action (e.g., noise, light, ground disturbance); and (3) if so, a determination is made regarding whether the listed species' biological response to that exposure corresponds to the statutory and regulatory definitions of take (*i.e.*, kill, wound, capture, harm, etc.). Applied in this way, the "reasonable certainty" standard does not require a guarantee that a take will result, rather, only that the Services establish a rational basis for a finding of take. While relying on the best available scientific and commercial data, the Services will necessarily apply their professional judgment in reaching these determinations and resolving uncertainties or information gaps. Application of the Services' judgment in this manner is consistent with the "reasonable certainty" standard. (80 FR 26832, 26837; May 15, 2015).

The preamble to the 1986 regulation implementing section 7 also discusses the Services' interpretation of the phrase "reasonably certain to occur." (51 FR 19926, 19932–19933; June 3, 1986— "For State and private actions to be considered in the cumulative effects analysis, there must exist more than a mere possibility that the action may proceed. On the other hand, "reasonably certain to occur" does not mean that there is a guarantee that an action will occur.")

It is important to note that both prongs of the causation standard must be met for the activity in question and the effects from that activity. So, for example, if an activity is not reasonably certain to occur, then the causation standard has not been met and neither the activity nor any effects from that activity are considered an effect of the proposed action.

In addition, for activities that are caused by the proposed action, we have established at §402.17 a standard and set of factors to consider in determining whether activities are reasonably certain to occur. We believe that the combination of requiring that an effect be both "but for" and "reasonably certain to occur" will reasonably define the reach of the effects analysis and address concerns about extending the analysis into an unreasonably wide arena. Finally, the proposed provision includes a reminder that the effects of the action may occur throughout the action area and on an ongoing, or even delayed, timeframe after completion of the action that was the subject of consultation. Thus, under the proposed rule, there would no longer be a need for a separate definition of "indirect effects," since the intent of the new definition is that the effects covered by that term are still included. And similarly, the new definition should not, in practice, change the determination or scope of the "action area" in a consultation.

As stated previously, the Services' intent is to simplify and clarify the definition of effects of the action, without altering the scope of what constitutes an effect. We seek comment on (1) the extent to which the proposed revised definition simplifies and clarifies the definition of "effects of the action"; (2) whether the proposed definition alters the scope of effects considered by the Services; (3) the extent to which the scope of the proposed revised definition is appropriate for the purposes of the Act; and (4) how the proposed revised definition may be improved.

Definition of Environmental Baseline

We are proposing a stand-alone definition for "environmental baseline" as referenced in the discussion above in the proposed revised definition for "effects of the action." The definition for environmental baseline retains its current wording. Moving it to a standalone definition clarifies that the environmental baseline is a separate consideration that sets the stage for analyzing the effects of the proposed action on the listed species and critical habitat within the action area by providing the foundation upon which to build the analysis of the effects of the action under consultation. The environmental baseline does not include the effects of the action under review in the consultation (See Consultation Handbook, at 4-22).

The Services are seeking public comment on potential revisions to the definition of "environmental baseline" as it relates to ongoing Federal actions. It has sometimes been challenging for the Services and Federal agencies to determine the appropriate baseline for those consultations involving ongoing agency actions. The complexities presented in these consultations include issues such as: What constitutes an "ongoing" action; if an ongoing action is changed, is the incremental change in the ongoing action the only focus of the consultation or is the entire action or some other subset reviewed; is the effects analysis different if the ongoing action has never been the subject of consultation as compared to if there is a current biological opinion for the ongoing action; if a change is made to an ongoing action that lessens, but does not eliminate, the harmful impact to listed species or critical habitat, is that by definition a "beneficial action"; and can a "beneficial action" ever jeopardize listed species or destroy or adversely modify critical habitat. Further, the

Services request comments as to whether the following language would address these issues: "Environmental baseline is the state of the world absent the action under review and includes the past, present and ongoing impacts of all **past and ongoing** Federal, State, or private actions and other human activities in the action area, the anticipated impacts of all proposed Federal projects in the action area that have already undergone formal or early section 7 consultation, and the impact of State or private actions in the action area which are contemporaneous with the consultation in process. Ongoing means impacts or actions that would continue in the absence of the action under review.'

As indicated above, we propose to move the instruction that the effects of the action shall be added to the environmental baseline from the definition of "effects of the action" into § 402.14(g) to retain this important step of the analytical process.

Definition of Programmatic Consultation

We propose to add a definition of "programmatic consultation." This term is included in revised § 402.14(c)(4) to codify an optional consultation technique that is being used with increasing frequency and to promote the use of programmatic consultations as effective tools that can improve both process efficiency and conservation in consultations. Programmatic consultations can be completed under informal and formal consultation processes. They can be used to evaluate the effects of multiple actions anticipated within a particular geographic area; or to evaluate Federal agency programs that guide implementation of the agency's future actions by establishing standards, guidelines, or governing criteria to which future actions will adhere. By consulting on the program, plan, policy, regulation, series, or suites of activities as a whole, the Services can reduce the number of single, project-by-project consultations, streamline the consultation process, and increase predictability and consistency for action agencies. In addition, by looking across numerous individual actions at the programmatic level, the Federal action agencies and applicants can propose project design criteria, best management practices, standard operating procedures, and/or standards and guidelines that avoid, minimize, or offset the action's effects on listed species and/or designated critical habitat. Federal agencies and applicants often propose measures to avoid, minimize, and/or offset effects to listed

species and/or designated critical habitat as part of their proposed action when they consult with the Services. The Services consider these measures as part of the proposed action when they evaluate the effects of the proposed action.

Types of Programmatic Consultations

1. Programmatic consultations that address multiple similar, frequently occurring, or routine actions expected to be implemented in particular geographic areas. These are generally categories of actions for which there is a good understanding of the likely effects on resources listed under the Act, although the categories encompass future site-specific actions of which the precise details are not yet known. Many, but not all, of these types of programmatic consultations have been referred to as "batched" consultations in the past. They do not rely on, or specifically incorporate by reference, consultations on a higher level of Federal action or plan. Examples of these types of programmatic consultations would be consultations that involve a variety of routine activities such as a regional road maintenance program by State departments of transportation, or a U.S. Army Corps of Engineers general permitting program at the regional level that covers routine construction activities for in-and-over-water structures.

Programmatic consultations that address a proposed program, plan, policy, or regulation providing a framework for future actions. These programmatic consultations cover programs, plans, governing policies, and/or regulations such as a national or regional program, plan, policy, or regulation, where the Federal agency is generally not able to provide detailed specificity about the number, location, timing, frequency, precise methods and intensity of the activities expected to be implemented, or to determine the sitespecific adverse effects the activities will have on listed species or critical habitat. In these cases, the Service conducts a more generalized review of effects and provides the appropriate section 7(a)(2) determination in a letter of concurrence or biological opinion for the programmatic consultation. In the future, when the site-specific information is known, and it is determined the project "may affect" a listed species or critical habitat, typically a subsequent consultation is completed. That subsequent consultation may, not exclusively, be referred to as a "step-down" or "tiered consultation." The subsequent

consultation commonly incorporates by reference portions of the previous consultation on the program, plan, policy, or regulations. A typical example of this type of programmatic action is a land management plan. A land management agency may have a program addressing issuance of a special use permit for various activities. The program, as a part of land management planning, has certain standards and guidelines to which each subsequent program action must adhere. A consultation on the program would examine generally what types of effects would be caused by the program and whether those effects were consistent with section 7(a)(2) of the Act. In the future, as issuance of specific permits are anticipated, the Federal agency will return to the Service later for consultation, and an additional consultation would take place on the site-specific facts of that permit issuance. However, the subsequent or "step-down" or "tiered" consultation would benefit from the initial programlevel consultation, thus streamlining and reducing the amount of analysis needed for each site-specific consultation.

The Services recently promulgated changes to the section 7(a)(2) implementing regulations that define framework and mixed programmatic actions that address certain types of policies, plans, regulations, and programs (80 FR 26832, May 11, 2015). The types of programmatic consultations described above align with the suite of activities described in the 2015 rule.

The Services encourage Federal agencies to coordinate with us in order to determine what programmatic approach would be applicable and streamline the consultation process for their program or suite of actions.

Section 402.03—Applicability

In order to increase efficiency in implementing section 7(a)(2) consultations and capitalize upon the considerable experience the Services have gained in implementing the Act, the Services seek comment on the advisability of clarifying the circumstances upon which Federal agencies are not required to consult. More specifically, the Services seek comment regarding revising § 402.03 to preclude the need to consult when the Federal agency does not anticipate take and the proposed action will: (1) Not affect listed species or critical habitat; or (2) have effects that are manifested through global processes and (i) cannot be reliably predicted or measured at the scale of a listed species' current range,

or (ii) would result at most in an extremely small and insignificant impact on a listed species or critical habitat, or (iii) are such that the potential risk of harm to a listed species or critical habitat is remote, or (3) result in effects to listed species or critical habitat that are either wholly beneficial or are not capable of being measured or detected in a manner that permits meaningful evaluation. The Services have learned through time that such actions are far removed from any potential for jeopardy or destruction or adverse modification of critical habitat, and that consultation on these actions does little to accomplish the intent of section 7(a)(2) of the Act-to ensure that any action authorized, funded, or carried out by a Federal agency is not likely to jeopardize the continued existence of listed species or result in the destruction or adverse modification of critical habitat.

In prior consultations under section 7(a)(2), agencies with regulatory authority have consulted on actions that include effects to listed species or designated critical habitat that occur outside of the specific area over which they have regulatory jurisdiction. We also seek comment on whether the scope of a consultation under section 7(a)(2) should be limited to only the activities, areas, and effects within the jurisdictional control and responsibility of the regulatory agency.

Section 402.13—Deadline for Informal Consultation

Informal consultation is an optional process that includes all discussions, correspondence, etc., between the Service and the Federal agency to assist the Federal agency in determining whether formal consultation or a conference is required. During informal consultation, the Service may suggest modifications to the action that the Federal agency and any applicant could implement to avoid the likelihood of adverse effects to listed species or critical habitat. Finally, the Services may issue a written concurrence with a Federal agency's determination that the action is not likely to adversely affect the listed species or critical habitat.

There is currently no deadline for the Services to complete an informal consultation, unlike formal consultations, which by regulation should be completed within 90 days unless extended under the terms at § 402.14(e). The Service's goal is to either complete the Letter of Concurrence for the project, or request additional information that is necessary to complete the consultation, within 30 days. NMFS completes approximately 1,200-1,500 individual informal consultations per year. Of the informal actions not under a programmatic Biological Opinion, 36 percent are within their 30-day goal, and 61 percent are within 3 months. NMFS currently has about 46 individual informal consultations that have been open for greater than 200 days as of July 31, 2017, that the agency is actively working to complete as soon as possible. Between fiscal years 2011 and 2017, FWS completed an average of 11,344 (ranging from 9,656 to 12,793) informal consultations per year. During those years, FWS completed between 78 percent and 85 percent of the informal consultations in less than 30 days, averaging between 26 and 39 days to complete informal consultation.

The Services are considering whether to add a 60-day deadline, subject to extension by mutual consent, for informal consultations. We seek comment on (1) whether a deadline would be helpful in improving the timeliness of review; (2) the appropriate length for a deadline (if not 60 days); and (3) how to appropriately implement a deadline (e.g., which portions of informal consultation the deadline should apply to [e.g., technical assistance, response to requests for concurrence, etc.], when informal consultation begins, and the ability to extend or "pause the clock" in certain circumstances, etc.).

Section 402.14—Formal Consultation

Consistent with the Services' existing practice, we propose to revise §402.14(c) to clarify what is necessary to initiate formal consultation. Decades of experience have demonstrated valuable time is lost due to lack of clarity in what information the Services need to initiate consultation. This often results in an ongoing exchange of documents (e.g., biological assessments, biological evaluations, National Environmental Policy Act (NEPA) documents) in which the Federal agencies and Services seek to compile the necessary information, which results in significant inefficiencies and frustrations on the part of both the Federal agencies and the Services. The proposed revision is intended to eliminate the confusion and misunderstanding existing in the current regulations and significantly increase the efficiency of the process for both the Federal agencies and the Services. It is important to note the Services are not proposing to require more information than existing practice; instead, we are proposing to clarify in the regulations what is needed to

initiate consultation in order to improve the consultation process.

The proposed revisions to §402.14(c) would further describe the information from the Federal agency necessary to initiate consultation. This set of information is commonly called the "initiation package," and that term is also used in our proposed regulations for alternative formal consultation procedures to refer to the information required in §402.14(c). Consistent with § 402.06 (Coordination with other environmental reviews), we also propose at § 402.14(c) to allow the Services to consider other documents as initiation packages, such as: a document prepared for the sole purpose of providing the Service with information relevant to an agency's consultation, a document that has been prepared under NEPA or other authority that contains the necessary information to initiate consultation, or other such documents (e.g., grant application, State of Washington Joint Aquatic Resources Permit Application, California Environmental Quality Act Environmental Impact Report, etc.) that meet the requirements for initiating consultation.

When such documents consider two or more alternative actions, the request for consultation must describe the specific alternative or action proposed for consultation and the specific locations in the document where the relevant information is found. The Services evaluate only the Federal agency's proposed alternative during the consultation process. If the Federal agency either adopts another alternative as its final agency action, or substantively modifies the proposed alternative, reinitiation of consultation may be required.

The proposed regulations describe categories of information that should be in an initiation package to initiate formal consultation. Information must be provided in a sufficient level of detail consistent with the nature and scope of the proposed action. Consistent with the Service's existing practice, the requirement to include sufficient detail ensures the Service has enough information to understand the action as proposed and conduct an informed analysis of the effects of the action, including with regard to those measures intended to avoid, minimize, or offset effects. See Consultation Handbook, at B-54 (Description of the proposed action should be "detailed enough so that the reviewer can fully understand what the components of the action include and how the project will affect the species.") Such information should include a description of the proposed

action, including any measures intended to avoid, minimize, or offset the effects of the proposed action, a description of the area affected (the action area), information about species or critical habitat in the action area, a description of potential effects of the proposed action on individuals of any listed species or critical habitat, a description of the cumulative effects, a summary of information from the applicant, if any, and any other relevant information.

Service Responsibilities

We propose to revise portions of § 402.14(g) that describe the Services' responsibilities during formal consultation. We propose to clarify the analytical steps the Services undertake in formulating a biological opinion. These changes are intended to better reflect the Services' approach to analyzing jeopardy and adverse modification as well as address revisions to the definition of "effects of the action." In summary, these analytical steps are: (1) Review all relevant information, (2) evaluate current status of the species and critical habitat and environmental baseline, (3) evaluate effects of the proposed action and cumulative effects, (4) add effects of the action and cumulative effects to the environmental baseline, and, in light of the status of the species and critical habitat, determine if the proposed action is likely to jeopardize listed species or result in the destruction or adverse modification of critical habitat. While we identify distinct steps in our analytical approach, each step is related to the others and necessarily informs and influences our analysis. For example, the condition of the environmental baseline is relevant to the nature and extent of the effects of the action. Effects of the action that in isolation would be of minor consequence may be amplified and of greater consequence when analyzed in light of the condition of the environmental baseline.

In 402.14(g)(2), we propose to move from the current definition of "effects of the action" the instruction that the effects of the action shall be added to the environmental baseline to where this provision more logically fits with the rest of the analytical process, and we retain this important step of that process. In $\S402.14(g)(4)$, we propose revisions to better reflect the manner in which the Services integrate and synthesize their analyses of effects of the action with cumulative effects, the environmental baseline, and status of the species and critical habitat to reach our jeopardy and adverse modification

determinations. Again, this proposed change reflects the Service's existing approach. *See* Consultation Handbook, at 4–33 ("The conclusion section presents the Services' opinion regarding whether the aggregate effects of the factors analyzed under "environmental baseline," "effects of the action," and "cumulative effects" in the action area—when viewed against the status of the species or critical habitat as listed or designated—are likely to jeopardize the continued existence of the species or result in destruction or adverse modification of critical habitat.")

We propose clarifications to §402.14(g)(8) regarding whether and how the Service should consider measures included in a proposed action that are intended to avoid, minimize, or offset adverse effects to listed species or critical habitat. Federal agencies often include these types of measures as part of the proposed action. However, the Service's reliance on a Federal agency's commitment that the measures will actually occur as proposed has been repeatedly questioned in court. The resulting judicial decisions have created confusion regarding what level of certainty is required to demonstrate that a measure will in fact be implemented before the Service can consider it in a biological opinion. In particular, the Ninth Circuit has held that even an expressed sincere commitment by a Federal agency or applicant to implement future improvements to benefit a species must be rejected absent "specific and binding plans" with "a clear, definite commitment of resources for future improvements." Nat'l Wildlife Fed'n v. Nat'l Marine Fisheries Serv., 524 F.3d 917, 935-36 (9th Cir. 2008).

This judicially created standard is not required by the Act or the existing regulations. The Act requires Federal agencies to consult with the Services, as appropriate, on "any action authorized, funded or carried out by such agency." When a Federal agency proposes to take an action that it has the discretion and authority to implement, and where that proposed action or parts thereof "may affect" a listed species or its critical habitat, the section 7(a)(2) consultation process is triggered. Where these conditions are met, the Service's role is to assume that the action will be implemented as proposed and proceed to analyze the effects of that proposed action on listed species and critical habitat. Just as with the components of a proposed action with adverse effects, there is no additional or heightened standard or threshold requirement necessitating the Service to independently evaluate whether the proposed measures to avoid, minimize,

or offset adverse effects will be implemented.

In some situations, a Federal agency may propose a suite or program of measures that will be implemented over time. The future components of the proposed action often have some uncertainty with regard to the specific details of projects that will be implemented. Nevertheless, a Federal agency or applicant may be fully capable of committing to specific levels and types of actions (e.g., habitat restoration) and specific populations or species that will be the focus of the effort. If the Federal agency provides information in sufficient detail for the Services to meaningfully evaluate the effects of measures proposed to avoid, minimize, or offset adverse effects, the Services must consider the proposed measures during a consultation, as the Act requires the Services to issue their expert opinion on "how the agency action affects the species or its critical habitat," 16 U.S.C. 1536(b)(3)(A), and thus, are entitled to rely on that information as proposed. Therefore, we are proposing revisions to 402.14(c)(1) with respect to the information a Federal agency must submit to initiate formal consultation. Under this proposed rule and consistent with the Service's existing approach, a Federal agency must submit a description of the proposed action, including available information about any measures intended to avoid, minimize, or offset effects of the proposed action. As discussed above, the requirement for sufficient detail regarding all aspects of the proposed action ensures the Services have the information needed to conduct an informed analysis of the effects of all activities included in the proposed action. Provided the Federal agency submits the information required by § 402.14(c), the Services will take into consideration the effects of the action as proposed, both beneficial and adverse.

By describing what is included in the proposed action, the Federal agency has made a commitment and retains independent obligations to insure that its action is not likely to jeopardize listed species or destroy or adversely modify critical habitat. Should new information arise or our assumptions set forth in the consultation change during implementation—for instance, where the action or elements thereof are not implemented as proposed—the Federal agency must continue to ensure compliance with the Act and has several options to do so. This may include reinitiating consultation with the Service(s) to evaluate the changed circumstances. If an incidental take

statement includes reasonable and prudent measures and terms and conditions intended to minimize the impact of incidental take, the Federal agency must carry out those measures or risk losing the exemption afforded by the incidental take statement. Ultimately, as consulting and action agencies, the Act's statutory and regulatory provisions provide distinct responsibilities such that there is no requirement for the Service to independently evaluate whether the Federal agency is likely to carry out its commitments. This is the Services' longstanding position, as reflected in other provisions of the regulations (for instance, those governing development of Reasonable and Prudent Alternatives), and is consistent with the Act. Therefore, we propose revisions to § 402.14(g)(8) to clarify there is no requirement for measures that avoid, minimize, or offset the adverse effects of an action that are included in the proposed action to be accompanied by 'specific and binding plans," ''a clear, definite commitment of resources", or meet other such criteria.

Biological Opinions

We propose to add new paragraphs (h)(3) and (h)(4) to the current § 402.14(h) to allow the Services to adopt all or part of a Federal agency's initiation package in its biological opinion. Additionally, we propose to allow the Services to adopt all or part of their own analyses and findings that are required to issue a permit under section 10(a) of the Act in its biological opinion.

The Services have more than 30 years of experience in conducting consultation pursuant to section 7(a)(2)of the Act under the existing regulations. Based upon that experience, we have determined that the current regulations would be more efficient and clear if we were to codify or create additional optional procedures within formal consultation (Service adoption of all or part of a Federal agency's initiation package and expedited consultations) and streamline duplicative processes (consultation on permits issued under section 10 of the Act). We recognize that several factors, including the scope and complexity of the proposed action, the magnitude and extent of the effects that flow from the proposed action, and the expertise of various Federal agencies, all warrant more than the two general types of consultation provided for in the current regulations. In addition, the experience of recent decades has led to significant improvements in consultation efficiency and species conservation as a result of

the effective use of streamlined or programmatic approaches. We believe that these alternative consultation procedures will promote flexibility and efficiency for the action agencies, applicants, and the Services, and can be implemented in compliance with the Act while not compromising the conservation of listed species.

We propose that the Service may adopt all or part of a Federal agency's initiation package or the Services' analyses and findings that are required to issue a permit under section 10(a) of the Act in its biological opinion. This provision would allow the Services to utilize portions of these documents in the development of our biological opinion to improve efficiency in the consultation process and reduce duplicative efforts. Adoption or incorporation by reference is typically done during consultations, and this provision codifies that approach.

Further, the provision explicitly applies this approach to the Service's issuance of permits under section 10 of the Act. The review and analyses undertaken to develop a finding that various criteria have been met for issuing a permit pursuant to section 10(a)(1)(A) or 10(a)(1)(B) contain many of the elements reviewed and analyzed in a section 7 consultation. Therefore, we propose to adopt the analyses and review that supports issuance of these permits as part of the biological opinion required to meet the applicable provisions of the part 402 consultation regulations. As a result, the section 7 analysis and document can be streamlined to just those portions necessary to present a complete finding under section 7(a)(2) and 7(b)(3). We note also that the Service issuing the permit would have to ensure that its determination regarding jeopardy and destruction or adverse modification is not limited to the species for which the permit is authorizing take, but that it covers all listed species and all designated critical habitat under the Service's jurisdiction affected by the proposed action. In cases where issuance of a section 10 permit by one of the Services (e.g., FWS) may affect listed species or critical habitat under the jurisdiction of the other Service (e.g., NMFS), the permitting agency will still need to consult with the other Service, as well.

While it is the responsibility of the Federal agency to develop the initiation package, we propose a collaborative process to facilitate the Federal agency's development of an initiation package that could be used as all or part of the Service's biological opinion. First, the Federal agency and the Service must mutually agree that the adoption process is appropriate for the proposed action. Subsequently, the Services and the Federal agency may develop coordination procedures that would facilitate adoption. This agreement must be explained in the Federal agency's initiation package and acknowledged in the Services' biological opinion. The purpose of the collaboration is to bring the information and expertise of both the Federal agency and the Service (and any applicant) into the resulting initiation package to facilitate a more efficient and effective consultation process. The end result of the adoption consultation process is expected to be the adoption of the initiation package with any necessary supplementary analyses and incidental take statement to be added by the Service as the Secretary's biological opinion in fulfillment of section 7(b) of the Act.

Expedited Consultation

We propose to add a new provision titled "Expedited consultations" at §402.14(l) to offer opportunities to streamline consultation, particularly for actions that have minimal adverse effects or predictable effects based on previous consultation experience. This consultation process is proposed to provide an efficient means to complete formal consultation on projects ranging from those that have a minimal impact, to those projects with a potentially broad range of effects that are known and predictable, but that are unlikely to cause jeopardy or destruction or adverse modification. The Services have developed a vast knowledge of projects, and in the course of doing so, have concluded that some types of projects can be consulted on in a more expeditious manner without compromising the conservation of listed species or critical habitat. For example, a habitat-restoration project that results in high conservation value for the species but may have a small amount of incidental take through construction or monitoring would likely lend itself to this type of consultation (for Streamlined Consultation Guidance for Restoration and Recovery Projects, see https://www.fws.gov/endangered/esalibrary/index.html#consultations under "Policies" for guidance documents for consultations with the Fish and Wildlife Service).

Two elements are important to the successful implementation of this form of consultation. First is the mutual agreement between the Service and the Federal agency that this form of consultation is appropriate for the proposed action. Informal consultation has been an available optional process

for 30 years and is most often utilized to address proposed actions that are not likely to adversely affect listed species or critical habitat. In contrast, expedited consultations are a new process and likely involve proposed actions that would otherwise go through the regular formal consultation process and require an incidental take statement. We make mutual agreement a required first step in the expedited consultation process to avoid wasted effort if Federal agencies propose actions for expedited consultation that would not be suitable for expedited analysis by the Service. The second important element is the development of a sufficient initiation package (as described in § 402.14(c) of the regulations) that provides all the information needed to allow the Service to prepare a streamlined consultation response within mutually agreed-upon expedited timeframes. We expect that a combination of one-on-one collaboration with Federal agency staff and the availability of guidance and templates will ensure the most efficient process for development of initiation packages and expedited biological opinions. For a NMFS example of a similar effort for informal consultations through the development of guidance, see https://www.greateratlantic. fisheries.noaa.gov/protected/section7/ guidance/consultation/index.html# writing.

In § 402.14, we propose to redesignate current paragraph (l) as paragraph (m) to accommodate the addition of the proposed new paragraph (l).

Section 402.16—Reinitiation of Consultation

We propose two changes to this section. First, we propose to remove the term "formal" from the title and text of this section to acknowledge that the requirement to reinitiate consultation applies to all section 7(a)(2)consultations. By practice, action agencies have reinitiated informal consultations when a trigger for reinitiation has been met. Courts have also held that reinitiation is required in the context of informal consultation. See Forest Guardians v. Johanns, 450 F.3d 455, 458 (9th Cir. 2006). Second, we propose to amend this section to address issues arising under the Ninth Circuit's decision in *Cottonwood* Environmental Law Center v. U.S. Forest Service, 789 F.3d 1075 (9th Cir. 2015), cert. denied, 137 S. Ct. 293 (2016). In Cottonwood, the court held that the Forest Service was required to reinitiate consultation on certain forest management plans due to the designation of Canada lynx critical habitat. The court held that, even if an

approved land management plan is considered to be a completed action, the Forest Service nonetheless was obligated to reinitiate consultation since it retained "discretionary Federal involvement or control" over the plan. *Cottonwood*, 789 F.3d at 1084–85.

We propose to make non-substantive redesignations and then revise § 402.16 by adding a new paragraph (b) to clarify that the duty to reinitiate does not apply to an existing programmatic land management plan prepared pursuant to the Federal Land Policy Management Act (FLPMA), 43 U.S.C. 1701 *et seq.*, or the National Forest Management Act (NFMA), 16 U.S.C. 1600 *et seq.* when a new species is listed or new critical habitat is designated.

We reaffirm that only affirmative discretionary actions are subject to reinitiation under our regulations, and the mere existence of a programmatic land management plan is not affirmative discretionary action. See generally Southern Utah Wilderness Alliance v. Norton, 542 U.S. 55 (2004). See also National Ass'n of Homebuilders v. Defenders of Wildlife, 551 U.S. 644 (2007). While the Act does not expressly mandate reinitiation on discretionary affirmative actions, in 1986 we determined that the Act's legislative history and conservation goals supported reinitiation if certain triggers are met. After decades of experience cooperating with action agencies across the Federal Government, we have gained the expertise of when reinitiation of consultation is most effective to meeting the overall goals of the Act. Reinitiating on a purely programmatic land management plan when new species are listed or critical habitat designated does little to further these goals. Both the Bureau of Land Management (BLM) and U.S. Forest Service (USFS) are required to periodically update their land management plans, at which time they would consult on any newly listed species or designated critical habitat. BLM is required to periodically evaluate and revise Resource Management Plans (see 43 CFR 1610); the interval between reevaluations should not exceed 5 years (see BLM Handbook H–1601–1 at p. 34). USFS is required to revise their land management plans at least every 15 vears (see 36 CFR 219.7). In addition to being required to periodically revise their land management plans, both BLM and USFS are required to consult on any specific on-the-ground actions that implement the land management plans if those actions may affect listed species or critical habitat. We are thus exercising our discretion and narrowing § 402.16 to exclude two types of plans

that have no immediate on-the-ground effects. Requiring reinitiation on these completed plans based on newly listed species or critical habitat often results in impractical and disruptive burdens.

Moreover, reinitiating consultation on a programmatic land management plan results in little benefit to the newly listed species or critical habitat because the plan's mere existence does not result in any immediate effects upon either, thus rendering any reinitiation under these conditions inefficient and ineffective. In contrast, specific on-theground actions that implement the plan are subject to their own section 7 consultations if those actions may affect listed species or critical habitat. These on-the-ground, action-specific consultations allow us to direct our limited resources to those actions that actually cause effects and ensure that the USFS and the BLM fulfill their obligations under section 7. Thus, this new proposed regulation also restates our position that, while a completed programmatic land management plan does not require reinitiation upon the listing of new species or critical habitat, any on-the-ground subsequent actions taken pursuant to the plan must be subject to a separate section 7 consultation if those actions may affect the newly listed species or critical habitat.

Rather than reinitiation of a section 7(a)(2) consultation at the plan level, the Services recommend these agencies develop section 7(a)(1) conservation programs in consultation with the Services when a new species is listed or critical habitat designated. This proactive, conservation planning process will enable them to better synchronize their actions and programs with the conservation and recovery needs of listed and proposed species. Such planning can help Federal agencies develop specific, pre-approved design criteria to ensure their actions are consistent with the conservation and recovery needs of the species. Additionally, these section 7(a)(1)programs will facilitate efficient development of the next programmatic section 7(a)(2) consultations when the land management plan is renewed.

In addition to seeking comment on the proposed revision to 50 CFR 402.16, we are seeking comments on whether to exempt other types of programmatic land or water management plans in addition to those prepared pursuant to FLPMA and NFMA from the requirement to reinitiate consultation when a new species is listed or critical habitat designated. We are also seeking comment on this proposed revision in light of the recently enacted Wildfire Suppression Funding and Forest Management Activities Act, H.R. 1625, Division O, which was included in the Omnibus Appropriations bill for fiscal year 2018.

Section 402.17—Other Provisions

We propose to add a new §402.17 titled "Other provisions." Within this new section, we propose a new provision titled "Activities that are reasonably certain to occur," in order to clarify the application of the "reasonably certain to occur" standard referenced in § 402.02 (defining effects of the action and cumulative effects) in two specific contexts. This new proposed provision applies only to activities caused by but not included in the proposed action and activities under cumulative effects. We propose to address reasonable certainty in these two contexts due to the substantial confusion that has sometimes resulted from determining when these sorts of activities should be considered. The proposed text addresses the relative level of certainty required and is intended to avoid inclusion of activities whose occurrence would be considered speculative, but also to avoid requiring an expectation that the activity is absolutely certain to occur. We also identify a non-exclusive list of factors that inform the determination of whether an activity should be considered reasonably certain to occur. For example, one of the factors to consider is the existence of any relevant plans (e.g., community plans, management plans, transportation plans, etc.). We also specify that this provision only applies to activities caused by but not included in the proposed action and activities under cumulative effects. Consistent with the Act, existing regulations, and agency practice, we do not propose to apply the reasonable certainty standard to whether the proposed action itself will be implemented, but again, only to the analysis of the effects of the action to ensure that the effects analysis does not focus on speculative impacts. This provision reflects the fundamental nature of consultation under section 7(a)(2) in which the Services consult on the action as proposed.

Request for Information

We intend that a final regulation will consider information and recommendations from all interested parties. We therefore solicit comments, information, and recommendations from governmental agencies, Native American tribes, the scientific community, industry groups, environmental interest groups, and any other interested parties. All comments and materials received by the date listed in **DATES** above will be considered prior to the approval of a final document.

You may submit your information concerning this proposed rule by one of the methods listed in **ADDRESSES**. If you submit information via http:// www.regulations.gov, your entire submission-including any personal identifying information—will be posted on the website. If your submission is made via a hardcopy that includes personal identifying information, you may request at the top of your document that we withhold this personal identifying information from public review. However, we cannot guarantee that we will be able to do so. We will post all hardcopy submissions on http:// www.regulations.gov.

Information and supporting documentation that we receive in response to this proposed rule will be available for you to review at *http:// www.regulations.gov*, or by appointment, during normal business hours, at the U.S. Fish and Wildlife Service, Division of Environmental Review (see **FOR FURTHER INFORMATION CONTACT**).

Required Determinations

Regulatory Planning and Review— Executive Orders 12866 and 13563

Executive Order 12866 provides that the Office of Information and Regulatory Affairs (OIRA) in the Office of Management and Budget (OMB) will review all significant rules. OIRA has determined that this rule is significant.

Executive Order 13563 reaffirms the principles of E.O. 12866 while calling for improvements in the nation's regulatory system to promote predictability, to reduce uncertainty, and to use the best, most innovative, and least burdensome tools for achieving regulatory ends. The executive order directs agencies to consider regulatory approaches that reduce burdens and maintain flexibility and freedom of choice for the public where these approaches are relevant, feasible, and consistent with regulatory objectives. E.O. 13563 emphasizes further that regulations must be based on the best available science and that the rulemaking process must allow for public participation and an open exchange of ideas. We have developed this rule in a manner consistent with these requirements. This proposed rule is consistent with Executive Order 13563, and in particular with the requirement of retrospective analysis of existing rules, designed "to make the agency's regulatory program more

effective or less burdensome in achieving the regulatory objectives."

Executive Order 13771

This proposed rule is expected to be a deregulatory action under E.O. 13771.

Regulatory Flexibility Act

Under the Regulatory Flexibility Act (as amended by the Small Business **Regulatory Enforcement Fairness Act** (SBREFA) of 1996; 5 U.S.C. 601 et seq.), whenever a Federal agency is required to publish a notice of rulemaking for any proposed or final rule, it must prepare, and make available for public comment, a regulatory flexibility analysis that describes the effect of the rule on small entities (i.e., small businesses, small organizations, and small government jurisdictions). However, no regulatory flexibility analysis is required if the head of an agency, or his or her designee, certifies that the rule will not have a significant economic impact on a substantial number of small entities. SBREFA amended the Regulatory Flexibility Act to require Federal agencies to provide a statement of the factual basis for certifying that a rule will not have a significant economic impact on a substantial number of small entities. We certify that, if adopted as proposed, this proposed rule would not have a significant economic effect on a substantial number of small entities. The following discussion explains our rationale.

This rulemaking revises and clarifies existing requirements for Federal agencies under the Endangered Species Act. Federal agencies are the only entities that are directly affected by this rule, and they are not considered to be small entities under SBA's size standards. No other entities are directly affected by this rule. Moreover, this proposed rulemaking action is not a major rule under SBREFA.

This proposed rule, if made final, would be applied in determining whether a Federal agency has insured, in consultation with the Services, that any action it would authorize, fund, or carry out is not likely to jeopardize listed species or result in the destruction or adverse modification of critical habitat. This proposed rule is substantially unlikely to affect our determinations as to whether or not proposed actions are likely to jeopardize listed species or result in the destruction or adverse modification of critical habitat. The proposed rule would serve to provide clarity to the standards with which we will evaluate agency actions pursuant to section 7 of the Endangered Species Act.

Unfunded Mandates Reform Act (2 U.S.C. 1501 et seq.)

In accordance with the Unfunded Mandates Reform Act (2 U.S.C. 1501 *et seq.*):

(a) On the basis of information contained in the Regulatory Flexibility Act section above, this proposed rule would not "significantly or uniquely" affect small governments. We have determined and certify pursuant to the Unfunded Mandates Reform Act, 2 U.S.C. 1502, that this rule would not impose a cost of \$100 million or more in any given year on local or State governments or private entities. A Small Government Agency Plan is not required. As explained above, small governments would not be affected because the proposed rule would not place additional requirements on any city, county, or other local municipalities.

(b) This proposed rule would not produce a Federal mandate on State, local, or tribal governments or the private sector of \$100 million or greater in any year; that is, this proposed rule is not a "significant regulatory action" under the Unfunded Mandates Reform Act. This proposed rule would impose no additional management or protection requirements on State, local, or tribal governments.

Takings (E.O. 12630)

In accordance with Executive Order 12630, this proposed rule would not have significant takings implications. This proposed rule would not pertain to "taking" of private property interests, nor would it directly affect private property. A takings implication assessment is not required because this proposed rule (1) would not effectively compel a property owner to suffer a physical invasion of property and (2) would not deny all economically beneficial or productive use of the land or aquatic resources. This proposed rule would substantially advance a legitimate government interest (conservation and recovery of endangered species and threatened species) and would not present a barrier to all reasonable and expected beneficial use of private property.

Federalism (E.O. 13132)

In accordance with Executive Order 13132, we have considered whether this proposed rule would have significant Federalism effects and have determined that a federalism summary impact statement is not required. This proposed rule pertains only to improving and clarifying the interagency consultation processes under the Endangered Species Act and would not have substantial direct effects on the States, on the relationship between the Federal Government and the States, or on the distribution of power and responsibilities among the various levels of government.

Civil Justice Reform (E.O. 12988)

This proposed rule does not unduly burden the judicial system and meets the applicable standards provided in sections 3(a) and 3(b)(2) of Executive Order 12988. This proposed rule would clarify the interagency consultation processes under the Endangered Species Act.

Government-to-Government Relationship With Tribes

In accordance with the President's memorandum of April 29, 1994, "Government-to-Government Relations with Native American Tribal Governments" (59 FR 22951), Executive Order 13175, and the Department of the Interior's manual at 512 DM 2, we readily acknowledge our responsibility to communicate meaningfully with recognized Federal Tribes on a government-to-government basis.

Paperwork Reduction Act

This rule does not contain any new collections of information other than those already approved under the Paperwork Reduction Act (44 U.S.C. 3501 *et seq.*). 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.

National Environmental Policy Act

We are analyzing this proposed regulation in accordance with the criteria of NEPA, the Department of the Interior regulations on implementation of NEPA (43 CFR 46.10-46.450), the Department of the Interior Manual (516 DM 8), the NOAA Administrative Order 216-6A, and the companion manual, "Policy and Procedures for Compliance with the National Environmental Policy Act and Related Authorities," which became effective January 13, 2017. We invite the public to comment on the extent to which this proposed regulation may have a significant impact on the human environment, or fall within one of the categorical exclusions for actions that have no individual or cumulative effect on the quality of the human environment. We will complete our analysis, in compliance with NEPA, before finalizing this regulation.

Energy Supply, Distribution or Use (E.O. 13211)

Executive Order 13211 requires agencies to prepare Statements of Energy Effects when undertaking certain actions. The proposed revised regulations are not expected to affect energy supplies, distribution, and use. Therefore, this action is a not a significant energy action, and no Statement of Energy Effects is required.

Clarity of the Rule

We are required by Executive Orders 12866 and 12988 and by the Presidential Memorandum of June 1, 1998, to write all rules in plain language. This means that each rule we publish must:

(1) Be logically organized;

(2) Use the active voice to address readers directly;

(3) Use clear language rather than jargon;

(4) Be divided into short sections and sentences; and

(5) Use lists and tables wherever possible.

If you feel that we have not met these requirements, send us comments by one of the methods listed in the **ADDRESSES** section. To better help us revise the rule, your comments should be as specific as possible. For example, you should tell us the numbers of the sections or paragraphs that are unclearly written, which sections or sentences are too long, the sections where you feel lists or tables would be useful, etc.

References Cited

A complete list of all references cited in this document is available on the internet at *http://www.regulations.gov* in Docket No. FWS–HQ–ES–2018–0009 or upon request from the U.S. Fish and Wildlife Service (see **FOR FURTHER INFORMATION CONTACT**).

Authors

The primary authors of this proposed rule are the staff members of the Ecological Services Program, U.S. Fish and Wildlife Service, 5275 Leesburg Pike, Falls Church, VA 22041–3803, and the National Marine Fisheries Service's Endangered Species Division, 1335 East-West Highway, Silver Spring, MD 20910.

Authority

We issue this proposed rule under the authority of the Endangered Species Act, as amended (16 U.S.C. 1531 *et seq.*).

List of Subjects in 50 CFR Part 402

Endangered and threatened species.

Proposed Regulation Promulgation

Accordingly, we propose to amend subparts A and B of part 402, subchapter A of chapter IV, title 50 of the Code of Federal Regulations, as set forth below:

PART 402—INTERAGENCY COOPERATION—ENDANGERED SPECIES ACT OF 1973, AS AMENDED

■ 1. The authority citation for part 402 continues to read as follows:

Authority: 16 U.S.C. 1531 et seq.

■ 2. Amend § 402.02 by revising the definitions of "Destruction or adverse modification," "Director," and "Effects of the action" and adding definitions for "Environmental baseline" and "Programmatic consultation" in alphabetic order to read as follows:

§402.02 Definitions.

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Destruction or adverse modification means a direct or indirect alteration that appreciably diminishes the value of critical habitat as a whole for the conservation of a listed species.

Director refers to the Assistant Administrator for Fisheries for the National Marine Fisheries Service, or his or her authorized representative; or the Director of the U.S. Fish and Wildlife Service, or his or her authorized representative.

Effects of the action are all effects on the listed species or critical habitat that are caused by the proposed action, including the effects of other activities that are caused by the proposed action. An effect or activity is caused by the proposed action if it would not occur but for the proposed action and it is reasonably certain to occur. Effects of the action may occur later in time and may include effects occurring outside the immediate area involved in the action.

Environmental baseline includes the past and present impacts of all Federal, State, or private actions and other human activities in the action area, the anticipated impacts of all proposed Federal projects in the action area that have already undergone formal or early section 7 consultation, and the impact of State or private actions which are contemporaneous with the consultation in process.

* * * *

Programmatic consultation is a consultation addressing an agency's multiple actions on a program, region, or other basis. Programmatic consultations allow the Services to

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consult on the effects of programmatic actions such as:

(1) Multiple similar, frequently occurring or routine actions expected to be implemented in particular geographic areas; and

(Ž) A proposed program, plan, policy, or regulation providing a framework for future proposed actions.

* * *

■ 3. Amend § 402.14 by:

■ a. Revising paragrapȟs (c), (g)(2),

(g)(4), (g)(8), and (h):

 b. Redesignating paragraph (l) as paragraph (m); and

c. Adding a new paragraph (l).

*

The revisions and addition read as follows:

§402.14 Formal consultation. *

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(c) Initiation of formal consultation. (1) A written request to initiate formal consultation shall be submitted to the Director and shall include:

*

(i) A description of the proposed action, including any measures intended to avoid, minimize, or offset effects of the action. Consistent with the nature and scope of the proposed action, the description shall provide sufficient detail to assess the effects of the action on listed species and critical habitat, including:

(A) The purpose of the action;

(B) The duration and timing of the action:

(C) The location of the action;

(D) The specific components of the action and how they will be carried out;

(E) Maps, drawings, blueprints, or similar schematics of the action; and

(F) Any other available information related to the nature and scope of the proposed action relevant to its effects on listed species or designated critical habitat.

(ii) A map or description of all areas to be affected directly or indirectly by the Federal action, and not merely the immediate area involved in the action (i.e., the action area as defined at §402.02).

(iii) Information obtained by or in the possession of the Federal agency and any applicant on the listed species and designated critical habitat in the action area (as required by paragraph (c)(1)(ii) of this section), including available information such as the presence, abundance, density, or periodic occurrence of listed species and the condition and location of species' habitat, including any critical habitat.

(iv) A description of the effects of the action and an analysis of any cumulative effects.

(v) A summary of any relevant information provided by the applicant, if available.

(vi) Any other relevant available information on the effects of the proposed action on listed species or designated critical habitat, including any relevant reports such as environmental impact statements and environmental assessments.

(2) A Federal agency may submit existing documents prepared for the proposed action such as NEPA analyses or other reports in substitution for the initiation package outlined in this paragraph (c). However, any such substitution shall be accompanied by a written summary specifying the location of the information that satisfies the elements above in the submitted document(s).

(3) Formal consultation shall not be initiated by the Federal agency until any required biological assessment has been completed and submitted to the Director in accordance with §402.12.

(4) Any request for formal consultation may encompass, subject to the approval of the Director, a number of similar individual actions within a given geographical area, a programmatic consultation, or a segment of a comprehensive plan. This provision does not relieve the Federal agency of the requirements for considering the effects of the action or actions as a whole.

* * * * *

(g) * * *

(2) Evaluate the current status and environmental baseline of the listed species or critical habitat. *

(4) Add the effects of the action and cumulative effects to the environmental baseline and in light of the status of the species and critical habitat, formulate the Service's opinion as to whether the action is likely to jeopardize the continued existence of listed species or result in the destruction or adverse modification of critical habitat. * * *

(8) In formulating its biological opinion, any reasonable and prudent alternatives, and any reasonable and prudent measures, the Service will use the best scientific and commercial data available and will give appropriate consideration to any beneficial actions as proposed or taken by the Federal agency or applicant, including any actions taken prior to the initiation of consultation. Measures included in the proposed action or a reasonable and prudent alternative that are intended to avoid, minimize, or offset the effects of an action are considered like other portions of the action and do not require any additional demonstration of specific binding plans or a clear, definite commitment of resources.

(h) Biological opinions.

(1) The biological opinion shall include:

(i) A summary of the information on which the opinion is based;

(ii) A detailed discussion of the effects of the action on listed species or critical habitat: and

(iii) The Service's opinion on whether the action is:

(A) Likely to jeopardize the continued existence of a listed species or result in the destruction or adverse modification of critical habitat (a "jeopardy" biological opinion); or

(B) Not likely to jeopardize the continued existence of a listed species or result in the destruction or adverse modification of critical habitat (a "no jeopardy" biological opinion). (2) A "jeopardy" biological opinion

shall include reasonable and prudent alternatives, if any. If the Service is unable to develop such alternatives, the Service will indicate that to the best of its knowledge there are no reasonable and prudent alternatives.

(3) The Service may adopt all or part of:

(i) A Federal agency's initiation package: or

(ii) The Service's analysis required to issue a permit under section 10(a) of the Act in its biological opinion.

(4) A Federal agency and the Service may agree to follow an optional collaborative process that would further the ability of the Service to adopt the information and analysis provided by the Federal agency during consultation in the development of the Service's biological opinion to improve efficiency in the consultation process and reduce duplicative efforts. The Federal agency and the Service shall consider the nature, size, and scope of the action or its anticipated effects on listed species or critical habitat, and other relevant factors to determine whether an action or a class of actions is appropriate for this process. The Federal agency and the Service may develop coordination procedures that would facilitate adoption. The end result of the adoption consultation process is expected to be the adoption of the initiation package with any necessary supplementary analyses and incidental take statement to be added by the Service, if appropriate, as the Service's biological opinion in fulfillment of section 7(b) of the Act.

(1) Expedited consultations. Expedited consultation is an optional formal consultation process that a Federal

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agency and the Service may enter into upon mutual agreement. To determine whether an action or a class of actions is appropriate for this type of consultation, the Federal agency and the Service shall consider the nature, size, and scope of the action or its anticipated effects on listed species or critical habitat and other relevant factors. Conservation actions whose primary purpose is to have beneficial effects on listed species will likely be considered appropriate for expedited consultation.

(1) Upon agreement to use this expedited consultation process, the Federal agency and the Service shall establish the expedited timelines for the completion of this consultation process.

(2) Federal agency responsibilities: To request initiation of expedited consultation, the Federal agency shall provide all the information required to initiate consultation under paragraph (c) of this section. To maximize efficiency and ensure that it develops the appropriate level of information, the Federal agency is encouraged to develop its initiation package in coordination with the Service.

(3) *Service responsibilities:* In addition to the Service's responsibilities under the provisions of this section, the Service will:

(i) Provide relevant species information to the Federal agency and guidance to assist the Federal agency in completing its effects analysis in the initiation package; and

(ii) Conclude the consultation and issue a biological opinion within the agreed-upon timeframes.

* * * * *

follows:

- 4. Amend § 402.16 by:
- a. Revising the section heading;
- b. Redesignating paragraphs (a)

through (d) as paragraphs (a)(1) through (a)(4);
■ c. Designating the introductory text as

a c. Designating the introductory text as paragraph (a) and revising the newly designated paragraph (a); and

d. Adding a new paragraph (b).
 The revisions and addition read as

§402.16 Reinitiation of consultation.

(a) Reinitiation of consultation is required and shall be requested by the Federal agency or by the Service, where discretionary Federal involvement or control over the action has been retained or is authorized by law and:

(b) An agency shall not be required to reinitiate consultation after the approval of a land management plan prepared pursuant to 43 U.S.C. 1712 or 16 U.S.C. 1604 upon listing of a new species or designation of new critical habitat, provided that any authorized actions that may affect the newly listed species or designated critical habitat will be addressed through a separate actionspecific consultation.

■ 5. Add § 402.17 to read as follows:

§402.17 Other provisions.

(a) Activities that are reasonably certain to occur. To be considered reasonably certain to occur, the activity cannot be speculative but does not need to be guaranteed. Factors to consider include, but are not limited to:

(1) Past relevant experiences;

(2) Any existing relevant plans; and

(3) Any remaining economic, administrative, and legal requirements necessary for the activity to go forward.

(b) The provisions in paragraph (a) of this section apply only to activities caused by but not included in the proposed action and activities considered under cumulative effects.

§402.40 [Amended]

■ 6. In § 402.40, amend paragraph (b) by removing ''§ 402.14(c)(1)–(6)" and in its place adding ''§ 402.14(c)''.

Dated: July 18, 2018.

Ryan K. Zinke,

Secretary, Department of the Interior. Dated: July 16, 2018.

Wilbur Ross,

Secretary, Department of Commerce. [FR Doc. 2018–15812 Filed 7–24–18; 8:45 am] BILLING CODE 3510–22–P; 4333–15–P

DEPARTMENT OF THE INTERIOR

Fish and Wildlife Service

DEPARTMENT OF COMMERCE

National Oceanic and Atmospheric Administration

50 CFR Part 424

[Docket No. FWS-HQ-ES-2018-0006; Docket No. 180202112-8112-01; 4500030113]

RIN 1018-BC88; 0648-BH42

Endangered and Threatened Wildlife and Plants; Revision of the Regulations for Listing Species and Designating Critical Habitat

AGENCIES: U.S. Fish and Wildlife Service, Interior; National Marine Fisheries Service, National Oceanic and Atmospheric Administration, Commerce.

ACTION: Proposed rule.

SUMMARY: We, the U.S. Fish and Wildlife Service (FWS) and the National

Marine Fisheries Service (NMFS) (collectively referred to as the "Services" or "we"), propose to revise portions of our regulations that implement section 4 of the Endangered Species Act of 1973, as amended (Act). The proposed revisions to the regulations clarify, interpret, and implement portions of the Act concerning the procedures and criteria used for listing or removing species from the Lists of Endangered and Threatened Wildlife and Plants and designating critical habitat. We also propose to make multiple technical revisions to update existing sections or to refer appropriately to other sections. **DATES:** We will accept comments from all interested parties until September 24, 2018. Please note that if you are using the Federal eRulemaking Portal (see ADDRESSES below), the deadline for submitting an electronic comment is 11:59 p.m. Eastern Standard Time on this date.

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

(1) *Electronically*: Go to the Federal eRulemaking Portal: *http:// www.regulations.gov.* In the Search box, enter FWS-HQ-ES-2018-0006, which is the docket number for this rulemaking. Then, in the Search panel on the left side of the screen, under the Document Type heading, click on the Proposed Rules link to locate this document. You may submit a comment by clicking on "Comment Now!"

(2) *By hard copy:* Submit by U.S. mail or hand-delivery to: Public Comments Processing, Attn: FWS–HQ–ES–2018– 0006; U.S. Fish & Wildlife Service, MS: BPHC, 5275 Leesburg Pike, Falls Church, VA 22041–3803 or National Marine Fisheries Service, Office of Protected Resources, 1315 East-West Highway, Silver Spring, MD 20910.

We request that you send comments only by the methods described above. We will post all comments on *http:// www.regulations.gov*. This generally means that we will post any personal information you provide us (see Public Comments below for more information).

FOR FURTHER INFORMATION CONTACT:

Bridget Fahey, U.S. Fish and Wildlife Service, Division of Conservation and Classification, 5275 Leesburg Pike, Falls Church, VA 22041–3803, telephone 703/358–2171; or Samuel D. Rauch, III, National Marine Fisheries Service, Office of Protected Resources, 1315 East-West Highway, Silver Spring, MD 20910, telephone 301/427–8403. If you use a telecommunications device for the deaf (TDD), call the Federal Information Relay Service (FIRS) at 800/877–8339. **SUPPLEMENTARY INFORMATION:**

Background

The Endangered Species Act of 1973, as amended ("Act"; 16 U.S.C. 1531 et seq.), states that the purposes of the Act are to provide a means to conserve the ecosystems upon which listed species depend, to develop a program for the conservation of listed species, and to achieve the purposes of certain treaties and conventions. 16 U.S.C. 1531(b). Moreover, the Act states that it is the policy of Congress that the Federal Government will seek to conserve threatened and endangered species, and use its authorities to further the purposes of the Act. 16 U.S.C. 1531(c)(1).

The Act defines an endangered species as any species that is "in danger of extinction throughout all or a significant portion of its range" and a threatened species as any species "that is likely to become an endangered species within the foreseeable future throughout all or a significant portion of its range." 16 U.S.C. 1532(6); (20). The Act requires the Services to determine whether species meet either of these definitions. 16 U.S.C. 1533(a); 1532(15). Section 4 of the Act and its implementing regulations in Title 50 of the Code of Federal Regulations at 50 CFR part 424 set forth the procedures for adding, removing, or reclassifying species to the Federal Lists of Endangered and Threatened Wildlife and Plants (lists). The lists are in 50 CFR 17.11(h) (wildlife) and 17.12(h) (plants). Section 4(a)(1) of the Act sets forth the factors that we evaluate when we issue rules for species to list (adding a species to one of the lists), delist (removing a species from one of the lists), and reclassify (changing a species classification or its status).

One of the tools provided by the Act to conserve species is the designation of critical habitat. The purpose of critical habitat is to identify the areas that are essential to the conservation of the species. The Act generally requires that the Services, to the maximum extent prudent and determinable, designate critical habitat when determining that a species is either an endangered species or a threatened species. 16 U.S.C. 1533(a)(3)(A).

The Secretaries of the Interior and Commerce (the "Secretaries") share responsibilities for implementing most of the provisions of the Act. Generally, marine and anadromous species are under the jurisdiction of the Secretary of Commerce, and all other species are under the jurisdiction of the Secretary of the Interior. Authority to administer the Act has been delegated by the Secretary of the Interior to the Director of FWS and by the Secretary of Commerce to the Assistant Administrator for NMFS.

Proposed Regulatory Revisions

In carrying out Executive Order 13777, "Enforcing the Regulatory Reform Agenda," the Department of the Interior (DOI) published a document with the title "Regulatory Reform" in the **Federal Register** of June 22, 2017 (82 FR 28429). The document requested public comment on how DOI can improve implementation of regulatory reform initiatives and policies and identify regulations for repeal, replacement, or modification. This proposed rule addresses comments that DOI has received in response to the regulatory reform docket.

As part of implementing E.O. 13777, the National Oceanic and Atmospheric Administration (NOAA) published a notice entitled, "Streamlining Regulatory Processes and Reducing Regulatory Burden" (82 FR 31576, July 7, 2017). The notice requested public comments on how NOAA could continue to improve the efficiency and effectiveness of current regulations and regulatory processes. This proposed rule addresses comments NOAA received from the public.

This proposed rule is one of three related proposed rules, two of which are joint between the Services, that are publishing in today's **Federal Register**. All of these documents propose revisions to various regulations that implement the ESA.

Beyond the specific revisions to the regulations highlighted in this proposed rule, the Services are comprehensively reconsidering the processes and interpretations of statutory language set out in part 424. Thus, this rulemaking should be considered as applying to all of part 424, and as part of the rulemaking initiated today, the Services will consider whether additional modifications to the regulations setting out procedures and criteria for listing or delisting species and designating critical habitat would improve, clarify, or streamline the administration of the Act. We seek public comments recommending, opposing, or providing feedback on specific changes to any provisions in part 424 of the regulations, including but not limited to revising or adopting as regulations existing practices or policies, or interpreting terms or phrases from the Act. In particular, we seek public comment on whether we should consider modifying the definitions of "geographical area occupied by the species" or "physical or biological features" in section 424.02. Based on comments received and on our experience in administering the Act, the

final rule may include revisions to any provisions in part 424 that are a logical outgrowth of this proposed rule, consistent with the Administrative Procedure Act.

In proposing the specific changes to the regulations in this rule and setting out the accompanying clarifying discussion in this preamble, the Services are proposing prospective standards only. Nothing in these proposed revisions to the regulations is intended to require (at such time as this rule becomes final) that any prior final listing, delisting, or reclassification determinations or previously completed critical habitat designations be reevaluated on the basis of any final regulations.

Section 424.11—Factors for Listing, Delisting, or Reclassifying Species

Economic Impacts

We propose to remove the phrase, "without reference to possible economic or other impacts of such determination", from paragraph (b) to more closely align with the statutory language. Section 4(b)(1)(A) of the Act requires the Secretary to make determinations based "solely on the basis of the best scientific and commercial data available after conducting a review of the status of the species". The word "solely" was added in the 1982 amendments to the Act (Pub. L. 97-304, 96 Stat. 1411) to clarify that the determination of endangered or threatened status was intended to be made "solely upon biological criteria and to prevent non-biological considerations from affecting such decisions." In making the clarification, Congress expressed concerns with the requirements of the Regulatory Flexibility Act, Paperwork Reduction Act, and E.O. 12291 potentially introducing economic and other factors into the basis for determinations under the Act (H.R. Rep. No. 97-567 at 19-20, May 17, 1982).

In removing the phrase, the Services will continue to make determinations based solely on biological considerations. However, there may be circumstances where referencing economic, or other impacts may be informative to the public. For example, the Environmental Protection Agency conducts benefits and costs analyses of each proposed or revised National Ambient Air Quality Standard. These regulatory impact analyses are designed to inform the public and state, local, and tribal governments about the potential costs and benefits of implementation; however, the regulatory impact analyses are not a part of the standard selection

process. While Congress precluded consideration of economic and other impacts from being the basis of a listing determination, it did not prohibit the presentation of such information to the public. Since 1982, Congress has consistently expressed support for informing the public as to the impacts of regulations in subsequent amendments to statutes and executive orders governing the rulemaking process.

In removing the phrase, "without reference to possible economic or other impacts of such determination", the Services are not suggesting that all listing determinations will include a presentation of economic or other impacts. Rather, there may be circumstances where such impacts are referenced while ensuring that biological considerations remain the sole basis for listing determinations. The Services seek comment on this modification.

Foreseeable Future

We propose to add to section 424.11 a new paragraph (d) that sets forth a framework for how the Services will consider the foreseeable future. Section 3(20) of the Act defines a "threatened species" as "any species which is likely to become endangered within the foreseeable future throughout all or a significant portion of its range." The term "foreseeable future" is not further described within either the Act or the Services' current implementing regulations. Guidance addressing the concept of the foreseeable future within the context of determining the status of species is articulated in a 2009 opinion from the Department of the Interior, Office of the Solicitor (M-37021, January 16, 2009). The Services have found the reasoning and conclusions expressed in this document to be wellfounded, and this guidance has been widely applied by both Services. We are proposing to amend section 424.11 to include a framework that sets out how the Services will determine what constitutes the foreseeable future when determining the status of species.

Specifically, we propose the following framework: In determining whether a species is a threatened species, the Services must analyze whether the species is likely to become an endangered species within the foreseeable future. The term foreseeable future extends only so far into the future as the Services can reasonably determine that the conditions potentially posing a danger of extinction in the foreseeable future are probable. The Services will describe the foreseeable future on a case-by-case basis, using the best available data and taking into account considerations such as the species' life-history characteristics, threat-projection timeframes, and environmental variability. The Services need not identify the "foreseeable future" in terms of a specific period of time, but may instead explain the extent to which they can reasonably determine that both the future threats and the species' responses to those threats are probable.

As stated above, under the proposed section 424.11(d), as under current practice, the foreseeable future will be described on a case-by-case basis. Congress did not set a uniform timeframe for the Secretary's consideration of whether a species was likely to become an endangered species. nor did Congress intend that the Secretary set a uniform timeframe. For each species considered for listing, the Services must review the best scientific and commercial data available regarding the likelihood of extinction over time, and then determine, with each status review, whether the species meets the definition of an endangered species or a threatened species. The foreseeable future is uniquely related to the particular species, the relevant threats, and the data available. Courts have expressly endorsed the Services' approach of tailoring analysis of the foreseeable future to each listing determination and considering the foreseeability of each key threat and the species' likely response. See, e.g., In Re Polar Bear Endangered Species Act Listing and Section 4(d) Rule Litigation. 709 F.3d 1, 15–16 (D.C. Cir. 2013) (noting that FWS "determines what constitutes the 'foreseeable' future on a case-by-case basis in each listing decision" based on how far into the future the available data allow for reliable prediction of effects to the species from key threats), cert. denied sub nom. Safari Club Intern. v. Jewell, 134 S. Ct. 310 (2013).

The analysis of the foreseeable future should, to the extent practicable, account for any relevant environmental variability, such as hydrological cycles or oceanographic cycles, which may affect the reliability of projections. Analysis of the foreseeable future should consider the timeframes applicable to the relevant threats and to the species' likely responses to those threats in view of its life-history characteristics. Data that are typically relevant to assessing the species biological response include speciesspecific factors such as lifespan, reproductive rates or productivity, certain behaviors, and other demographic factors.

Under proposed section 424.11(d), as under current practice, the foreseeable future for a particular status determination extends only so far as predictions about the future are reliable. "Reliable" does not mean "certain"; it means sufficient to provide a reasonable degree of confidence in the prediction. "Reliable predictions" is also used here in a non-technical, ordinary sense and not necessarily in a statistical sense.

As outlined in section 4(b)(1)(A) of the Act, status determinations must be based on the best scientific and commercial data available. By extension, in the context of determining whether a species meets the definition of a threatened species, the foreseeable future must also be based on the best scientific and commercial data available. The Services assess the data concerning each threat and the degree to which reliable predictions can be made. In many instances, the amount or quality of data available is likely to vary with respect to the relevant issues evaluated in a particular status determination; consequently, the Services may find varying degrees of foreseeability with respect to the multiple threats and their effects on a particular species. Although the Secretary's analysis as to the future status of a species may be based on reliable predictions with respect to multiple trends and threats over different periods of time or even threats without specific time periods associated with them, the final conclusion is a synthesis of that information. Thus, the foreseeable future is not necessarily reducible to a particular number of years. Nevertheless, if the information or data are susceptible to such precision, it may be helpful to identify the time scale used.

Depending on the nature and quality of the available data, predictions regarding the future status of a particular species may be based on analyses that range in form from quantitative population-viability models and modelling of threats to qualitative analyses describing how threats will affect the status of the species. In some circumstances, such analyses may include reliance on the exercise of professional judgment by experts where appropriate. In cases where the available data allow for quantitative modelling or projections, the time horizon presented in these analyses does not necessarily dictate what constitutes the "foreseeable future" or set the specific threshold for determining when a species may be in danger of extinction. Rather, the foreseeable future can extend only as far as the Services can reasonably depend

on the available data to formulate a reliable prediction and avoid speculation and preconception. Regardless of the type of data available underlying the Service's analysis, the key to any analysis is a clear articulation of the facts, the rationale, and conclusions regarding foreseeability. Ultimately, to determine that a species is likely to become an endangered species in the foreseeable future, the Services must be able to determine that the conditions potentially posing a danger of extinction in the future are probable. The Services will avoid speculating as to what is hypothetically possible.

Factors Considered in Delisting Species

In section 424.11, we propose to redesignate current paragraph (d) as paragraph (e) and revise it to clarify that we determine whether a species is a threatened species or an endangered species using the same standards regardless of whether a species is or is not listed at the time of that determination. After identifying a "species" as defined under the Act and conducting a review of the species' status considering the factors under section 4(a)(1) of the Act, the Services determine if the species meets the definition of a threatened species or an endangered species. If the species does not meet either definition, the species should not be listed (if it is not already), or should be delisted (if it is currently listed). The standard for a decision to delist a species is the same as the standard for a decision not to list it in the first instance. This is consistent with the statute, under which the five-factor analysis in section 4(a)(1) and the definitions of "endangered species" and "threatened species" in sections 3(6) and 3(20) establish the parameters for both listing and delisting determinations without distinguishing between them.

Additionally, we propose to modify the current regulatory text to clarify the situations in which it would not be appropriate for species to remain on the lists of endangered and threatened species. The current regulatory language was intended to provide examples of when a species should be removed from the lists; however, the language in the current regulations has been, in some instances, misinterpreted as establishing criteria for delisting. This proposed change is consistent with the Services' longstanding practice and the decision in Friends of Blackwater v. Salazar, 691 F.3d 428 (D.C. Cir. 2012). That decision confirms that, when reviewing whether a listed species should be delisted, the Services must apply the factors in

section 4(a) of the Act. 691 F.3d at 433 (upholding FWS's decision to delist the West Virginia northern flying squirrel because the agency was not required to demonstrate that all of the recovery plan criteria had been met before it could delist the species and it was reasonable to construe the recovery plan as predictive of the delisting analysis rather than controlling it). In that case, the court held that "Section 4(a)(1) of the Act provides the Secretary 'shall' consider the five statutory factors when determining whether a species is endangered, and section 4(c) makes clear that a decision to delist 'shall be made in accordance' with the same five factors." Id. at 432.

To more clearly align section 424.11 with section 4(a) of the Act we are proposing to streamline it. As is currently the case, any determination to remove a species from the lists because it is has become extinct is subject to the Act's requirement that any determination as to the species' status must be based on the best scientific and commercial data available. Thus, we are proposing to retain text at the beginning of the new section 424.11(e) that states; "The Secretary will delist a species if the Secretary finds that, after conducting a status review based on the best scientific and commercial data available:"

Secondly, to align more closely with the Act, we are proposing to replace the current section 424.11(d)(1) with a new section 424.11(e)(1) that simply states the first reason for delisting a species as, "The species is extinct." Our conclusion that a species is extinct will be based on the best scientific and commercial data available, as required under section 4(b)(1)(A), which may include survey data and information regarding the period of time since the last detection (e.g., documented occurrence or sighting) of the species. It is unnecessary, and potentially confusing in the context of particular determinations, to specifically address these matters in the regulatory text. Our evaluations will be conducted on a caseby-case basis, considering the speciesspecific biological evidence for species extinction.

Third, we are replacing current section 424.11(d)(2), which referred to "recovery," with language in new section 424.11(e)(2) that aligns with the statutory definitions of an endangered species or a threatened species. Although we are proposing to remove the word "recovery" from the current section 424.11(d)(2), we intend the proposed language to continue to refer, among other things, to species that have been recovered, because species that have been recovered no longer meet the definition of either an endangered species or a threatened species.

Fourth, we are proposing to add a new provision, section 424.11(e)(3), clarifying that listed entities will be delisted if they do not meet the definition of "species" as set forth in the Act. This could occur if new information, or new analysis of existing information, leads the Secretary to determine that a currently listed entity is neither a taxonomic species or subspecies, nor a "distinct population segment." For example, where, after the time of listing, the Services conclude that a species or subspecies should no longer be recognized as a valid taxonomic entity, the listed entity would be removed from the list because it no longer meets the definition of a "species." In other instances, new data could indicate that a particular listed distinct population segment does not meet the criteria of the Services' Policy Regarding the Recognition of Distinct Vertebrate Population Segments Under the Endangered Species Act ("DPS Policy"; 61 FR 4722, February 7, 1996). In either circumstance, the entity would not meet the definition of a "species" and would not qualify for listing under the Act.

Fifth, we are proposing to remove current section 424.11(d)(3), which specifies that delisting could be due to error in the original data that the Services relied upon when adding species to the lists. This language is unnecessary because any circumstance in which a species was listed in error would be covered by new section 424.11(e)(2) or (e)(3).

Lastly, we are proposing technical changes to the existing regulations that remain in place to accommodate the proposed revisions discussed above. We are proposing to modify current section 424.11(b) to include a reference to the proposed section 424.11(d) regarding the foreseeable future and the proposed section 424.11(e) regarding delisting. We are proposing to modify current section 424.11(c) by adding minor clarifying language to specify that this paragraph refers to the statutory definitions of an endangered species and a threatened species.

Section 424.12—Criteria for Designating Critical Habitat

Not Prudent Determinations

We propose to revise section 424.12(a)(1) to set forth a nonexhaustive list of circumstances in which the Services may find it is not prudent to designate critical habitat as contemplated in section 4(a)(3)(A) of the Act. Under the clarifications that we propose in this revision, the Services would have the authority but would not be required to find that designation would not be prudent in the enumerated circumstances. This is a change from the current framework, which sets forth two situations in which critical habitat is not prudent. We anticipate that not-prudent determinations would continue to be rare. While this provision is intended to reduce the burden of regulation in rare circumstances in which designation of critical habitat does not contribute to the conservation of the species, the Services recognize the value of critical habitat as a conservation tool and expect to designate it in most cases.

We propose to retain the circumstance described in the longstanding language of current section 424.12(a)(1)(i), which is that the species is threatened by taking or other human activity and identification of critical habitat can be expected to increase the degree of such threat to the species.

We propose to remove the language in section 424.12(a)(1)(ii) indicating that it would not be prudent to designate critical habitat when "designation of critical habitat would not be beneficial to the species." In a number of cases, courts have remanded not-prudent findings to the Service(s) because the courts construed "would not be beneficial" in ways the Services had not intended. For example, a number of courts have held that it was unreasonable for FWS to make a notprudent determination simply because most or all of the areas that would be designated would not be subject to consultations under ESA section 7. E.g., Natural Resources Defense Council v. U.S. Dept. of Interior, 113 F.3d 1121 (9th Cir. 1997); Conservation Council for Hawaii v. Babbitt, 2 F. Supp. 2d 1280 (D. Haw. 1998). In Conservation Council, the court concluded that FWS had not determined that designation would "not be beneficial to the species" because designating critical habitat could bring other benefits to the species beyond consultation, such as informational benefits. 2 F. Supp. 2d at 1288. In NRDC, the court held that determining critical habitat to be not prudent because the majority of the areas that would be designated as critical habitat would not be subject to consultation was based on an improper interpretation of the regulatory phrase "not beneficial to the species" to mean "not beneficial to most of the species." 113 F.3d 1125–16. The existing regulatory language is not in the statute, and the Services consider the language unnecessary and difficult to understand and apply.

Basing determinations on whether particular circumstances are present, rather than on whether a designation would be beneficial, provides an interpretation of the statute that is clearer, more transparent, and more straightforward. In some situations, the Services may conclude, after a review of the best available scientific data, that a designation would nevertheless be prudent even in the enumerated circumstances. Conversely, the Services may find in some circumstances that are not enumerated in the proposed language that a designation of critical habitat would otherwise be not prudent.

We propose a number of circumstances in which designation of critical habitat would generally be not prudent, including some circumstances that were already captured in the current regulations at section 424.12(a)(1)(ii) and some additional circumstances that we have identified based on our experience in designating critical habitat. We propose to retain and move into new section 424.12(a)(1)(iv) the circumstance described in current section 424.12(a)(1)(ii), which is that no areas meet the definition of critical habitat. It is not possible for us to designate critical habitat when no areas meet the definition of critical habitat in the Act; therefore, in these cases, designation is not prudent. We also propose to retain and expand the concept of current section 424.12(a)(1)(ii) regarding the lack of habitat-based threats to the species.

In our 2016 revision of section 424.12(a)(1)(ii) (81 FR 7414, February 11, 2016), we clarified that, in determining whether designation may not be prudent, the Services could consider whether the present or threatened destruction, modification, or curtailment of a species' habitat or range (i.e., considerations under section 4(a)(1)(A) of the Act (Factor A)) is not a threat to the species. In the 2016 revision, we provided an example of a designation that would not be prudent due to the lack of habitat-based threats: A species is threatened primarily by disease, but the habitat upon which it relies remains intact without threat and would support conservation of the species if not for the threat of disease. Since then, we have encountered situations in which threats to the species' habitat stem solely from causes that cannot be addressed by management actions that may be identified through consultation under section 7(a)(2) of the Act. In those situations, a designation could create a regulatory burden without providing any conservation value to the species

concerned. Examples would include species experiencing threats stemming from melting glaciers, sea level rise, or reduced snowpack but no other habitatbased threats. In such cases, a critical habitat designation and any resulting section 7(a)(2) consultation, or conservation effort identified through such consultation, could not prevent glaciers from melting, sea levels from rising, or increase the snowpack. Thus, we propose in section 424.12(a)(1)(ii) that designation of critical habitat in these cases may not be prudent because it would not serve its intended function to conserve the species.

We also propose to add as an additional circumstance under section 424.12(a)(1)(iii) situations where critical habitat areas under the jurisdiction of the United States provide negligible conservation value for a species that primarily occurs in areas outside of U.S. jurisdiction. In our 2016 revision of these regulations, we noted in the preamble that this could be a basis for determining that critical habitat designation would be not prudent; however, we find it is clearer to add this consideration directly to the regulatory text. We would apply this determination only to species that primarily occur outside U.S. jurisdiction, and where no areas under U.S. jurisdiction contain features essential to the conservation of the species. The circumstances when a critical habitat designation would provide negligible conservation value for a species will be determined on a case-by-case basis and may consider such factors as threats to the species or habitat and the species needs.

Designating Unoccupied Areas

On February 11, 2016, the Services published a final rule revising the regulations at section 424.12, which establish criteria for designating critical habitat (81 FR 7439). One of the revisions we made was to eliminate the following paragraph (e): "The Secretary shall designate as critical habitat outside the geographical area presently occupied by a species only when a designation limited to its present range would be inadequate to ensure the conservation of the species." The Services explained in the preamble to the final rule that we had concluded that the "rigid step-wise approach" prescribed in that prior regulatory language may not be the best conservation strategy for the species and in some circumstances may result in a designation that is geographically larger, but less efficient as a conservation tool (81 FR 7415). Nonetheless, we are aware of continued perceptions that, by eliminating this provision, the Services

intended to designate as critical habitat expansive areas of unoccupied habitat. To address this concern, the Services propose to revise section 424.12(b)(2) by restoring the requirement that the Secretary will first evaluate areas occupied by the species. We also propose to clarify when the Secretary may determine unoccupied areas are essential for the conservation of the species.

In the Act, the term "geographical area occupied by the species" is further modified by the clause "at the time it is listed." However, if critical habitat is not designated concurrently with listing, or is revised years after the species was listed, it can be difficult to discern what was occupied at the time of listing. The known distribution of a species can change after listing for many reasons, such as discovery of additional localities, extirpation of populations, or emigration of individuals to new areas. In many cases, information concerning a species' distribution, particularly on private lands, is limited because surveys are not routinely carried out on private lands. Although surveys may be performed as part of an environmental analysis for a particular development proposal, such surveys typically focus on listed rather than non-listed species. Thus, our knowledge of a species distribution at the time of listing in these areas is often limited and the information in our listing rule may not detail all areas occupied by the species at that time.

Thus, while some of these changes in a species' known distribution reflect changes in the actual distribution of the species, some reflect only changes in the quality of our information concerning distribution. In these circumstances, the determination of which geographic areas were occupied at the time of listing may include data developed since the species was listed. This interpretation was supported by the court's decision, Otav Mesa Property L.P. v. DOI, 714 F. Supp. 2d 73 (D.D.C. 2010), rev'd on other grounds, 646 F.3d 914 (D.C. Cir. 2011) (San Diego fairy shrimp). In that decision, the judge noted that the clause "occupied at the time of listing" allows FWS to make a post-listing determination of occupancy based on the currently known distribution of the species in some circumstances. Although the D.C. Circuit disagreed with the district court that the record contained sufficient data to support the FWS' determination of occupancy in that case, the D.C. Circuit did not express disagreement with (or otherwise address) the district court's underlying conclusion that the Act allows FWS to make a post-listing

determination of occupancy if based on adequate data. The Services acknowledge that to make a post-listing determination of occupancy we must distinguish between actual changes to species occupancy and changes in available information.

The Act defines unoccupied critical habitat in terms of a determination that such areas are essential for the conservation of the species. The proposed section 424.12(b)(2) specifies how the Services would determine whether unoccupied areas are essential. The proposed language states the Services would only consider unoccupied areas to be essential in two situations: When a critical habitat designation limited to geographical areas occupied would (1) be inadequate to ensure the conservation of the species, or (2) result in less-efficient conservation for the species. The proposed changes will provide additional predictability to the process of determining when designating unoccupied habitat may be appropriate. For example, the Services could consider unoccupied habitat to be essential when a designation limited to occupied habitat would result in a geographically larger but less effective designation.

There are situations where a designation focused on occupied critical habitat would result in less efficient conservation for the species than a designation that includes a mix of occupied and unoccupied critical habitat. In these cases, the designation of some unoccupied areas would result in the same or greater conservation for the species but would do so more efficiently. Efficient conservation for the species refers to situations where the conservation is effective, societal conflicts are minimized, and resources expended are commensurate with the benefit to the species. The flexibility to include unoccupied areas in a designation where limiting the designation to occupied areas would have resulted in less-efficient conservation of the species will allow the Services to focus agency resources thoughtfully in both designating critical habitat and conducting future consultations on the critical habitat.

In addition, we propose to further clarify when the Secretary may determine that an unoccupied area may be essential for the conservation of the species. In order for an unoccupied area to be considered essential, the Secretary must determine that there is a reasonable likelihood that the area will contribute to the conservation of the species. In making a determination as to whether such a reasonable likelihood exists, the Services will continue to take into account the best available science regarding species-specific and areaspecific factors. This could include such factors as: (a) Whether the area is currently or is likely to become usable habitat for the species; (b) the likelihood that interagency consultation under Section 7 will be triggered, *i.e.*, whether any federal agency actions are likely to be proposed with respect to the area; and, (c) how valuable the potential contributions of the area are to the biological needs of the species.

When the Services evaluate if an area is now, or is likely to become, usable habitat for the species we would take into account, among other things, the current state of the area and extent to which extensive restoration would be needed for the area to become usable. For example, the Services might conclude that an area is unlikely to contribute to the conservation of the species where it would require extensive affirmative restoration that does not seem likely to occur such as when a non-federal landowner or necessary partners are unwilling to undertake or allow such restoration. Although the expressed intentions of such landowners or partners will not necessarily be determinative, the Services would consider those intentions in light of the mandatory duties and conservation purposes of the Act.

When the Services evaluate the likelihood that interagency consultation under section 7 will be triggered, we would consider whether there are any federal agency actions likely to be proposed within the area (*i.e.*, federal nexus). Because the only regulatory effect of a designation of critical habitat is the requirement that federal agencies avoid authorizing, funding, or undertaking actions that may destroy or adversely modify such habitat, the likelihood that an area will contribute to conservation is, in most cases, greater for public lands and lands for which such federal actions can be reasonably anticipated than for other types of land.

However, the Services would continue to consider the conservation purposes of the Act in determining how valuable the potential contributions of the area are to the biological needs of the species. In practice, this means that, in the rare instance where the potential contribution of the unoccupied area to the conservation of the listed species is extremely valuable, a lower threshold than "likely" may be appropriate. For example, where an area represents the only potential habitat of its type (*i.e.*, is uniquely able to support certain life functions of the species), the Services may reasonably classify that area as essential even in the face of a low likelihood that the area would contribute to species conservation. Conversely, a greater showing of likelihood may be required for an area that provides less significant conservation value.

Public Comments

You may submit your comments and materials concerning the proposed rule by one of the methods listed in **ADDRESSES**. Comments must be submitted to *http://www.regulations.gov* before 11:59 p.m. (Eastern Time) on the date specified in **DATES**. We will not consider hand-delivered comments that we do not receive, or mailed comments that are not postmarked, by the date specified in **DATES**.

We will post your entire comment including your personal identifying information—on *http:// www.regulations.gov.* If you provide personal identifying information in your comment, you may request at the top of your document that we withhold this information from public review. However, we cannot guarantee that we will be able to do so. Comments and materials we receive, as well as supporting documentation we used in preparing this proposed rule, will be available for public inspection on *http:// www.regulations.gov.*

Required Determinations

Regulatory Planning and Review— Executive Orders 12866 and 13563

Executive Order 12866 provides that the Office of Information and Regulatory Affairs (OIRA) in the Office of Management and Budget will review all significant rules. OIRA has determined that this rule is significant.

Executive Order 13563 reaffirms the principles of E.O. 12866 while calling for improvements in the nation's regulatory system to promote predictability, to reduce uncertainty, and to use the best, most innovative, and least burdensome tools for achieving regulatory ends. The executive order directs agencies to consider regulatory approaches that reduce burdens and maintain flexibility and freedom of choice for the public where these approaches are relevant, feasible, and consistent with regulatory objectives. E.O. 13563 emphasizes further that regulations must be based on the best available science and that the rulemaking process must allow for public participation and an open exchange of ideas. We have developed this rule in a manner consistent with these requirements. This proposed rule

is consistent with Executive Order 13563, and in particular with the requirement of retrospective analysis of existing rules, designed "to make the agency's regulatory program more effective or less burdensome in achieving the regulatory objectives."

Executive Order 13771

This proposed rule is expected to be an Executive Order 13771 deregulatory action.

Regulatory Flexibility Act

Under the Regulatory Flexibility Act (as amended by the Small Business Regulatory Enforcement Fairness Act (SBREFA) of 1996; 5 U.S.C. 601 et seq.), whenever a Federal agency is required to publish a notice of rulemaking for any proposed or final rule, it must prepare, and make available for public comment, a regulatory flexibility analysis that describes the effect of the rule on small entities (*i.e.*, small businesses, small organizations, and small government jurisdictions). However, no regulatory flexibility analysis is required if the head of an agency, or his designee, certifies that the rule will not have a significant economic impact on a substantial number of small entities. SBREFA amended the Regulatory Flexibility Act to require Federal agencies to provide a statement of the factual basis for certifying that a rule will not have a significant economic impact on a substantial number of small entities. We certify that, if adopted as proposed, this proposed rule would not have a significant economic effect on a substantial number of small entities. The following discussion explains our rationale.

This rulemaking revises and clarifies requirements for NMFS and FWS regarding factors for listing, delisting, or reclassifying species and designating critical habitat under the Endangered Species Act to reflect agency experience and to codify current agency practices. The proposed changes to these regulations do not expand the reach of species protections or designations of critical habitat.

NMFS and FWS are the only entities that are directly affected by this rule because we are the only entities that list species and designate critical habitat under the Endangered Species Act. No external entities, including any small businesses, small organizations, or small governments, will experience any economic impacts from this rule.

Unfunded Mandates Reform Act (2 U.S.C. 1501 et seq.)

In accordance with the Unfunded Mandates Reform Act

(2 U.S.C. 1501 et seq.):

(a) On the basis of information contained in the Regulatory Flexibility Act section above, this proposed rule would not "significantly or uniquely" affect small governments. We have determined and certify pursuant to the Unfunded Mandates Reform Act, 2 U.S.C. 1502, that this rule would not impose a cost of \$100 million or more in any given year on local or State governments or private entities. A Small Government Agency Plan is not required. As explained above, small governments would not be affected because the proposed rule would not place additional requirements on any city, county, or other local municipalities.

(b) This proposed rule would not produce a Federal mandate on State, local, or tribal governments or the private sector of \$100 million or greater in any year; that is, this proposed rule is not a "significant regulatory action" under the Unfunded Mandates Reform Act. This proposed rule would impose no obligations on State, local, or tribal governments.

Takings (E.O. 12630)

In accordance with Executive Order 12630, this proposed rule would not have significant takings implications. This proposed rule would not pertain to "taking" of private property interests, nor would it directly affect private property. A takings implication assessment is not required because this proposed rule (1) would not effectively compel a property owner to suffer a physical invasion of property and (2) would not deny all economically beneficial or productive use of the land or aquatic resources. This proposed rule would substantially advance a legitimate government interest (conservation and recovery of endangered species and threatened species) and would not present a barrier to all reasonable and expected beneficial use of private property.

Federalism (E.O. 13132)

In accordance with Executive Order 13132, we have considered whether this proposed rule would have significant Federalism effects and have determined that a federalism summary impact statement is not required. This proposed rule pertains only to factors for listing, delisting, or reclassifying species and designation of critical habitat under the Endangered Species Act, and would not have substantial direct effects on the States, on the relationship between the Federal Government and the States, or on the distribution of power and responsibilities among the various levels of government.

Civil Justice Reform (E.O. 12988)

This proposed rule does not unduly burden the judicial system and meets the applicable standards provided in sections 3(a) and 3(b)(2) of Executive Order 12988. This proposed rule would clarify factors for listing, delisting, or reclassifying species and designation of critical habitat under the Endangered Species Act.

Government-to-Government Relationship With Tribes

In accordance with Executive Order 13175, "Consultation and Coordination with Indian Tribal Governments," the Department of the Interior's manual at 512 DM 2, and the Department of Commerce (DOC) Tribal Consultation and Coordination Policy (May 21, 2013), DOC Departmental Administrative Order (DAO) 218-8 (April 2012), and NOAA Administrative Order (NAO) 218-8 (April 2012), we are considering possible effects of this proposed rule on federally recognized Indian Tribes. We will continue to collaborate/coordinate with tribes on issues related to federally listed species and their habitats. See Ioint Secretarial Order 3206 ("American Indian Tribal Rights, Federal-Tribal Trust Responsibilities, and the Endangered Species Act," June 5, 1997).

Paperwork Reduction Act

This proposed rule does not contain any new collections of information that require approval by the OMB under the Paperwork Reduction Act. This proposed rule will not impose recordkeeping or reporting requirements on State, local, or Tribal governments, individuals, businesses, or organizations. 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.

National Environmental Policy Act

We are analyzing this proposed regulation in accordance with the criteria of the National Environmental Policy Act (NEPA), the Department of the Interior regulations on Implementation of the National Environmental Policy Act (43 CFR 46.10–46.450), the Department of the Interior Manual (516 DM 8), the NOAA Administrative Order 216-6A, and the NOAA Companion Manual (CM),

"Policy and Procedures for Compliance

with the National Environmental Policy Act and Related Authorities" (effective January 13, 2017).

We anticipate that the categorical exclusion found at 43 CFR 46.210(i) likely applies to the proposed regulation changes. At 43 CFR 46.210(i), the Department of the Interior has found that the following category of actions would not individually or cumulatively have a significant effect on the human environment and are, therefore, categorically excluded from the requirement for completion of an environmental assessment or environmental impact statement: "Policies, directives, regulations, and guidelines: that are of an administrative, financial, legal, technical, or procedural nature.'

NOAA's NEPA procedures include a similar categorical exclusion for "preparation of policy directives, rules, regulations, and guidelines of an administrative, financial, legal, technical, or procedural nature." (Categorical Exclusion G7, at CM Appendix E).

We invite the public to comment on the extent to which this proposed regulation may have a significant impact on the human environment, or fall within one of the categorical exclusions for actions that have no individual or cumulative effect on the quality of the human environment. We will complete our analysis, in compliance with NEPA, before finalizing this regulation.

Energy Supply, Distribution or Use (E.O. 13211)

Executive Order 13211 requires agencies to prepare Statements of Energy Effects when undertaking certain actions. The proposed revised regulations are not expected to affect energy supplies, distribution, and use. Therefore, this action is not a significant energy action, and no Statement of Energy Effects is required.

Clarity of the Rule

We are required by Executive Orders 12866 and 12988 and by the Presidential Memorandum of June 1, 1998, to write all rules in plain language. This means that each rule we publish must:

(1) Be logically organized;

(2) Use the active voice to address readers directly:

(3) Use clear language rather than jargon;

(4) Be divided into short sections and sentences; and

(5) Use lists and tables wherever possible.

If you feel that we have not met these requirements, send us comments by one

of the methods listed in ADDRESSES. To better help us revise the rule, your comments should be as specific as possible. For example, you should tell us the numbers of the sections or paragraphs that are unclearly written, which sections or sentences are too long, the sections where you feel lists or tables would be useful, etc.

Authority

We issue this proposed rule under the authority of the Endangered Species Act, as amended (16 U.S.C. 1531 et seq).

List of Subjects in 50 CFR Part 424

Administrative practice and procedure, Endangered and threatened species.

Proposed Regulation Promulgation

For the reasons set out in the preamble, we hereby propose to amend part 424, subchapter A of chapter IV, title 50 of the Code of Federal Regulations, as set forth below:

PART 424—LISTING ENDANGERED AND THREATENED SPECIES AND **DESIGNATING CRITICAL HABITAT**

■ 1. The authority citation for part 424 continues to read as follows:

Authority: 16 U.S.C. 1531 et seq.

■ 2. Amend § 424.11 by revising paragraphs (b) through (f) and adding a new paragraph (g) to read as follows:

§424.11 Factors for listing, delisting, or reclassifying species. *

*

(b) The Secretary shall make any determination required by paragraphs (c), (d), and (e) of this section *solely* on the basis of the best available scientific and commercial information regarding a species' status.

(c) A species shall be listed or reclassified if the Secretary determines, on the basis of the best scientific and commercial data available after conducting a review of the species' status, that the species meets the definition of an endangered species or a threatened species because of any one or a combination of the following factors:

(1) The present or threatened destruction, modification, or curtailment of its habitat or range;

(2) Overutilization for commercial, recreational, scientific, or educational purposes;

(3) Disease or predation;

(4) The inadequacy of existing regulatory mechanisms; or

(5) Other natural or manmade factors affecting its continued existence.

(d) In determining whether a species is a threatened species, the Services

must analyze whether the species is likely to become an endangered species within the foreseeable future. The term foreseeable future extends only so far into the future as the Services can reasonably determine that the conditions potentially posing a danger of extinction in the foreseeable future are probable. The Services will describe the foreseeable future on a case-by-case basis, using the best available data and taking into account considerations such as the species' life-history characteristics, threat-projection timeframes, and environmental variability. The Services need not identify the foreseeable future in terms of a specific period of time, but may instead explain the extent to which they can reasonably determine that both the future threats and the species' responses to those threats are probable.

(e) The Secretary will delist a species if the Secretary finds that, after conducting a status review based on the best scientific and commercial data available:

(1) The species is extinct;

(2) The species does not meet the definition of an endangered species or a threatened species. In making such a determination, the Secretary shall consider the same factors and apply the same standards set forth in paragraph (c) of this section regarding listing and reclassification; or

(3) The listed entity does not meet the statutory definition of a species.

(f) The fact that a species of fish, wildlife, or plant is protected by the Convention on International Trade in Endangered Species of Wild Fauna and Flora (see part 23 of this title 50) or a similar international agreement on such species, or has been identified as requiring protection from unrestricted commerce by any foreign nation, or to be in danger of extinction or likely to become so within the foreseeable future by any State agency or by any agency of a foreign nation that is responsible for the conservation of fish, wildlife, or plants, may constitute evidence that the species is endangered or threatened. The weight given such evidence will vary depending on the international agreement in question, the criteria pursuant to which the species is eligible for protection under such authorities, and the degree of protection afforded the species. The Secretary shall give consideration to any species protected under such an international agreement, or by any State or foreign nation, to determine whether the species is endangered or threatened.

(g) The Secretary shall take into account, in making determinations under paragraphs (c) or (e) of this section, those efforts, if any, being made by any State or foreign nation, or any political subdivision of a State or foreign nation, to protect such species, whether by predator control, protection of habitat and food supply, or other conservation practices, within any area under its jurisdiction, or on the high seas.

■ 3. Amend § 424.12 by revising paragraphs (a)(1) and (b)(2) to read as follows:

§ 424.12 Criteria for designating critical habitat.

(a) * * *

(1) The Secretary may, but is not required to, determine that a designation would not be prudent in the following circumstances:

(i) The species is threatened by taking or other human activity and identification of critical habitat can be expected to increase the degree of such threat to the species;

(ii) The present or threatened destruction, modification, or curtailment of a species' habitat or range is not a threat to the species, or threats to the species' habitat stem solely from causes that cannot be addressed through management actions resulting from consultations under section 7(a)(2) of the Act;

(iii) Areas within the jurisdiction of the United States provide no more than negligible conservation value, if any, for a species occurring primarily outside the jurisdiction of the United States;

(iv) No areas meet the definition of critical habitat; or

(v) After analyzing the best scientific data available, the Secretary otherwise determines that designation of critical habitat would not be prudent.

- * *
- (b) * * *

(2) The Secretary will designate as critical habitat, at a scale determined by the Secretary to be appropriate, specific areas outside the geographical area occupied by the species only upon a determination that such areas are essential for the conservation of the species. When designating critical habitat, the Secretary will first evaluate areas occupied by the species. The Secretary will only consider unoccupied areas to be essential where a critical habitat designation limited to geographical areas occupied would be inadequate to ensure the conservation of the species or would result in less efficient conservation for the species. Efficient conservation for the species refers to situations where the conservation is effective, societal conflicts are minimized, and resources expended are commensurate with the benefit to the species. In addition, for an unoccupied area to be considered essential, the Secretary must determine that there is a reasonable likelihood that the area will contribute to the conservation of the species.

* * * *

Dated: July 18, 2018

Ryan K. Zinke,

Secretary, Department of the Interior.

Dated: July 16, 2018.

Wilbur Ross,

Secretary, Department of Commerce. [FR Doc. 2018–15810 Filed 7–24–18; 8:45 am]

BILLING CODE 4333-15-P; 3510-22-P

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.

COMMISSION ON CIVIL RIGHTS

Notice of Public Meetings of the Oklahoma Advisory Committee to the U.S. Commission on Civil Rights

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 that the Oklahoma Advisory Committee (Committee) will hold a meeting on Wednesday August 8, 2018 at 11 a.m. Central time. The Committee will discuss civil rights concerns in the state as they work to identify their next topic of study.

DATES: The meeting will take place on Wednesday August 8, 2018 at 11 a.m. Central.

Public Call Information: Dial: 866–290–0883, Conference ID: 2456203. FOR FURTHER INFORMATION CONTACT: Ana Fortes, DFO, at *afortes@usccr.gov* or (213) 894–3437.

SUPPLEMENTARY INFORMATION: Members of the public may listen to this discussion through the above call in number. An open comment period will be provided to allow members of the public to make a statement as time allows. The conference call operator will ask callers to identify themselves, the organization they are affiliated with (if any), and an email address prior to placing callers into the conference room. Callers can expect to incur regular charges for calls they initiate over wireless lines, according to their wireless plan. 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 1-800-8778339 and providing the Service with the conference call number and conference ID number.

Members of the public are entitled to submit written comments; the comments must be received in the regional office within 30 days following the meeting. Written comments may be mailed to the Regional Programs Unit, U.S. Commission on Civil Rights, 230 S Dearborn, Suite 2120, Chicago, IL 60604. They may also be faxed to the Commission at (312) 353–8324, or emailed to Corrine Sanders at *csanders*@ *usccr.gov.* Persons who desire additional information may contact the Regional Programs Unit at (312) 353– 8311.

Records generated from this meeting may be inspected and reproduced at the Regional Programs Unit Office, as they become available, both before and after the meeting. Records of the meeting will be available via www.facadatabase.gov under the Commission on Civil Rights, Oklahoma Advisory Committee link (https://facadatabase.gov/committee/ *meetings.aspx?cid=269*). Click on "meeting details" and then "documents" to download. Persons interested in the work of this Committee are directed to the Commission's website, http://www.usccr.gov, or may contact the Regional Programs Unit at the above email or street address.

Agenda

Welcome and Roll Call Civil Rights in Oklahoma: Project topics Future Plans and Actions Public Comment Adjournment Dated: July 20, 2018.

Dateu. July 20, 2010

David Mussatt,

Supervisory Chief, Regional Programs Unit. [FR Doc. 2018–15899 Filed 7–24–18; 8:45 am] BILLING CODE P

COMMISSION ON CIVIL RIGHTS

Notice of Public Meeting of the California Advisory Committee

AGENCY: U.S. Commission on Civil Rights.

ACTION: Announcement of meeting.

SUMMARY: Notice is hereby given, pursuant to the provisions of the rules and regulations of the U.S. Commission on Civil Rights (Commission) and the Federal Advisory Committee Act (FACA) that a meeting of the California State Advisory Committee (Committee) to the Commission will be held at 10:00 a.m. (Pacific Time) Tuesday, July 31, 2018. The purpose of the meeting is for the Committee to review project proposal examining Proposition 47. **DATES:** The meeting will be held on

Tuesday, July 31, 2018, at 10:00 a.m. PT. *Public Call Information: Dial:* 800–946–0783. *Conference ID:* 2620359.

FOR FURTHER INFORMATION CONTACT: Ana Victoria Fortes at *afortes@usccr.gov* or (213) 894–3437.

SUPPLEMENTARY INFORMATION: This meeting is available to the public through the following toll-free call-in number: 800-946-0783, conference ID number: 2620359. 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 landline 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. They may be faxed to the Commission at (213) 894-0508, or emailed Ana Victoria Fortes at afortes@ usccr.gov. Persons who desire additional information may contact the Regional Programs Unit at (213) 894-3437.

Records and documents discussed during the meeting will be available for public viewing prior to and after the meeting at *https://facadatabase.gov/ committee/meetings.aspx?cid=237.* Please click on the "Meeting Details" and "Documents" links. Records generated from this meeting may also be inspected and reproduced at the

Notices

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

I. Welcome

- II. Discuss Prop 47 Project Proposal a. USCCR feedback
- b. Committee feedback
- III. Public Comment
- IV. Next Steps and Potential Meeting Date
- V. Adjournment

Exceptional Circumstance: Pursuant to 41 CFR 102–3.150, the notice for this meeting is given less than 15 calendar days prior to the meeting because of the exceptional circumstance of staffing limitations that require immediate action.

Dated: July 19, 2018.

David Mussatt,

Supervisory Chief, Regional Programs Unit. [FR Doc. 2018–15828 Filed 7–24–18; 8:45 am] BILLING CODE P

COMMISSION ON CIVIL RIGHTS

Notice of Public Meeting of the Nevada Advisory Committee

AGENCY: U.S. Commission on Civil Rights.

ACTION: Announcement of meeting.

SUMMARY: Notice is hereby given, pursuant to the provisions of the rules and regulations of the U.S. Commission on Civil Rights (Commission) and the Federal Advisory Committee Act (FACA) that a meeting of the Nevada Advisory Committee (Committee) to the Commission will be held at 9:00 a.m. to 5:00 p.m. (Pacific Time) Thursday, August 9, 2018, the purpose of meeting is for the Committee to receive testimony on the impact of Nevada policing practices on the administration of justice as it relates to mental health, with a special emphasis on the impact on veterans and people of color.

DATES: The meeting will be held on Thursday, August 9, 2018, at 9:00 a.m. to 5:00 p.m.

ADDRESSES: Embassy Suites; 4315 Swenson Street, Las Vegas, NV 89119; Flamingo 1 Conference Room.

FOR FURTHER INFORMATION CONTACT: Ana Victoria Fortes (DFO) at *afortes@ usccr.gov* or (213) 894–3437.

SUPPLEMENTARY INFORMATION: Members of the public are entitled to make

comments during the open period at the end of the meeting. Members of the public may also submit written comments; the comments must be received in the Regional Programs Unit within 30 days following the meeting. Written comments may be mailed to the Western Regional Office, U.S. Commission on Civil Rights, 300 North Los Angeles Street, Suite 2010, Los Angeles, CA 90012. They may be faxed to the Commission at (213) 894–0508, or emailed Ana Victoria Fortes at *afortes*@ usccr.gov. Persons who desire additional information may contact the Regional Programs Unit at (213) 894-3437.

Records and documents discussed during the meeting will be available for public viewing prior to and after the meeting at http://facadatabase.gov/ committee/meetings.aspx?cid=261.

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, *http:// www.usccr.gov*, or may contact the Regional Programs Unit at the above email or street address.

Agenda

- I. Opening Remarks and Introductions (9:00 a.m.-9:15 a.m.)
- II. Panel Presentations
 - Community Policing & Crime Reduction (9:15 a.m.–10:30 a.m.)
 - Understanding Mental Illness and the Criminal Justice System (10:45 a.m.–11:45 a.m.)
 - Open Forum (11:45 a.m.-12:15 p.m.) Break (12:15 a.m.-1:30 p.m.)
- Potential Solutions (1:30 p.m.–2:30 p.m.)
- Community Voices (2:45 p.m.–4:00 p.m.)

Open Forum (4:00 p.m.–5:00 p.m.) III. Closing Remarks (5:00 p.m.–5:15

- p.m.)
- Dated: July 19, 2018.

David Mussatt,

Supervisory Chief, Regional Programs Unit. [FR Doc. 2018–15827 Filed 7–24–18; 8:45 am] BILLING CODE P

COMMISSION ON CIVIL RIGHTS

Notice of Public Meeting of the Alaska Advisory Committee

AGENCY: U.S. Commission on Civil Rights.

ACTION: Announcement of meeting.

SUMMARY: Notice is hereby given, pursuant to the provisions of the rules and regulations of the U.S. Commission on Civil Rights (Commission) and the Federal Advisory Committee Act (FACA) that a meeting of the Alaska Advisory Committee (Committee) to the Commission will be held at 12:00 p.m. (Alaska Time) Thursday, August 2, 2018. The purpose of the meeting is for the Committee to hear from testimony Virgene Hanna and Jessica Passini, authors of the Institute of Social and Economic Research report: (https:// iseralaska.org/publications/?id=1712), Perceptions of Universal Ballot Delivery Systems.

DATES: The meeting will be held on Thursday, August 2, 2018, at 12:00 p.m. AKT.

Public Call Information: Dial: 800–580–5706. Conference ID: 8880393.

Web Access Information: (visual only) The online portion of the meeting may be accessed through the following link: https://cc.readytalk.com/r/glmodes6 apfy&eom.

FOR FURTHER INFORMATION CONTACT: Ana Victoria Fortes (DFO) at *afortes*@ *usccr.gov* or (213) 894–3437.

SUPPLEMENTARY INFORMATION: This meeting is available to the public through the following toll-free call-in number: 800-580-5706, conference ID number: 8880393. 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 landline 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. They may be faxed to the Commission at (213) 894-0508, or emailed Ana Victoria Fortes at afortes@ usccr.gov. Persons who desire additional information may contact the

Regional Programs Unit at (213) 894– 3437.

Records and documents discussed during the meeting will be available for public viewing prior to and after the meeting at https://facadatabase.gov/ committee/meetings.aspx?cid=234. Please click on the "Meeting Details" and "Documents" links. Records generated from this meeting may also be inspected and reproduced at the Regional Programs Unit, as they become available, both before and after the meeting. Persons interested in the work of this Committee are directed to the Commission's website, https:// www.usccr.gov, or may contact the Regional Programs Unit at the above email or street address.

Agenda:

I. Welcome

II. Presentations by Virgene Hanna and Jessica Passini

III. Public Comment

- IV. Next Steps
- V. Adjournment

Exceptional Circumstance: Pursuant to 41 CFR 102–3.150, the notice for this meeting is given less than 15 calendar days prior to the meeting because of the exceptional circumstance of staffing limitations that require immediate action.

Dated: July 20, 2018.

David Mussatt,

Supervisory Chief, Regional Programs Unit. [FR Doc. 2018–15931 Filed 7–24–18; 8:45 am] BILLING CODE P

DEPARTMENT OF COMMERCE

Economic Development Administration

Notice of Petitions by Firms for Determination of Eligibility To Apply for Trade Adjustment Assistance

AGENCY: Economic Development Administration, U.S. Department of Commerce. **ACTION:** Notice and opportunity for public comment.

SUMMARY: The Economic Development Administration (EDA) has received petitions for certification of eligibility to apply for Trade Adjustment Assistance from the firms listed below. Accordingly, EDA has initiated investigations to determine whether increased imports into the United States of articles like or directly competitive with those produced by each of the firms contributed importantly to the total or partial separation of the firms' workers, or threat thereof, and to a decrease in sales or production of each petitioning firm.

SUPPLEMENTARY INFORMATION:

LIST OF PETITIONS RECEIVED BY EDA FOR CERTIFICATION OF ELIGIBILITY TO APPLY FOR TRADE ADJUSTMENT ASSISTANCE

[07/11/2018 through 07/17/2018]

Firm name			Firm address	Date accepted for investigation	Product(s)
Mectron Inc	Engineering	Company,	400 South Industrial Drive, Saline, MI 48176.	7/13/2018	The firm manufactures high-speed industrial inspec- tion machinery.
Seidel, LLC			2223 Thomaston Avenue, Water- bury, CT 06704.	7/13/2018	The firm provides aluminum anodizing finishes for various industries and applications.
Meyer Wells, Inc			421 3rd Avenue West, Seattle, WA 98119.	7/17/2018	The firm manufactures commercial and residential furniture, mostly made of reclaimed wood.

Any party having a substantial interest in these proceedings may request a public hearing on the matter. A written request for a hearing must be submitted to the Trade Adjustment Assistance Division, Room 71030, Economic Development Administration, U.S. Department of Commerce, Washington, DC 20230, no later than ten (10) calendar days following publication of this notice. These petitions are received pursuant to section 251 of the Trade Act of 1974, as amended.

Please follow the requirements set forth in EDA's regulations at 13 CFR 315.9 for procedures to request a public hearing. The Catalog of Federal Domestic Assistance official number and title for the program under which these petitions are submitted is 11.313, Trade Adjustment Assistance for Firms.

Irette Patterson,

Program Analyst.

[FR Doc. 2018–15850 Filed 7–24–18; 8:45 am]

BILLING CODE 3510-WH-P

DEPARTMENT OF COMMERCE

Bureau of Industry and Security

Notice of Request for Public Comments on Section 232 National Security Investigation of Imports of Uranium

AGENCY: Bureau of Industry and Security, Office of Technology Evaluation, U.S. Department of Commerce.

ACTION: Notice of request for public comments.

SUMMARY: The Secretary of Commerce has initiated an investigation to determine the effects on the national security of imports of uranium. This investigation has been initiated under section 232 of the Trade Expansion Act of 1962, as amended.

Interested parties are invited to submit written comments, data, analyses, or other information pertinent to the investigation to the Department of Commerce's Bureau of Industry and Security. This notice identifies issues on which the Department is especially interested in obtaining the public's views.

DATES: Comments may be submitted at any time but must be received by September 10, 2018.

ADDRESSES: All written comments on the notice must be submitted by one of the following methods:

• By the Federal eRulemaking Portal: http://www.regulations.gov. Comments on this notice may be submitted to regulations.gov docket number BIS– 2018–0011.

• By mail or delivery to Michael Vaccaro, Acting Director, Office of Technology Evaluation, Bureau of Industry and Security, U.S. Department of Commerce, 1401 Constitution Avenue NW, Room 1093, Washington, DC 20230.

• By email directly to *Uranium232*@ *bis.doc.gov.*

FOR FURTHER INFORMATION CONTACT:

Michael Vaccaro, Acting Director, Office of Technology Evaluation, Bureau of Industry and Security, U.S. Department of Commerce (202) 482–4060, *Uranium232@bis.doc.gov.* For more information about the section 232 program, including the regulations and the text of previous investigations, see *www.bis.doc.gov/232.*

SUPPLEMENTARY INFORMATION:

Background

On July 18, 2018, the Secretary of Commerce ("Secretary") initiated an investigation under section 232 of the Trade Expansion Act of 1962, as amended (19 U.S.C. 1862), to determine the effects on the national security of imports of uranium.

Written Comments

This investigation is being undertaken in accordance with part 705 of the National Security Industrial Base Regulations (15 CFR parts 700 to 709) ("NSIBR"). Interested parties are invited to submit written comments, data, analyses, or information pertinent to this investigation to the Office of Technology Evaluation, U.S. Department of Commerce ("the Department"), no later than September 10, 2018.

The Department is particularly interested in comments and information directed to the criteria listed in § 705.4 of the regulations as they affect national security, including the following: (a) Quantity of or other circumstances related to the importation of uranium; (b) Domestic production and productive capacity needed for uranium to meet projected national defense requirements; (c) Existing and anticipated availability of human resources, products, raw materials, production equipment, and facilities to produce uranium; (d) Growth requirements of the uranium industry to meet national defense requirements and/or requirements to assure such growth; (e) The impact of foreign competition on the economic welfare of the uranium industry; (f) The displacement of any domestic uranium production causing substantial unemployment, decrease in the revenues of government, loss of investment or specialized skills and productive capacity, or other serious effects; (g) Relevant factors that are causing or will cause a weakening of our national economy; and (h) Any other relevant factors.

Material submitted by members of the public that is business confidential information will be exempted from public disclosure as provided for by § 705.6 of the regulations. Anyone submitting business confidential information should clearly identify the business confidential portion of the submission, file a statement justifying nondisclosure and referring to the specific legal authority claimed, and provide a non-confidential submission which can be placed in the public file. Communications from agencies of the United States Government will not be made available for public inspection. If public hearings are held in support of this investigation, a separate **Federal Register** notice will be published.

The Bureau of Industry and Security does not maintain a separate public inspection facility. Requesters should first view the Bureau's web page, which can be found at *https:// efoia.bis.doc.gov/* (see "Electronic FOIA" heading). If requesters cannot access the website, they may call 202– 482–0795 for assistance. The records related to this assessment are made accessible in accordance with the regulations published in part 4 of title 15 of the Code of Federal Regulations (15 CFR 4.1 *et seq.*).

Dated: July 19, 2018.

Wilbur Ross,

Secretary of Commerce. [FR Doc. 2018–15891 Filed 7–24–18; 8:45 am] BILLING CODE 3510–33–P

DEPARTMENT OF COMMERCE

International Trade Administration

[A-570-814]

Carbon Steel Butt-Weld Pipe Fittings From the People's Republic of China: Preliminary Affirmative Determination of Circumvention of the Antidumping Duty Order

AGENCY: Enforcement and Compliance, International Trade Administration, Department of Commerce.

SUMMARY: The Department of Commerce (Commerce) preliminarily determines that carbon steel butt-weld pipe fittings (butt-weld pipe fittings) exported from Malaysia, which were completed in Malaysia using finished or unfinished butt-weld pipe fittings sourced from the People's Republic of China (China), are circumventing the antidumping duty (AD) order on butt-weld pipe fittings from China.

DATES: Applicable July 25, 2018. **FOR FURTHER INFORMATION CONTACT:** Jerry Huang or Susan Pulongbarit, AD/CVD Operations, Office V, Enforcement and Compliance, International Trade Administration, U.S. Department of Commerce, 1401 Constitution Avenue NW, Washington, DC 20230; telephone: (202) 482–4047 or (202) 482–4031, respectively.

SUPPLEMENTARY INFORMATION:

Background

On July 6, 1992, Commerce issued the AD order on imports of butt-weld pipe fittings from China.¹ Additionally, on March 31, 1994. Commerce issued an affirmative final anti-circumvention determination finding that imports into the United States of pipe fittings that were finished in Thailand from unfinished pipe fittings produced in China constituted circumvention of the Order within the meaning of section 781(b) of the Tariff Act of 1930, as amended (the Act).² Commerce applied this finding of circumvention to all imports of butt-weld pipe fittings from Thailand, regardless of manufacturer/ producer, unless accompanied by a certification stating that such pipe fittings have not been produced from unfinished pipe fittings sourced from China.³

On May 22, 2017, Tube Forgings of America, Inc., Mills Iron Works, Inc., and Hackney Ladish, Inc., (collectively, the domestic parties), alleged that imports of butt-weld pipe fittings which were completed in Malaysia using finished or unfinished butt-weld pipe fittings sourced from China are circumventing the Order.⁴ In their allegation, the domestic parties requested that Commerce initiate an anti-circumvention inquiry pursuant to section 781(b) of the Act, and 19 CFR 351.225(h), to determine whether imports of butt-weld pipe fittings sourced from unfinished or finished butt-weld pipe fittings from the PRC have undergone minor finishing processes, or were simply marked with "Malaysia" as the country of origin, in Malaysia, before export to the United States constitutes circumvention of the Order. The domestic parties also requested that Commerce reach an affirmative determination of circumvention for all imports of butt-

² See Certain Carbon Steel Butt-Weld Pipe Fittings from the People's Republic of China; Affirmative Final Determination of Circumvention of Antidumping Duty Order, 59 FR 15155 (March 31, 1994).

³ Id., at 15158–59.

⁴ See Letter from the domestic parties to the Secretary of Commerce, "Carbon Steel Butt-Weld Pipe Fittings from the People's Republic of China, A–570–814; Request for Circumvention Ruling Pursuant to Section 781(b) of the Tariff Act of 1930," dated May 22, 2017.

¹ See Antidumping Duty Order and Amendment to the Final Determination of Sales at Less Than Fair Value; Certain Carbon Steel Butt-Weld Pipe Fittings from the People's Republic of China, 57 FR 29702 (July 6, 1992) (Order).

weld pipe fittings from Malaysia, regardless of producer or exporter.

On August 25, 2017, Commerce published in the Federal Register the notice of initiation of this anticircumvention inquiry.⁵ For a complete description of the events that followed the initiation of this inquiry, see the Preliminary Decision Memorandum.⁶ A list of topics included in the Preliminary Decision Memorandum is included as Appendix I to this notice. The Preliminary Decision Memorandum is a public document and is on file electronically via Enforcement and Compliance's Antidumping and Countervailing Duty Centralized Electronic Service System (ACCESS). ACCESS is available to registered users at https://access.trade.gov, and to all parties in the Central Records Unit, room B8024 of the main Department of Commerce building. In addition, a complete version of the Preliminary Decision Memorandum can be accessed directly at http://enforcement.trade.gov/ *frn/.* The signed and the electronic versions of the Preliminary Decision Memorandum are identical in content.

Scope of the Order

The products covered by the *Order* are carbon steel butt-weld pipe fittings. For a complete description of the scope of the *Order, see* the Preliminary Decision Memorandum.⁷

Scope of the Anti-Circumvention Inquiry

This anti-circumvention inquiry covers butt-weld pipe fittings exported from Malaysia to the United States, which were completed in Malaysia using finished or unfinished butt-weld pipe fittings sourced from China (inquiry merchandise). This preliminary ruling applies to all shipments of inquiry merchandise on or after the date of the initiation of this inquiry.

Methodology

Commerce is conducting this anticircumvention inquiry in accordance with section 781(b) of the Act. For a full description of the methodology underlying Commerce's preliminary determination, *see* the Preliminary Decision Memorandum.

Preliminary Finding

As detailed in the Preliminary Decision Memorandum, we preliminarily determine that butt-weld pipe fittings exported from Malaysia, which were completed in Malaysia using finished or unfinished butt-weld pipe fittings from China, or were simply marked with "Malaysia" as the country of origin are circumventing the Order. As such, we preliminarily determine that it is appropriate to include this merchandise within the Order and to instruct U.S. Customs and Border Protection (CBP) to suspend any entries of butt-weld pipe fittings from Malaysia, which were completed in Malaysia using finished or unfinished butt-weld pipe fittings from China, or were simply marked with "Malaysia" as the country of origin. We also preliminarily determine that Arah Dagang Sdn. Bhd. (Arah Dagang), Solidbend Fittings & Flanges Sdn. Bhd. (Solidbend), and Sumitomo Corporation Asia & Oceania Pte. Ltd. (Sumitomo) have not exported butt-weld pipe fittings which were completed in Malaysia using finished or unfinished butt-weld pipe fittings from China.

Suspension of Liquidation

In accordance with 19 CFR 351.225(l)(2), Commerce will direct CBP to suspend liquidation and to require a cash deposit of estimated duties on unliquidated entries of butt-weld pipe fittings completed or simply marked in Malaysia from Chinese-origin finished or unfinished butt-weld pipe fittings that were entered, or withdrawn from warehouse, for consumption on or after August 21, 2017, the date of initiation of the anti-circumvention inquiry.

The suspension of liquidation instructions will remain in effect until further notice. Commerce will instruct CBP to require AD cash deposits equal to the China-wide rate of 182.90 percent, unless the importer/exporter can certify to CBP that the Chineseorigin finished or unfinished butt-weld pipe fittings completed in Malaysia were supplied by a Chinese manufacturer with a company-specific separate rate. In that instance, the cash deposit rate will be the rate of the Chinese butt-weld pipe fittings manufacturer that has its own rate.⁸

Butt-weld pipe fittings completed in Malaysia from finished and unfinished butt-weld pipe fittings that are not of Chinese-origin are not subject to this inquiry. Therefore, cash deposits are not required for such merchandise, subject to the following certification requirements.9 An importer of butt-weld pipe fittings from Malaysia claiming that its butt-weld pipe fittings were not completed from finished and unfinished Chinese butt-weld pipe fittings must meet the certification and documentation requirements described in Appendix II. Appendix II requires the importer to prepare and retain certifications and documents not only on its own behalf, but also get a certification from the exporter of this merchandise. Specifically, importers of such butt-weld pipe fittings must prepare and maintain an Importer Certification (see Appendix III) as well as documentation supporting the Importer Certification. Besides the Importer Certification, the importer must also maintain a copy of the appropriate Exporter Certification (see Appendix IV) and relevant supporting documentation from its exporter of buttweld pipe fittings that were not completed using Chinese-origin finished and unfinished butt-weld pipe fittings. Importers must ensure that their exporters of butt-weld pipe fittings completed from finished and unfinished butt-weld pipe fittings of non-Chinese origin must prepare and maintain an Exporter Certification and documentation supporting the Exporter Certification (see Appendix IV).

Verification

As provided in 19 CFR 351.307, Commerce intends to verify information relied upon in making its final determination.

Public Comment

Case briefs or other written comments may be submitted to the Assistant Secretary for Enforcement and Compliance no later than seven days after the date on which the last final verification report is issued in this anticircumvention inquiry, unless the Secretary alters the time limit. Rebuttal briefs, limited to issues raised in case briefs, may be submitted no later than five days after the deadline date for case

⁵ See Carbon Steel Butt-Weld Pipe Fittings from the People's Republic of China: Initiation of Anti-Circumvention Inquiry on the Antidumping Duty Order, 82 FR 40556 (August 25, 2017).

⁶ See Memorandum, "Preliminary Decision Memorandum for the Anti-Circumvention Inquiry on the Antidumping Duty Order on Certain Carbon Steel Butt-Weld Pipe Fittings from the People's Republic of China," dated concurrently with, and hereby adopted by, this notice (Preliminary Decision Memorandum).

⁷ Id.

⁸ See, e.g., Glycine from the People's Republic of China: Preliminary Partial Affirmative Determination of Circumvention of the Antidumping Duty Order and Initiation of Scope Inquiry, 77 FR 21532, 21535 (April 10, 2012), unchanged in Glycine from the People's Republic of China: Final Partial Affirmative Determination of Circumvention of the Antidumping Duty Order, 77 FR 73426 (December 10, 2012).

⁹ In light of our preliminary determination that Arah Dagang, Solidbend, and Sumitomo have not exported butt-weld pipe fittings which were completed or marked in Malaysia using finished or unfinished butt-weld pipe fittings from China, we will not instruct CBP to suspend liquidation of any unliquidated entries of non-Chinese origin buttweld pipe fittings, subject to their meeting the certification requirements.

briefs.¹⁰ Pursuant to 19 CFR 351.309(c)(2) and (d)(2), parties who submit case briefs or rebuttal briefs in this anti-circumvention inquiry are encouraged to submit with each argument: (1) A statement of the issue; (2) a brief summary of the argument; and (3) a table of authorities.

Pursuant to 19 CFR 351.310(c), interested parties who wish to request a hearing, limited to issues raised in the case and rebuttal briefs, must submit a written request to the Assistant Secretary for Enforcement and Compliance, U.S. Department of Commerce, within 30 days after the date of publication of this notice. Requests should contain the party's name, address, and telephone number, the number of participants, whether any participant is a foreign national, and a list of the issues to be discussed. If a request for a hearing is made, Commerce intends to hold the hearing at the U.S. Department of Commerce, 1401 Constitution Avenue NW, Washington, DC 20230, at a time and date to be determined. Parties should confirm by telephone the date, time, and location of the hearing two days before the scheduled date.

International Trade Commission Notification

Commerce, consistent with section 781(e) of the Act, has notified the International Trade Commission (ITC) of this preliminary determination to include the merchandise subject to this anti-circumvention inquiry within the *Order.* Pursuant to section 781(e) of the Act, the ITC may request consultations concerning Commerce's proposed inclusion of the inquiry merchandise. If, after consultations, the ITC believes that a significant injury issue is presented by the proposed inclusion, it will have 60 days from the date of notification by Commerce to provide written advice.

Notification to Interested Parties

This determination is issued and published in accordance with section 781(b) of the Act and 19 CFR 351.225(f).

Dated: July 18, 2018.

Gary Taverman,

Deputy Assistant Secretary for Antidumping and Countervailing Duty Operations, performing the non-exclusive functions and duties of the Assistant Secretary for Enforcement and Compliance.

Appendix I

List of Topics Discussed in the Preliminary Decision Memorandum

I. Summary

II. Background

- III. Scope of the Order
- IV. Scope of the Anti-Circumvention Inquiry
- V. Period of Inquiry
- VI. Statutory Framework
- VII. Use of Facts Available With an Adverse Inference
- VIII. Anti-circumvention Determination
- IX. Country-Wide Determination
- X. Certification for Not Using Chinese-Origin Butt-Weld Pipe Fittings XI. Recommendation

Appendix II

Certification Requirements

If an importer imports carbon steel buttweld pipe fittings (butt-weld pipe fittings) from Malaysia and claims that the butt-weld pipe fittings were completed in Malaysia using finished or unfinished butt-weld pipe fittings manufactured of non-Chinese origin, the importer is required to complete and maintain the importer certification, attached as Appendix III. The importer is further required to maintain a copy of the exporter certification, discussed below and attached as Appendix IV. The importer certification must be completed, signed, and dated by the time of filing of the entry summary for the relevant importation. Where the importer uses a broker to facilitate the entry process, it should obtain the entry number from the broker. Agents of the importer, such as brokers, however, are not permitted to make this certification on behalf of the importer.

The exporter is required to complete and maintain the exporter certification, attached as Appendix IV, and is further required to provide the importer a copy of that certification and all supporting documentation. The exporter certification must be completed, signed, and dated by the time of shipment of the relevant entries. The exporter certification should be completed by the party selling the merchandise manufactured in Malaysia to the United States, which is not necessarily the producer of the product.

The importer will not be required to submit the certifications or supporting documentation to CBP as part of the entry process. However, the importer and the exporter will be required to present the certifications and supporting documentation, to Commerce and/or U.S. Customs and Border Protection (CBP), as applicable, upon request by the respective agency. Additionally, the claims made in the certifications and any supporting documentation are subject to verification by Commerce and/or CBP. The importer and exporter are required to maintain the certifications and supporting documentation for the later of (1) a period of five years from the date of entry or (2) a period of three years after the conclusion of any litigation in United States courts regarding such entries. If it is determined that the certification and/ or documentation requirements in a certification have not been met, Commerce intends to instruct CBP to suspend, under the antidumping duty (AD) order on butt-weld pipe fittings from the People's Republic of China, A-570-814, all unliquidated entries for which these requirements were not met and require the importer to post applicable

AD cash deposits equal to the rates as determined by Commerce. Entries suspended under A–570–814 will be liquidated pursuant to applicable administrative reviews of the China AD order or through the automatic liquidation process.

For butt-weld pipe fittings completed in Malaysia from finished or unfinished buttweld pipe fittings manufactured in China, Commerce has established the following third-country case number in the Automated Commercial Environment (ACE): A–557–994.

For entries suspended pursuant to the preliminary determination of this anticircumvention inquiry that were shipped and/or entered, or withdrawn from warehouse, for consumption during the period, August 21, 2017 (the date of initiation of this anti-circumvention inquiry) through the date of publication of the preliminary determination in the Federal Register, for which certifications are required, the importer and exporter certifications should be completed within 45 days of publication of the preliminary determination in the Federal Register. Accordingly, the relevant bullet in the certification should be edited to reflect that the certification was completed within this time frame. For example, the bullet in the importer certification that reads: "This certification was completed by the time of filing the entry summary," could be edited as follows: "The shipments/products referenced herein entered before the mm/dd/ yyyy publication of the Preliminary Determination Federal Register notice. This certification was completed on mm/dd/ yyyy, within 45 days of the Federal Register notice publication." Similarly, the bullet in the exporter certification that reads, "This certification was completed by the time of shipment," could be edited as follows: "The shipments/products referenced herein shipped before the mm/dd/yyyy publication of the Preliminary Determination Federal Register notice. This certification was completed on mm/dd/yyyy, within 45 days of the Federal Register notice publication." For such entries, importers and exporters each have the option to complete a blanket certification covering multiple entries, individual certifications for each entry, or a combination thereof. The importer certifications, and copies of the exporter certifications, should be maintained by the importer and provided to CBP or Commerce only upon request by the respective agency. The exporter must provide the importer a copy of the exporter certification within 45 days of the publication of the preliminary determination in the Federal Register.

For unliquidated entries (and entries for which liquidation has not become final) of merchandise entered as type 01 entries that were shipped and/or entered, or withdrawn from warehouse, for consumption during the period, August 21, 2017 (the date of initiation of this anti-circumvention inquiry) through the date of publication of the preliminary determination in the **Federal Register**, for which certifications are required, importers should file a Post Summary Correction with CBP, in accordance with CBP's regulations, regarding conversion of such entries from type 01 to type 03 entries and report those type 03 entries using the third-country case

 $^{^{10}}$ See 19 CFR 351.309; see also 19 CFR 351.303 (for general filing requirements).

number, A–557–994. Similarly, the importer should pay cash deposits on those entries consistent with the regulations governing post summary corrections that require payment of additional duties.

Appendix III

Importer Certification

I hereby certify that:

• My name is {COMPANY OFFICIAL'S NAME} and I am an official of {IMPORTING COMPANY};

• I have direct personal knowledge of the facts regarding the importation into the Customs territory of the United States of the carbon steel butt-weld pipe fittings completed in Malaysia that entered under entry number(s) {INSERT ENTRY NUMBER(S)} and are covered by this certification. "Direct personal knowledge" refers to facts the certifying party is expected to have in its own records. For example, the importer should have "direct personal knowledge" of the importation of the product (*e.g.*, the name of the exporter) in its records;

• I have personal knowledge of the facts regarding the production of the imported products covered by this certification. "Personal knowledge" includes facts obtained from another party, (*e.g.*, correspondence received by the importer (or exporter) from the producer regarding the source of the substrate used to produce the imported products);

• The carbon steel butt-weld pipe fittings completed in Malaysia do not contain finished or unfinished butt-weld pipe fittings manufactured in the People's Republic of China;

• I understand that {IMPORTING COMPANY} is required to maintain a copy of this certification and sufficient documentation supporting this certification (*i.e.*, documents maintained in the normal course of business, or documents obtained by the certifying party, for example, mill certificates, productions records, invoices, etc.) for the later of (1) a period of five years from the date of entry or (2) a period of three years after the conclusion of any litigation in the United States courts regarding such entries:

• I understand that {IMPORTING COMPANY} is required to provide this certification and supporting records, upon request, to U.S. Customs and Border Protection (CBP) and/or the Department of Commerce (Commerce);

• I understand that {IMPORTING COMPANY} is required to maintain a copy of the exporter's certification, (attesting to the production and/or export of the imported merchandise identified above), for the later of (1) a period of five years from the date of entry or (2) a period of three years after the conclusion of any litigation in United States courts regarding such entries;

• I understand that {IMPORTING COMPANY}is required to maintain and provide a copy of the exporter's certification and supporting records, upon request, to CBP and/or Commerce;

• I understand that the claims made herein, and the substantiating documentation, are subject to verification by CBP and/or Commerce; • I understand that failure to maintain the required certification and/or failure to substantiate the claims made herein will result in:

 $^{\odot}\,$ suspension of liquidation of all unliquidated entries (and entries for which liquidation has not become final) for which these requirements were not met; and

• the requirement that the importer post applicable antidumping duty (AD) and/or countervailing duty (CVD) cash deposits (as appropriate) equal to the rates determined by Commerce;

• I understand that agents of the importer, such as brokers, are not permitted to make this certification;

• This certification was completed by the time of filing the entry summary; and

• I am aware that U.S. law (including, but not limited to, 18 U.S.C. 1001) imposes criminal sanctions on individuals who knowingly and willfully make material false statements to the U.S. government. Signature

NAME OF COMPANY OFFICIAL

TITLE

Appendix IV

Exporter Certification

I hereby certify that:

• My name is {COMPANY OFFICIAL'S NAME HERE} and I am an official of {NAME OF EXPORTING COMPANY};

• I have direct personal knowledge of the facts regarding the production and exportation of the carbon steel butt-weld pipe fittings identified below. "Direct personal knowledge" refers to facts the certifying party is expected to have in its own books and records. For example, an exporter should have "direct personal knowledge" of the producer's identity and location;

• These carbon steel butt-weld pipe fittings completed in Malaysia do not contain finished or unfinished butt-weld pipe fittings manufactured in the People's Republic of China;

• I understand that {NAME OF EXPORTING COMPANY} is required to maintain a copy of this certification and sufficient documentation supporting this certification (*i.e.*, documents maintained in the normal course of business, or documents obtained by the certifying party, for example, mill certificates, productions records, invoices, etc.) for the later of (1) a period of five years from the date of entry or (2) a period of three years after the conclusion of any litigation in the United States courts regarding such entries;

• I understand that {NAME OF EXPORTING COMPANY} must provide this Exporter Certification to the U.S. importer by the time of shipment. The shipments/ products referenced herein shipped before the mm/dd/yyyy publication of the *Preliminary Determination* Federal Register notice. This certification was completed on DD/MM/YY, within 45 days of the Federal Register notice publication;

• I understand that {NAME OF EXPORTING COMPANY} is required to provide a copy of this certification and supporting records, upon request, to U.S. Customs and Border Protection (CBP) and/or the Department of Commerce (Commerce);

• I understand that the claims made herein, and the substantiating documentation, are subject to verification by CBP and/or Commerce;

• I understand that failure to maintain the required certification and/or failure to substantiate the claims made herein will result in:

 $^{\odot}\,$ suspension of all unliquidated entries (and entries for which liquidation has not become final) for which these requirements were not met; and

 the requirement that the importer post applicable antidumping duty (AD) and/or countervailing duty (CVD) cash deposits (as appropriate) equal to the rates as determined by Commerce;

• This certification was completed at or prior to the time of shipment; and

• I am aware that U.S. law (including, but not limited to, 18 U.S.C. 1001) imposes criminal sanctions on individuals who knowingly and willfully make material false statements to the U.S. government. Signature

NĂME OF COMPANY OFFICIAL

TITLE

DATE

[FR Doc. 2018–15882 Filed 7–24–18; 8:45 am] BILLING CODE 3510–DS–P

DEPARTMENT OF COMMERCE

International Trade Administration

[C-570-968]

Aluminum Extrusions From the People's Republic of China: Final Results of Countervailing Duty Administrative Review; 2016

AGENCY: Enforcement and Compliance, International Trade Administration, Department of Commerce.

SUMMARY: The Department of Commerce (Commerce) determines that Liaoning Zhongwang Group Co. Ltd. (Liaoning) and Liaoyang Zhongwang Aluminum Profile Co. Ltd. (Liaoyang), exporters/ producers of aluminum extrusions from the People's Republic of China (China), received countervailable subsidies during the period of review (POR) January 1, 2016, through December 31, 2016.

DATES: Applicable July 25, 2018.

FOR FURTHER INFORMATION CONTACT: Davina Friedmann AD/CVD Operations, Office VI, Enforcement and Compliance, International Trade Administration, U.S. Department of Commerce, 1401 Constitution Avenue NW, Washington, DC 20230; telephone: (202) 482–0698. SUPPLEMENTARY INFORMATION:

Background

Commerce published the *Preliminary Results* of this administrative review in the **Federal Register** on March 15, 2018.¹ For a description of the events that occurred since the *Preliminary Results, see* the Issues and Decision Memorandum.²

Scope of the Order

The merchandise covered by the order is aluminum extrusions which are shapes and forms, produced by an extrusion process, made from aluminum alloys having metallic elements corresponding to the alloy series designations published by The Aluminum Association commencing with the numbers 1, 3, and 6 (or proprietary equivalents or other certifying body equivalents).

Imports of the subject merchandise are provided for under the following categories of the Harmonized Tariff Schedule of the United States (HTSUS): 6603.90.8100, 7616.99.51, 8479.89.94, 8481.90.9060, 8481.90.9085, 9031.90.9195, 8424.90.9080, 9405.99.4020, 9031.90.90.95, 7616.10.90.90, 7609.00.00, 7610.10.00, 7610.90.00, 7615.10.30, 7615.10.71, 7615.10.91, 7615.19.10, 7615.19.30, 7615.19.50, 7615.19.70, 7615.19.90, 7615.20.00, 7616.99.10, 7616.99.50, 8479.89.98, 8479.90.94, 8513.90.20, 9403.10.00, 9403.20.00, 7604.21.00.00, 7604.29.10.00, 7604.29.30.10, 7604.29.30.50, 7604.29.50.30, 7604.29.50.60, 7608.20.00.30, 7608.20.00.90, 8302.10.30.00, 8302.10.60.30, 8302.10.60.60, 8302.10.60.90, 8302.20.00.00, 8302.30.30.10.8302.30.30.60. 8302.41.30.00, 8302.41.60.15, 8302.41.60.45, 8302.41.60.50, 8302.41.60.80, 8302.42.30.10, 8302.42.30.15, 8302.42.30.65, 8302.49.60.35, 8302.49.60.45, 8302.49.60.55, 8302.49.60.85, 8302.50.00.00, 8302.60.90.00, 8305.10.00.50, 8306.30.00.00, 8414.59.60.90, 8415.90.80.45, 8418.99.80.05, 8418.99.80.50, 8418.99.80.60, 8419.90.10.00, 8422.90.06.40, 8473.30.20.00, 8473.30.51.00, 8479.90.85.00, 8486.90.00.00, 8487.90.00.80,

8503.00.95.20, 8508.70.00.00, 8515.90.20.00, 8516.90.50.00, 8516.90.80.50, 8517.70.00.00, 8529.90.73.00, 8529.90.97.60, 8536.90.80.85, 8538.10.00.00, 8543.90.88.80, 8708.29.50.60, 8708.80.65.90, 8803.30.00.60, 9013.90.50.00, 9013.90.90.00, 9401.90.50.81, 9403.90.10.40, 9403.90.10.50, 9403.90.10.85, 9403.90.25.40, 9403.90.25.80, 9403.90.40.05, 9403.90.40.10, 9403.90.40.60, 9403.90.50.05, 9403.90.50.10, 9403.90.50.80, 9403.90.60.05, 9403.90.60.10, 9403.90.60.80, 9403.90.70.05, 9403.90.70.10, 9403.90.70.80, 9403.90.80.10, 9403.90.80.15, 9403.90.80.20, 9403.90.80.41, 9403.90.80.51, 9403.90.80.61, 9506.11.40.80, 9506.51.40.00, 9506.51.60.00, 9506.59.40.40, 9506.70.20.90, 9506.91.00.10, 9506.91.00.20, 9506.91.00.30, 9506.99.05.10, 9506.99.05.20, 9506.99.05.30, 9506.99.15.00, 9506.99.20.00, 9506.99.25.80, 9506.99.28.00, 9506.99.55.00, 9506.99.60.80, 9507.30.20.00, 9507.30.40.00, 9507.30.60.00, 9507.90.60.00, and 9603.90.80.50.

The subject merchandise entered as parts of other aluminum products may be classifiable under the following additional Chapter 76 subheadings: 7610.10, 7610.90, 7615.19, 7615.20, and 7616.99, as well as under other HTSUS chapters. In addition, fin evaporator coils may be classifiable under HTSUS numbers: 8418.99.80.50 and 8418.99.80.60. While HTSUS subheadings are provided for convenience and customs purposes, the written description of the scope of this order is dispositive.³

Analysis of Comments Received

All issues raised in the parties' briefs are addressed in the Issues and Decision Memorandum, dated concurrently with, and hereby adopted by, this notice. A list of issues addressed is attached as an Appendix to this notice. The Issues and Decision Memorandum is a public document and is on file electronically via Enforcement and Compliance's Antidumping and Countervailing Duty Centralized Electronic Service System (ACCESS). ACCESS is available to registered users at http:// access.trade.gov; the Issues and Decision Memorandum is available to all parties in the Central Records Unit (CRU), Room B8024 of the main Department of Commerce building. In addition, a complete version of the

³ See Issues and Decision Memorandum for a complete description of the scope of the order.

Issues and Decision Memorandum can be accessed directly at *http:// enforcement.trade.gov/frn/*. The signed and electronic versions of the Issues and Decision Memorandum are identical in content.

Methodology

Commerce conducted this review in accordance with section 751(a)(1)(A) of the Tariff Act of 1930, as amended (the Act). For each of the subsidy programs found countervailable, we find that there is a subsidy, *i.e.*, a governmentprovided financial contribution that gives rise to a benefit to the recipient, and that the subsidy is specific.⁴ For a full description of the methodology underlying Commerce's conclusions, including any determination that relied upon the use of adverse facts available pursuant to sections 776(a) and (b) of the Act, see the Issues and Decision Memorandum.

Rescission of Review for No Shipments

In the *Preliminary Results*, we stated our intention to rescind the review with respect to certain companies that submitted no shipment certifications.⁵ We inquired with U.S. Customs and Border Protection (CBP) whether these companies had shipped merchandise to the United States during this review period, and CBP provided no evidence to contradict the claims made by these companies. Because no evidence of shipments was placed on the record following the Preliminary Results to contradict those claims, we are rescinding the administrative review of Guangdong Xin Wei Aluminum Products Co., Ltd., Xin Wei Aluminum Co. Ltd., and Xin Wei Aluminum Company Limited, pursuant to 19 CFR 351.213(d)(3).

Final Results of Administrative Review

In accordance with 19 CFR 351.221(b)(5), we determine the following final net subsidy rates for the 2016 administrative review: ⁶

Company	Ad valorem rate (percent)
Liaoning Zhongwang Group Co., Ltd	198.61
Liaoyang Zhongwang Alu- minum Profile Co., Ltd	198.61

⁴ 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.

⁵ See Preliminary Results and accompanying Preliminary Decision Memorandum at 3.

¹ See Aluminum Extrusions from the People's Republic of China: Preliminary Results of the Countervailing Duty Administrative Review, Rescission of Review, in Part, and Intent to Rescind, in Part; 2016, 83 FR 11501 (March 15, 2018) (Preliminary Results), and accompanying Preliminary Decision Memorandum.

² See Memorandum, "Decision Memorandum for the Final Results of Countervailing Duty Administrative Review: Aluminum Extrusions from the People's Republic of China, 2016," dated concurrently with, and hereby adopted by, this notice (Issues and Decision Memorandum).

⁶ See Issues and Decision Memorandum, at Comment 1.

Assessment Rates

Commerce intends to issue appropriate assessment instructions directly to CBP, 15 days after publication of these final results of review, to liquidate shipments of subject merchandise entered, or withdrawn from warehouse, for consumption on or after January 1, 2016, through December 31, 2016, at the *ad valorem* rates listed above.

Cash Deposit Requirements

Commerce also intends to instruct CBP to collect cash deposits of estimated countervailing duties in the amounts indicated above for each company listed on shipments of subject merchandise entered, or withdrawn from warehouse, for consumption on or after the date of publication of the final results of this administrative review. For all non-reviewed firms, we will instruct CBP to collect cash deposits of estimated countervailing duties at the most recent company-specific or allothers rate applicable to the company, as appropriate. Accordingly, the cash deposit requirements that will be applied to companies covered by this order, but not examined in this administrative review, are those established in the most recently completed segment of the proceeding for each company. These cash deposit requirements, when imposed, shall remain in effect until further notice.

Administrative Protective Order

This notice serves as a reminder to 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 the terms of an APO is a sanctionable violation.

We are issuing and publishing these results in accordance with sections 751(a)(1) and 777(i)(1) of the Act.

Dated: July 13, 2018.

Gary Taverman,

Deputy Assistant Secretary for Antidumping and Countervailing Duty Operations, performing the non-exclusive functions and duties of the Assistant Secretary for Enforcement and Compliance.

Appendix I—List of Topics Discussed in the Issues and Decision Memorandum

- I. Summary
- II. Background
- III. Scope of the Order
- IV. Analysis of Comments

Comment 1: Continuation of Application of AFA for Mandatory Respondents V. Recommendation

[FR Doc. 2018–15798 Filed 7–24–18; 8:45 am] BILLING CODE 3510–DS–P

DEPARTMENT OF COMMERCE

International Trade Administration

Proposed Information Collection; Comment Request; Swiss-U.S. Privacy Shield; Invitation for Applications for Inclusion on the Supplemental List of Arbitrators

AGENCY: International Trade Administration, U.S. Department of Commerce.

ACTION: Notice.

SUMMARY: The Department of Commerce, as part of its continuing effort to reduce paperwork and respondent burden, invites the general public and other Federal agencies to take this opportunity to comment on a continuing information collection, as required by the Paperwork Reduction Act of 1995.

DATES: Written comments must be submitted on or before September 24, 2018.

ADDRESSES: Direct all written comments to Jennifer Jessup, Departmental Paperwork Clearance Officer, Department of Commerce, Room 6616, 14th and Constitution Avenue NW, Washington, DC 20230 (or via the internet at *PRAcomments@doc.gov*.

FOR FURTHER INFORMATION CONTACT: Requests for additional information or copies of the information collection instrument and instructions should be directed to David Ritchie, International Trade Administration, 202–482–4936 or *david.ritchie@trade.gov*. More information on the arbitration mechanism may be found at *https:// www.trade.gov/td/services/odsi/swissus-privacyshield-framework.pdf.* SUPPLEMENTARY INFORMATION:

I. Abstract

The Swiss-U.S. Privacy Shield Framework was designed by the U.S. Department of Commerce (DOC) and the Swiss Administration (Swiss) to provide companies in both Switzerland and the United States with a mechanism to comply with data protection requirements when transferring personal data from Switzerland to the United States in support of transatlantic commerce. On January 12, 2017, the Swiss deemed the Swiss-U.S. Privacy Shield Framework (Swiss Privacy Shield) adequate to enable data transfers under Swiss law, and on April 12, 2017, the DOC began accepting selfcertifications from U.S. companies to join the program (82 FR 16375; April 12, 2017). For more information on the Privacy Shield, visit *www.privacyshield.gov.*

As described in Annex I of the Swiss Privacy Shield, the DOC and the Swiss committed to implement an arbitration mechanism to provide Swiss individuals with the ability to invoke binding arbitration to determine, for residual claims, whether an organization has violated its obligations under the Privacy Shield. Organizations voluntarily self-certify to the Swiss Privacy Shield and, upon certification, the commitments the organization has made to comply with the Swiss Privacy Shield become legally enforceable under U.S. law. Organizations that self-certify to the Swiss Privacy Shield commit to binding arbitration of residual claims if the individual chooses to exercise that option. Under the arbitration option, a Privacy Shield Panel^a (consisting of one or three arbitrators, as agreed by the parties) has the authority to impose individual-specific, non-monetary equitable relief (such as access, correction, deletion, or return of the individual's data in question) necessary to remedy the violation of the Swiss Privacy Shield only with respect to the individual. The parties will select the arbitrators from the list of arbitrators described below.

The DOC and the Swiss Administration are developing a list of up to five arbitrators to supplement the list of arbitrators developed under the EU-U.S. Privacy Shield Framework. To be eligible for inclusion on the supplemental list, applicants must be admitted to practice law in the United States and have expertise in both U.S. privacy law and European or Swiss data protection law. Applicants shall not be subject to any instructions from, or be affiliated with, any Privacy Shield organization, or the U.S., Šwitzerland, EU, or any EU Member State or any other governmental authority, public authority or enforcement authority.

The DOC received emergency approval for this information collection on March 26, 2018 under Control Number 0625–0278. Upon receiving that approval, the DOC accepted applications submitted by April 30, 2018 for inclusion on the Supplemental List of Arbitrators. The DOC is currently evaluating applicants who submitted by April 30, 2018 and is thus not currently

^a The Privacy Shield Panel would govern arbitration proceedings brought under either the Swiss-U.S. or EU-U.S. Privacy Shield Frameworks.

seeking additional applications. However, the DOC is now submitting a request for a 3-year approval through OMB's general PRA clearance process, because it may seek additional applications in the future as appropriate.

¹To be considered for inclusion on the Supplemental List of Arbitrators, eligible individuals are evaluated on the basis of independence, integrity, and expertise:

İndependence: Freedom from bias and prejudice.

Integrity: Held in the highest regard by peers for integrity, fairness and good judgment.

Demonstrates high ethical standards and commitment necessary to be an arbitrator.

Expertise

Required: Admission to practice law in the United States.

Level of demonstrated expertise in U.S. privacy law and European or Swiss data protection law.

Other expertise that may be considered includes any of the following:

Relevant educational degrees and professional licenses.

Relevant professional or academic experience or legal practice.

Relevant training or experience in arbitration or other forms of dispute resolution.

Evaluation of applications for inclusion on the list of arbitrators is undertaken by the DOC and the Swiss Administration. Selected applicants remain on the list for a period of 3 years, absent exceptional circumstances, change in eligibility, or for cause, renewable for one additional period of 3 years.

The DOC selected the International Centre for Dispute Resolution-American Arbitration Association (ICDR-AAA) as administrator for Privacy Shield arbitrations brought under either the Swiss-U.S. or EU-U.S. Privacy Shield Frameworks.^b Among other things, the ICDR–AAA facilitates arbitrator fee arrangements, including the collection and timely payment of arbitrator fees and other expenses. Arbitrators are expected to commit their time and effort when included on the supplemental Swiss-U.S. Privacy Shield List of Arbitrators and to take reasonable steps to minimize the costs or fees of the arbitration.

Arbitrators are subject to a code of conduct consistent with Annex I of the

Swiss-U.S. Privacy Shield Framework and generally accepted ethical standards for arbitrators. The DOC and the Swiss Administration agreed to adopt the arbitral procedures adopted under the EU-U.S. Privacy Shield Framework to govern the arbitral proceedings, subject to considerations identified in Annex I of the Swiss-U.S. Privacy Shield Framework, including that materials submitted to arbitrators will be treated confidentially and will only be used in connection with the arbitration. For more information, please visit https:// www.privacyshield.gov/article?id=G-Arbitration-Procedures where you can find information on the arbitration procedures. (Please note that the Arbitration procedures apply to both the EU-U.S. Privacy Shield Framework and the Swiss-U.S. Privacy Shield Framework.)

Applications

Applications must be typewritten and should be headed "Application for Inclusion on the Swiss-U.S. Privacy Shield Supplemental List of Arbitrators." Applications should include the following information, and each section of the application should be numbered as indicated:

—Name of applicant. —Address, telephone number, and

email address.

- 1. Independence
- —Description of the applicant's affiliations with any organization that has self-certified under either the Swiss-U.S. or EU–U.S. Privacy Shield Frameworks, or the U.S., Switzerland, any EU Member State or any other governmental authority, public authority, or enforcement authority.

2. Integrity

- —On a separate page, the names, addresses, telephone, and fax numbers of three individuals willing to provide information concerning the applicant's qualifications for service, including the applicant's character, reputation, reliability, and judgment.
- —Description of the applicant's willingness and ability to make time commitments necessary to be an arbitrator.
- 3. Expertise
- Demonstration of admittance to practice law in the United States.
 Relevant academic degrees and
- professional training and licensing. —Current employment, including title, description of responsibility, name and address of employer, and name and telephone number of supervisor or other reference.

- Employment history, including the dates and addresses of each prior position and a summary of responsibilities.
- —Description of expertise in U.S. privacy law and European or Swiss data protection law.
- –Description of training or experience in arbitration or other forms of dispute resolution, if applicable.
- —A list of publications, testimony, and speeches, if any, concerning U.S. privacy law and European or Swiss data protection law, with copies appended.

II. Method of Collection

As stated above, the DOC is not currently seeking additional applications, but may do so in the future as appropriate. OMB reviewed and approved this information collection on an emergency basis as of March 26, 2018 under Control Number 0625-0278. As the emergency approval is only valid for 180 days, the DOC is now submitting a request for a 3-year approval through OMB's full PRA clearance process. Future applications would be submitted to the U.S. Department of Commerce, either by email or by fax. More information on the arbitration mechanism may be found at *https://* www.trade.gov/td/services/odsi/swissus-privacyshield-framework.pdf.

III. Data

OMB Control Number: 0625–0278. Form Number(s): None. Type of Review: Regular submission. Affected Public: Private Individuals. Estimated Number of Respondents: 20.

Estimated Time per Response: 240 minutes.

Estimated Total Annual Burden Hours: 80.

Estimated Total Annual Cost to Public: \$0.

IV. Request for Comments

Comments are invited on: (a) Whether the proposed collection of information is necessary for the proper performance of the functions of the agency, including whether the information shall have practical utility; (b) the accuracy of the agency's estimate of the burden (including hours and cost) of the proposed collection of information; (c) ways to enhance the quality, utility, and clarity of the information to be collected; and (d) ways to minimize the burden of the collection of information on respondents, including through the use of automated collection techniques or other forms of information technology.

Comments submitted in response to this notice will be summarized and/or

^b For more information about the selection process and the role of the administrator, see https://www.privacyshield.gov/Arbitration-Fact-Sheet.

included in the request for OMB approval of this information collection; they also will become a matter of public record.

Sheleen Dumas,

Departmental Lead PRA Officer, Office of the Chief Information Officer. [FR Doc. 2018–15927 Filed 7–24–18; 8:45 am] BILLING CODE 3510–DR–P

DEPARTMENT OF COMMERCE

International Trade Administration

[C-570-984]

Drawn Stainless Steel Sinks From the People's Republic of China: Final Results of the Expedited First Sunset Review of the Countervailing Duty Order

AGENCY: Enforcement and Compliance, International Trade Administration, Department of Commerce. **SUMMARY:** As a result of this sunset review, the Department of Commerce (Commerce) finds that revocation of the countervailing duty order would be likely to lead to the continuation or recurrence of a countervailable subsidy at the levels indicated in the "Final Results of Review" section of this notice.

DATES: Applicable July 25, 2018. FOR FURTHER INFORMATION CONTACT: David Crespo, AD/CVD Operations, Office II, Enforcement and Compliance, International Trade Administration, U.S. Department of Commerce, 1401 Constitution Avenue NW, Washington, DC 20230; telephone: (202) 482–3693. SUPPLEMENTARY INFORMATION:

Background

On April 11, 2013, Commerce published its countervailing duty order on drawn stainless steel sinks from China.¹ On March 5, 2018, Commerce published the notice of initiation of the first sunset review of the countervailing duty order on drawn stainless steel sinks from China pursuant to section 751(c) of the Act.² On March 16, 2018, Commerce received a notice of intent to participate from Elkay Manufacturing Company (Elkay), a domestic interested party, within the deadline specified in 19 CFR 351.218(d)(1)(i).³ Elkay claimed interested party status under section 771(9)(C) of the Act as a producer of stainless steel sinks in the United States.

On April 2, 2018, Commerce received an adequate substantive response to the notice of initiation from Elkay within the 30-day deadline specified in 19 CFR 351.218(d)(3)(i).⁴ We received no substantive responses from respondent interested parties with respect to the order covered by this sunset review.

On April 10, 2018, Commerce notified the U.S. International Trade Commission (ITC) that it did not receive an adequate substantive response from respondent interested parties.⁵ As a result, pursuant to 751(c)(3)(B) of the Act and 19 CFR 351.218(e)(1)(ii)(C)(2), Commerce conducted an expedited (120-day) sunset review of the countervailing duty order on drawn stainless steel sinks from China.

Scope of the Order

The merchandise covered by the order includes drawn stainless steel sinks with single or multiple drawn bowls, with or without drain boards, whether finished or unfinished, regardless of type of finish, gauge, or grade of stainless steel. Mounting clips, fasteners, seals, and sound-deadening pads are also covered by the scope of this order if they are included within the sales price of the drawn stainless steel sinks.⁶ For purposes of this scope definition, the term "drawn" refers to a manufacturing process using metal forming technology to produce a smooth basin with seamless, smooth, and rounded corners. Drawn stainless steel sinks are available in various shapes and configurations and may be described in a number of ways including flush mount, top mount, or undermount (to indicate the attachment relative to the countertop). Stainless steel sinks with multiple drawn bowls that are joined through a welding operation to form one unit are covered by the scope of the order. Drawn stainless steel sinks are covered by the scope of the order whether or not they are sold in conjunction with non-subject accessories such as faucets (whether attached or unattached), strainers,

strainer sets, rinsing baskets, bottom grids, or other accessories.

Excluded from the scope of the order are stainless steel sinks with fabricated bowls. Fabricated bowls do not have seamless corners, but rather are made by notching and bending the stainless steel, and then welding and finishing the vertical corners to form the bowls. Stainless steel sinks with fabricated bowls may sometimes be referred to as "zero radius" or "near zero radius" sinks. The products covered by this order are currently classified in the Harmonized Tariff Schedule of the United States (HTSUS) under statistical reporting number 7324.10.0000 and 7324.10.0010. Although the HTSUS subheadings are provided for convenience and customs purposes, the written description of the scope of the order is dispositive.

Analysis of Comments Received

All issues raised in this sunset review are addressed in the Issues and Decision Memorandum,⁷ which is hereby adopted by this notice. The issues discussed in the Issues and Decision Memorandum are the likelihood of continuation or recurrence of a countervailable subsidy and the net countervailable subsidy likely to prevail if the order were revoked. The Issues and Decision Memorandum is a public document and is on file electronically via Enforcement and Compliance's Antidumping and Countervailing Duty Centralized Electronic Service System (ACCESS). ACCESS is available to registered users at http:// access.trade.gov, and to all in the Central Records Unit, Room B8024 of the main Department of Commerce building. In addition, a complete version of the Issues and Decision Memorandum can be accessed directly on the internet at *http://* enforcement.trade.gov/frn. The signed Issues and Decision Memorandum and the electronic version of the Issues and Decision Memorandum are identical in content

Final Results of Review

Pursuant to sections 751(c)(1) and 752(b) of the Act, Commerce determines that revocation of the countervailing duty order on drawn stainless steel sinks from China would be likely to lead to the continuation or recurrence of a

¹ See Drawn Stainless Steel Sinks from the People's Republic of China: Countervailing Duty Order, 78 FR 21596 (April 11,2013) (Order).

² See Initiation of Five-Year (Sunset) Reviews, 83 FR 9279 (March 5, 2018).

³ See Letter from Elkay "First Five-Year ('Sunset') Review of Countervailing Duty Order on Drawn Stainless Steel Sinks from the People's Republic of China/Elkay Manufacturing Company's Notice of Intent to Participate," dated March 16, 2018.

⁴ See Letter from Elkay "First Five-Year ('Sunset') Review of the Countervailing Duty Order on Drawn Stainless Steel Sinks from the People's Republic of China/Substantive Response to the Notice of Initiation," dated April 2, 2018.

 $^{^5\,}See$ Letter to the ITC re: "Sunset Reviews Initiated on March 5, 2018," dated April 10, 2018.

⁶ Mounting clips, fasteners, seals, and sounddeadening pads are not covered by the scope of this order if they are not included within the sales price of the drawn stainless steel sinks, regardless of whether they are shipped with or entered with drawn stainless steel sinks.

⁷ See Memorandum "Issues and Decision Memorandum for the Expedited First Sunset Review of the Countervailing Duty Order on Drawn Stainless Steel Sinks from the People's Republic of China," dated concurrently with this notice (Issues and Decision Memorandum).

countervailable subsidy at the rates listed below: ⁸

Producer/exporter	Net subsidy rate %
Guangdong Yingao Kitche Utensils Co., Ltd. and Forshan Magang Kitchen	
Utensils Co., Ltd	4.90
Zhongshan Superte Kitchen- ware Co., Ltd Foshan Zhaoshun Trade	12.31
Co., Ltd All Others	12.36 8.61

Notification to Interested Parties

This notice also serves as the only reminder to parties subject to administrative protective order (APO) of their responsibility concerning the return or destruction of proprietary information disclosed under APO in accordance with 19 CFR 351.305. Timely notification of the return or destruction of APO materials or conversion to judicial protective orders is hereby requested. Failure to comply with the regulations and terms of an APO is a violation which is subject to sanction.

We are issuing and publishing the final results and this notice in accordance with sections 751(c), 752(b), and 777(i)(1) of the Act and 19 CFR 351.218.

Dated: July 2, 2018.

Gary Taverman,

Deputy Assistant Secretary for Antidumping and Countervailing Duty Operations, performing the non-exclusive functions and duties of the Assistant Secretary for Enforcement and Compliance.

[FR Doc. 2018–15883 Filed 7–24–18; 8:45 am] BILLING CODE 3510–DS–P

DEPARTMENT OF COMMERCE

International Trade Administration

[C-542-801]

Certain New Pneumatic Off-The-Road Tires From Sri Lanka: Notice of Court Decision Not in Harmony With Final Affirmative Countervailing Duty Determination, Notice of Amended Final Determination and Revocation of Countervailing Duty Order

AGENCY: Enforcement and Compliance, International Trade Administration, Department of Commerce.

SUMMARY: On July 11, 2018, the United States Court of International Trade (CIT) entered its final judgment sustaining the final results of remand redetermination pursuant to court order by the

Department of Commerce (Commerce) pertaining to the countervailing duty (CVD) investigation of certain new pneumatic off-the-road tires (off road tires) from Sri Lanka. Commerce is notifying the public that the final judgment in this case is not in harmony with Commerce's final determination in the CVD investigation of off road tires from Sri Lanka. Pursuant to the CIT's final judgment, the mandatory respondent in the CVD investigation of off road tires from Sri Lanka received a net countervailable subsidy rate of 1.23 percent, a rate that is *de minimis* and, therefore, Commerce is hereby revoking this order.

DATES: Applicable July 21, 2018. FOR FURTHER INFORMATION CONTACT: Whitley Herndon, AD/CVD Operations, Office II, Enforcement and Compliance, International Trade Administration, U.S. Department of Commerce, 1401 Constitution Avenue NW, Washington, DC 20230; telephone: (202) 482–6274. SUPPLEMENTARY INFORMATION:

Background

On January 10, 2017, Commerce published the *Final Determination* in this proceeding.¹ Commerce reached an affirmative determination that countervailable subsidies were provided to mandatory respondent Camso Loadstar (Private), Ltd. (Camso Loadstar). Commerce published the countervailing duty order resulting from the investigation on March 6, 2017.²

Camso Loadstar and the Government of Sri Lanka (GOSL) appealed the Final Determination and countervailing duty order to the CIT, and on April 17, 2018, the CIT remanded the Final Determination.³ Specifically, the CIT remanded the Final Determination directing Commerce to eliminate any duties attributable to the Guaranteed Price Scheme for Rubber (GPS) program based on mere reimbursement for excessive rubber payments.⁴ On June 13, 2016, Commerce issued its final results of redetermination pursuant to remand in accordance with the CIT's order.⁵ On remand, Commerce, under

² See Certain New Pneumatic Off-the-Road Tires from India and Sri Lanka: Amended Final Affirmative Countervailing Duty Determination for India and Countervailing Duty Orders, 82 FR 12556 (Mar. 6, 2017) (Order).

³ See Government of Sri Lanka v. United States, Slip Op. 18–43 (CIT Apr. 17, 2018). ⁴ Id. at 20.

⁵ See Final Results of Redetermination on Remand Pursuant to Government of Sri Lanka v.

respectful protest,⁶ eliminated any duties attributable to the GPS program and recalculated the countervailable subsidy rate for Camso Loadstar accordingly. On July 11, 2018, the CIT sustained Commerce's *Final Redetermination.*⁷ Thus, the effective date of this notice is July 21, 2018.

Timken Notice

In its decision in *Timken*,⁸ as clarified by Diamond Sawblades,9 the Court of Appeals for the Federal Circuit (Federal Circuit) held that, pursuant to section 516A of the Tariff Act of 1930, as amended (the Act), Commerce must publish a notice of court decision that is not "in harmony" with a Commerce determination and must suspend liquidation of entries pending a "conclusive" court decision.¹⁰ The CIT's July 11, 2018, final judgment sustaining the Final Redetermination constitutes a final decision of that court that is not in harmony with Commerce's *Final Determination.* Thus, this notice is published in fulfillment of the publication requirements of *Timken* and section 516A of the Act.

Amended Final Determination

Because there is now a final court decision, Commerce is amending the *Final Determination* with respect to Camso Loadstar. The revised countervailable subsidy rate for Camso Loadstar for the period January 1, 2015, through December 31, 2015, is as follows:

Exporter or producer	Subsidy rate (percent)
Camso Loadstar (Pri- vate), Ltd	1.23 (<i>de minimis</i>).

Revocation of the Order

Pursuant to section 705(a)(3) of the Act, Commerce "shall disregard any countervailable subsidy that is de minimis as defined in section 703(b)(4)" of the Act. Furthermore, and pursuant to section 705(c)(2) of the Act, "the investigation shall be terminated upon publication of that negative

United States, Slip Op. 18–43 (CIT April 17, 2018), dated June 13, 2016 (*Final Redetermination*). See also https://enforcement.trade.gov/remands/18-43.pdf.

⁶ See Viraj Group, Ltd. v. United States, 343 F.3d 1371 (Fed. Cir. 2003).

⁷ See Government of Sri Lanka v. United States, Slip Op. 18–87, Consol. Court No. 17–00059 (CIT July 11, 2018) (Final Remand Order).

⁸ See Timken Co. v. United States, 893 F.2d. 337 (Fed. Cir. 1990) (*Timken*).

⁹ See Diamond Sawblades Mfrs. Coalition v. United States, 626 F.3d. 1374 (Fed. Cir. 2010)

(Diamond Sawblades).

¹⁰ See Sections 516A(c) and (e) of the Act.

⁸ See Order, 70 FR 21596, 21597.

¹ See Certain New Pneumatic Off-the-Road Tires from Sri Lanka: Final Affirmative Countervailing Duty Determination, and Final Determination of Critical Circumstances, 82 FR 2949, 2950 (January 10, 2017) (Final Determination) and accompanying Issues and Decision Memorandum.

d. at 20.

determination" and Commerce shall 'terminate the suspension of liquidation" and "release any bond or other security, and refund any cash deposit." As a result of the CIT's decision affirming Commerce's Final *Redetermination*, Commerce is revoking the countervailing duty order on off road tires from Sri Lanka¹¹ because the revised CVD margin for Camso Loadstar, the only mandatory respondent, is now de minimis.¹² Because the revised net countervailable subsidy rate for the sole mandatory respondent, Camso Loadstar, is de minimis, Commerce did not determine an all-others rate in the Final Redetermination. Accordingly, Commerce intends to issue instructions to U.S. Customs and Border Protection (CBP) to release any bonds or other security and refund cash deposits pertaining to any suspended entries pursuant to the Order. As a result of this revocation, Commerce will not initiate administrative reviews of this Order.13

Although section 705(c)(2)(A) of the Act instructs Commerce to terminate suspension of liquidation, we note that, pursuant to Timken, the suspension of liquidation must continue during the pendency of the appeals process. Thus, we will continue to instruct CBP at this time to (A) release any bond or other security, and refund any cash deposit made pursuant to the Order as discussed above; and (B) suspend liquidation of all unliquidated entries of subject merchandise from Sri Lanka at a cash deposit rate of 0.00 percent which are entered, or withdrawn from warehouse, for consumption on or after July 21, 2018, which is ten days after the court's decision, in accordance with section 516A of the Act.¹⁴ In the event that the CIT's judgment affirming the Final Redetermination is not appealed, or appealed and upheld by the U.S. Court of Appeals for the Federal Circuit,

¹² See section 703(b)(4)(B) of the Act; Developing and Least-Developed Country Designations under the Countervailing Duty Law, 63 FR 29945 (June 2, 1998).

¹³Commerce did not previously initiate any administrative review of the *Order*.

¹⁴ See, e.g., Drill Pipe from the People's Republic of China: Notice of Court Decision Not in Harmony with International Trade Commission's Injury Determination, Revocation of Antidumping and Countervailing Duty Orders Pursuant to Court Decision, and Discontinuation of Countervailing Duty Administrative Review, 79 FR 78037, 78038 (December 29, 2014); High Pressure Steel Cylinders From the People's Republic of China: Notice of Court Decision Not in Harmony With Final Determination in Less Than Fair Value Investigation, Notice of Amended Final Determination Pursuant to Court Decision, Notice of Revocation of Antidumping Duty Order in Part, and Discontinuation of Fifth Antidumping Duty Administrative Review, 82 FR 46758, 46760 (October 6, 2017).

Commerce will instruct CBP to terminate the suspension of liquidation and to liquidate those entries of subject merchandise without regard to countervailing duties. Notwithstanding the continued suspension described above, the countervailing duty order on off road tires from Sri Lanka is hereby revoked, as described above.

Lastly, we note that, at this time, Commerce remains enjoined by Court order from liquidating entries that were produced and/or exported by Camso Loadstar, and were entered, or withdrawn from warehouse, for consumption during the period June 20, 2016, through October 17, 2016, and from February 28, 2017, through December 31, 2017. These entries will remain enjoined pursuant to the terms of the injunction during the pendency of any appeals process.

Notification to Interested Parties

This notice serves as a reminder to 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 the destruction of APO materials or conversion to judicial protective order is hereby requested. Failure to comply with the regulations and the terms of the APO is a violation subject to sanction.

This notice is issued and published in accordance with section 516A(c)(1) and (e) of the Act.

Dated: July 19, 2018.

Gary Taverman,

Deputy Assistant Secretary for Antidumping and Countervailing Duty Operations, performing the non-exclusive functions and duties of the Assistant Secretary for Enforcement and Compliance. [FR Doc. 2018–15879 Filed 7–24–18; 8:45 am] BILLING CODE 3510–DS–P

DEPARTMENT OF COMMERCE

International Trade Administration

[A-423-813, A-301-803, and A-549-833]

Citric Acid and Certain Citrate Salts From Belgium, Colombia and Thailand: Antidumping Duty Orders

AGENCY: Enforcement and Compliance, International Trade Administration, Department of Commerce. SUMMARY: Based on affirmative final determinations by the Department of Commerce (Commerce) and the International Trade Commission (ITC), Commerce is issuing antidumping duty (AD) orders on citric acid and certain citrate salts (citric acid) from Belgium, Colombia and Thailand.

DATES: Applicable July 25, 2018.

FOR FURTHER INFORMATION CONTACT: Paul Stolz (Belgium), Stephanie Moore (Colombia) or Joy Zhang (Thailand); AD/CVD Operations, Office III, Enforcement and Compliance, International Trade Administration, U.S. Department of Commerce, 1401 Constitution Avenue NW, Washington, DC 20230; telephone: (202) 482–4474, (202) 482–3692, (202) 482–1168, respectively.

SUPPLEMENTARY INFORMATION:

Background

On June 5, 2018, in accordance with sections 735(d) and 777(i)(1) of the Tariff Act of 1930, as amended (the Act) and 19 CFR 351.210(c), Commerce published its affirmative final determinations in the less-than-fairvalue (LTFV) investigations of citric acid from Belgium, Colombia and Thailand.¹ On July 10, 2018, the ITC notified Commerce of its affirmative final determination, pursuant to section 735(d) of the Act, that an industry in the United States is materially injured within the meaning of section 735(b)(1)(A)(i) of the Act, by reason of the LTFV imports of citric acid from Belgium, Colombia, and Thailand, and its determination that critical circumstances do not exist with respect to imports of citric acid from Thailand subject to Commerce's affirmative critical circumstances determination.² On July 16, 2018, the ITC published its final determination in the Federal Register.³

² See Letter from the ITC to the Honorable Gary Taverman, dated July 10, 2018 (Notification of ITC Final Determination); see also Citric Acid from Belgium, Colombia, and Thailand, Investigation Nos. 731–TA–1374–1376 (Final) (July 2018). On October 20, 2017, the petitioners submitted a timely filed critical circumstances allegation with respect to imports from Colombia and Thailand. Commerce subsequently issued a negative critical circumstances determination with regard to the investigation for Colombia and, thus, the ITC did not address critical circumstances for Colombia in its final injury determination.

³ See Citric Acid from Belgium, Colombia, and Thailand; Determinations, 83 FR 32905 (July 16, 2018).

¹¹ See Order, 82 FR at 12556.

¹ See Citric Acid and Certain Citrate Salts from Belgium: Affirmative Final Determination of Sales at Less Than Fair Value, 83 FR 26001 (June 5, 2018) (Belgium Final Determination); see also Citric Acid and Certain Citrate Salts from Colombia: Affirmative Final Determination of Sales at Less Than Fair Value and Final Negative Determination of Critical Circumstances, 83 FR 26002 (June 5, 2018) (Colombia Final Determination); and Citric Acid and Certain Citrate Salts from Thailand: Affirmative Final Determination of Sales at Less Than Fair Value and Final Affirmative Determination of Critical Circumstances in Part, 83 FR 25998 (June 5, 2018) (Thailand Final Determination).

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Scope of the Order

The product covered by these orders is citric acid from Belgium, Colombia, and Thailand. For a complete description of the scope of these orders, *see* the Appendix to this notice.

Antidumping Duty Orders

In accordance with sections 735(b)(1)(A)(i) and 735(d) of the Act, the ITC notified Commerce of its final determination in these investigations that an industry in the United States is materially injured by reason of imports of citric acid from Belgium, Colombia, and Thailand.⁴ The ITC also notified Commerce of its determination that critical circumstances do not exist with respect to imports of citric acid from Thailand subject to Commerce's critical circumstances finding.⁵ Therefore, in accordance with section 735(c)(2) of the Act, Commerce is issuing these AD orders. Because the ITC determined that imports of citric acid from Belgium, Colombia, and Thailand are materially injuring a U.S. industry, unliquidated entries of such merchandise from Belgium, Colombia, and Thailand, entered or withdrawn from warehouse for consumption, are subject to the assessment of antidumping duties. Therefore, in accordance with section 736(a)(1) of the Act, Commerce will direct U.S. Customs and Border Protection (CBP) to assess, upon further instruction by Commerce, antidumping duties equal to the amount by which the normal value of the merchandise exceeds the export price (or constructed export price) of the merchandise, for all relevant entries of citric acid from Belgium, Colombia, and Thailand. Antidumping duties will be assessed on unliquidated entries of citric acid from Belgium, Colombia, and Thailand entered, or withdrawn from warehouse for consumption, on or after January 8, 2018, the date on which Commerce published its preliminary determinations in the Federal Register.⁶

Continuation of Suspension of Liquidation

In accordance with section 735(c)(1)(B) of the Act, Commerce will instruct CBP to continue to suspend liquidation of all relevant entries of citric acid from Belgium, Colombia, and Thailand. These instructions suspending liquidation will remain in effect until further notice.

Commerce will also instruct CBP to require cash deposits for estimated antidumping duties equal to the estimated cash deposit rates indicated below. Accordingly, effective the date of publication of the ITC's final affirmative injury determination, CBP will require, at the same time as importers would normally deposit estimated duties on the subject merchandise, a cash deposit equal to the cash deposit rates listed below. The relevant all-others rates apply to producers or exporters not specifically listed, as appropriate.

Critical Circumstances

With regard to the ITC's negative critical circumstances determination regarding imports of citric acid from Thailand, Commerce will instruct CBP to lift suspension and refund any cash deposits made to secure payment of estimated antidumping duties on subject merchandise entered, or withdrawn from warehouse, for consumption on or after October 10, 2017, (*i.e.*, 90 days prior to the date of publication of the Thailand preliminary determination), but before January 8, 2018, (*i.e.*, the date of publication of the Thailand preliminary determination).

Estimated Weighted-Average Dumping Margins

The estimated weighted-average AD margins and cash deposit rates are as follows:

Belgium—exporter/producer	Estimated weighted- average AD margin (percent)
S.A. Citrique Belge N.V All Others	19.30% 19.30%
Colombia—exporter/producer	Estimated weighted- average AD margin (percent)
Sucroal S.A All Others	28.48% 28.48%

Thailand—exporter/producer	Estimated weighted- average AD margin (percent)
COFCO Biochemical (Thai-	
land) Co., Ltd	15.71%
Niran (Thailand) Co., Ltd Sunshine Biotech Inter-	13.00%
national Co., Ltd	6.47%
All Others	11.25%

Notification to Interested Parties

This notice constitutes the AD orders with respect to citric acid from Belgium, Colombia, and Thailand, pursuant to section 736(a) of the Act. Interested parties can find a list of AD orders currently in effect at http:// enforcement.trade.gov/stats/ iastats1.html.

These orders are issued and published in accordance with section 736(a) of the Act and 19 CFR 351.211(b).

Dated: July 19, 2018.

Gary Taverman,

Deputy Assistant Secretary for Antidumping and Countervailing Duty Operations, performing the non-exclusive functions and duties of the Assistant Secretary for Enforcement and Compliance.

Appendix—Scope of the Orders

The merchandise covered by the scope of the Orders includes all grades and granulation sizes of citric acid, sodium citrate, and potassium citrate in their unblended forms, whether dry or in solution, and regardless of packaging type. The scope also includes blends of citric acid, sodium citrate, and potassium citrate; as well as blends with other ingredients, such as sugar, where the unblended form(s) of citric acid, sodium citrate, and potassium citrate constitute 40 percent or more, by weight, of the blend.

The scope also includes all forms of crude calcium citrate, including dicalcium citrate monohydrate, and tricalcium citrate tetrahydrate, which are intermediate products in the production of citric acid, sodium citrate, and potassium citrate.

The scope includes the hydrous and anhydrous forms of citric acid, the dihydrate and anhydrous forms of sodium citrate, otherwise known as citric acid sodium salt, and the monohydrate and monopotassium forms of potassium citrate. Sodium citrate also includes both trisodium citrate and monosodium citrate which are also known as citric acid trisodium salt and citric acid monosodium salt, respectively.

The scope does not include calcium citrate that satisfies the standards set forth in the United States Pharmacopeia and has been mixed with a functional excipient, such as dextrose or starch, where the excipient constitutes at least 2 percent, by weight, of the product.

Citric acid and sodium citrate are classifiable under 2918.14.0000 and 2918.15.1000 of the Harmonized Tariff

 $^{^4}$ See Notification of ITC Final Determination. 5 Id.

⁶ See Citric Acid and Certain Citrate Salts from Belgium: Preliminary Affirmative Determination of Sales at Less Than Fair Value, Postponement of Final Determination, and Extension of Provisional Measures, 83 FR 787 (January 1, 2018); see also Citric Acid and Certain Citrate Salts from Colombia: Preliminary Affirmative Determination of Sales at Less Than Fair Value, Preliminary Negative Critical Circumstances Determination Postponement of Final Determination, and Extension of Provisional Measures, 83 FR 791 (January 1, 2018), and Citric Acid and Certain Citrate Salts from Thailand: Preliminary Affirmative Determination of Sales at Less Than Fair Value, Preliminary Affirmative Critical Circumstances Determination, in Part, and Postponement of Final Determination and Extension of Provisional Measures, 83 FR 784 (January 1, 2018).

Schedule of the United States (HTSUS), respectively. Potassium citrate and crude calcium citrate are classifiable under 2918.15.5000 and, if included in a mixture or blend, 3824.99.9295 of the HTSUS. Blends that include citric acid, sodium citrate, and potassium citrate are classifiable under 3824.99.9295 of the HTSUS. Although the HTSUS subheadings are provided for convenience and customs purposes, the written description of the merchandise is dispositive.

[FR Doc. 2018–15885 Filed 7–24–18; 8:45 am] BILLING CODE 3510–DS–P

DEPARTMENT OF COMMERCE

International Trade Administration

[Application No. 84–29A12]

Export Trade Certificate of Review

ACTION: Notice of Application for an Amended Export Trade Certificate of Review by Northwest Fruit Exporters, Application No. 84–29A12.

SUMMARY: The Secretary of Commerce, through the International Trade Administration, Office of Trade and Economic Analysis ("OTEA"), has received an application for an amended Export Trade Certificate of Review ("Certificate") from Northwest Fruit Exporters. This notice summarizes the proposed amendment and seeks public comments on whether the amended Certificate should be issued.

FOR FURTHER INFORMATION CONTACT:

Joseph Flynn, Director, Office of Trade and Economic Analysis, International Trade Administration, by telephone at (202) 482–5131 (this is not a toll-free number) or email at *etca@trade.gov*.

SUPPLEMENTARY INFORMATION: Title III of the Export Trading Company Act of 1982 (15 U.S.C. 4001-21) authorizes the Secretary of Commerce to issue Export Trade Certificates of Review. An Export Trade Certificate of Review protects the holder and the members identified in the Certificate from State and Federal government antitrust actions and from private treble damage antitrust actions for the export conduct specified in the Certificate and carried out in compliance with its terms and conditions. Section 302(b)(1) of the Export Trading Company Act of 1982 and 15 CFR 325.6(a) require the Secretary to publish a notice in the Federal Register identifying the applicant and summarizing its proposed export conduct.

Request for Public Comments

Interested parties may submit written comments relevant to the determination whether an amended Certificate should be issued. If the comments include any privileged or confidential business information, it must be clearly marked and a nonconfidential version of the comments (identified as such) should be included. Any comments not marked as privileged or confidential business information will be deemed to be nonconfidential.

An original and five (5) copies, plus two (2) copies of the nonconfidential version, should be submitted no later than 20 days after the date of this notice to: Office of Trade and Economic Analysis, International Trade Administration, U.S. Department of Commerce, Room 21028, Washington, DC 20230.

Information submitted by any person is exempt from disclosure under the Freedom of Information Act (5 U.S.C. 552). However, nonconfidential versions of the comments will be made available to the applicant if necessary for determining whether or not to issue the amended Certificate. Comments should refer to this application as "Export Trade Certificate of Review, application number 84–29A12."

A summary of the current application follows.

Summary of the Application

Applicant: Northwest Fruit Exporters, 105 South 18th Street, Suite 227, Yakima, WA 98901.

Contract: Ered Coorlett

Contact: Fred Scarlett, Manager, (509) 576–8004.

Application No.: 84–29A12.

Date Deemed Submitted: July 10, 2018.

Proposed Amendment: Northwest Fruit Exporters seeks to amend its Certificate as follows:

1. Add the following companies as new Members of the Certificate within the meaning of section 325.2(l) of the Regulations (15 CFR 325.2(l)):

- Pine Canyon Growers LLC, Orondo, WA
- WP Packing LLC, Wapato, WA 2. Delete the following companies as
- Members of the Certificate: • Columbia Fruit Packers/Airport
- Division, Wenatchee, WAPhillippi Fruit Company, Inc.,
- Wenatchee, WA
 Western Traders LLC, E. Wenatchee, WA

3. Change the name of the following Members of the Certificate:

- Columbia Marketing International Corp., Wenatchee, WA, is now named CMI Orchards LLC, Wenatchee, WA
- Pride Packing Company, Wapato, WA, is now named Pride Packing Company LLC, Wapato, WA

4. Correct the name of the following Members of the Certificate:

- Diamond Fruit Growers, Odell, OR, is corrected to Diamond Fruit Growers, Inc., Odell, OR
- HoneyBear Growers, Inc., Brewster, WA, is corrected to HoneyBear Growers LLC, Brewster, WA
- Honey Bear Tree Fruit Co., LLC, Wenatchee, WA, is corrected to Honey Bear Tree Fruit Co LLC, Wenatchee, WA
- L&M Companies, Union Gap, WA, is corrected to L & M Companies, Union Gap, WA
- Polehn Farm's Inc., The Dalles, OR, is corrected to Polehn Farms, Inc., The Dalles, OR
- Valicoff Fruit Co., Inc., Wapato, WA, is corrected to Valicoff Fruit Company Inc., Wapato, WA

Northwest Fruit Exporter's proposed amendment of its Export Trade Certificate of Review would result in the following Membership list:

- 1. Allan Bros., Naches, WA
- 2. AltaFresh L.L.C. dba Chelan Fresh Marketing, Chelan, WA
- 3. Apple House Warehouse & Storage, Inc., Brewster, WA
- 4. Apple King, L.L.C., Yakima, WA
- 5. Auvil Fruit Co., Inc., Orondo, WA
- 6. Baker Produce, Inc., Kennewick, WA
- 7. Blue Bird, Inc., Peshastin, WA
- 8. Blue Star Growers, Inc., Cashmere, WA
- Borton & Sons, Inc., Yakima, WA
 Brewster Heights Packing & Orchards, LP, Brewster, WA
- 11. Broetje Orchards LLC, Prescott, WA
- 12. C.M. Holtzinger Fruit Co., Inc., Yakima, WA
- 13. Chelan Fruit Cooperative, Chelan, WA
- 14. Chiawana, Inc. dba Columbia Reach Pack, Yakima, WA
- 15. CMI Orchards LLC, Wenatchee, WA
- 16. Columbia Fruit Packers, Inc., Wenatchee, WA
- 17. Columbia Valley Fruit, L.L.C., Yakima, WA
- 18. Congdon Packing Co. L.L.C., Yakima, WA
- 19. Conrad & Adams Fruit L.L.C., Grandview, WA
- 20. Cowiche Growers, Inc., Cowiche, WA
- 21. CPC International Apple Company,
- Tieton, WA
- 22. Crane & Crane, Inc., Brewster, WA
- 23. Custom Apple Packers, Inc., Quincy and Wenatchee, WA
- 24. Diamond Fruit Growers, Inc., Odell, OR
- 25. Domex Superfresh Growers LLC, Yakima, WA
- 26. Douglas Fruit Company, Inc., Pasco, WA
- 27. Dovex Export Company, Wenatchee, WA
- 28. Duckwall Fruit, Odell, OR
- 29. E. Brown & Sons, Inc., Milton-Freewater, OR
- 30. Evans Fruit Co., Inc., Yakima, WA
- 31. E.W. Brandt & Sons, Inc., Parker, WA
- 32. Frosty Packing Co., LLC, Yakima, WA
- 33. G&G Orchards, Inc., Yakima, WA
- 34. Gilbert Orchards, Inc., Yakima, WA 35. Hansen Fruit & Cold Storage Co., Inc.,
- Yakima, WA
- 36. Henggeler Packing Co., Inc., Fruitland, ID
- 37. Highland Fruit Growers, Inc., Yakima,
- WA

- 38. HoneyBear Growers LLC, Brewster, WA
- 39. Honey Bear Tree Fruit Co LLC,
- Wenatchee, WA 40. Hood River Cherry Company, Hood River, OR
- 41. Ice Lakes LLC, East Wenatchee, WA
- 42. JackAss Mt. Ranch, Pasco, WA
- 43. Jenks Bros Cold Storage & Packing, Royal City, WA
- 44. Kershaw Fruit & Cold Storage, Co., Yakima, WA
- 45. L & M Companies, Union Gap, WA
- 46. Larson Fruit Co., Selah, WA
- 47. Legacy Fruit Packers LLC, Wapato, WA
- 48. Manson Growers Cooperative, Manson, WA
- 49. Matson Fruit Company, Selah, WA
- 50. McDougall & Sons, Inc., Wenatchee, WA
- 51. Monson Fruit Co., Selah, WA
- 52. Morgan's of Washington dba Double Diamond Fruit, Quincy, WA
- 53. Naumes, Inc., Medford, OR
- 54. Northern Fruit Company, Inc., Wenatchee, WA
- 55. Olympic Fruit Co., Moxee, WA
- 56. Oneonta Trading Corp., Wenatchee, WA
- 57. Orchard View Farms, Inc., The Dalles, OR
- 58. Pacific Coast Cherry Packers, LLC, Yakima, WA
- 59. Peshastin Hi-Up Growers, Peshastin, WA
- 60. Piepel Premium Fruit Packing LLC, East Wenatchee, WA
- 61. Pine Canyon Growers LLC, Orondo, WA
- 62. Polehn Farms, Inc., The Dalles, OR 63. Price Cold Storage & Packing Co., Inc.,
- Yakima, WA
- 64. Pride Packing Company LLC, Wapato, WA
- 65. Quincy Fresh Fruit Co., Quincy, WA
- 66. Rainier Fruit Company, Selah, WA
- 67. Roche Fruit, Ltd., Yakima, WA
- 68. Sage Fruit Company, L.L.C., Yakima, WA
- 69. Smith & Nelson, Inc., Tonasket, WA
- 70. Stadelman Fruit, L.L.C., Milton-Freewater, OR, and Zillah, WA
- 71. Stemilt Growers, LLC, Wenatchee, WA
- 72. Strand Apples, Inc., Cowiche, WA
- 73. Symms Fruit Ranch, Inc., Caldwell, ID74. The Dalles Fruit Company, LLC,
- Dallesport, WA 75. Underwood Fruit & Warehouse Co., Bingen, WA
- 76. Valicoff Fruit Company Inc., Wapato, WA
- 77. Washington Cherry Growers, Peshastin, WA
- 78. Washington Fruit & Produce Co., Yakima, WA
- 79. Western Sweet Cherry Group, LLC, Yakima, WA
- 80. Whitby Farms, Inc. dba: Farm Boy Fruit Snacks LLC, Mesa, WA
- 81. WP Packing LLC, Wapato, WA
- 82. Yakima Fresh, Yakima, WA
- 83. Yakima Fruit & Cold Storage Co., Yakima, WA
- 84. Zirkle Fruit Company, Selah, WA

Dated: July 20, 2018.

Joseph Flynn,

Director, Office of Trade and Economic Analysis, International Trade Administration. [FR Doc. 2018–15925 Filed 7–24–18; 8:45 am] BILLING CODE 3510–DR–P

DEPARTMENT OF COMMERCE

International Trade Administration

[A-570-970]

Multilayered Wood Flooring From the People's Republic of China: Notice of Court Decision Not in Harmony With the Second Amended Final Determination and Notice of Third Amended Final Determination of the Antidumping Duty Investigation

AGENCY: Enforcement and Compliance, International Trade Administration, Department of Commerce.

SUMMARY: On July 3, 2018, the United States Court of International Trade (CIT or Court) entered its final judgment in Changzhou Hawd Flooring Co., et al. v. United States, sustaining, in part, the final results of remand redetermination pursuant to court order by the Department of Commerce (Commerce) pertaining to the less-than-fair-value (LTFV) investigation on multilayered wood flooring from the People's Republic of China (China). Commerce is notifying the public that the final judgment in this case is not in harmony with Commerce's final determination in the LTFV investigation of multilayered wood flooring from China. Pursuant to the CIT's final judgment, Dunhua City Jisen Wood Industry Co., Ltd., Fine Furniture (Shanghai) Limited, and Armstrong Wood Products (Kunshan) Co., Ltd. are being excluded from the order.

DATES: Applicable July 13, 2018.

FOR FURTHER INFORMATION CONTACT: Aleksandras Nakutis, Office IV, Enforcement and Compliance, International Trade Administration, U.S. Department of Commerce, 1401 Constitution Avenue NW, Washington, DC 20230; telephone: (202) 482–3147.

SUPPLEMENTARY INFORMATION:

Background

The litigation in this case relates to Commerce's final determination in the antidumping duty investigation covering multilayered wood flooring from China,¹ which was later amended.² In the *First Amended Final Determination and Order*, Commerce assigned a rate of 3.30 percent to all

separate rate respondents.³ Commerce derived this rate by averaging the rates of the two individually investigated respondents with weighted-average margins above *de minimis*, pursuant to section 735(c)(5)(A) of the Tariff Act of 1930, as amended (the Act). Pursuant to a series of remand orders issued by the Court that resulted in five remand redeterminations, Commerce (1) revised its calculation of dumping margins for two mandatory respondents and the China-wide entity; and, (2) made certain findings regarding the dumping margins that were calculated for eight separate rate respondents that were plaintiffs in the litigation.

Regarding the dumping margins for two mandatory respondents in the investigation, on April 23, 2014, the Court granted a consent motion for severance and entered final judgment in Baroque Timber Industries (Zhongshan) Company, Limited v. United States with respect to Lavo Wood and the Samling Group.⁴ Consistent with the decision of the United States Court of Appeals for the Federal Circuit (CAFC) in Timken Co. v. United States, 893 F.2d 337 (Fed. Cir. 1990) (Timken), as clarified by Diamond Sawblades Mfrs. Coalition v. United States, 626 F.3d 1374 (Fed. Cir. 2010) (Diamond Sawblades), Commerce gave notice of this decision, as well as the amended dumping margins of zero percent calculated for Lavo Wood and Samling Group.⁵ Further, because Commerce changed the surrogate values in its first remand redetermination for mandatory respondents Layo Wood and Samling Group,⁶ the highest calculated transaction-specific rate on the record became 25.62 percent, which Commerce assigned to the China-wide entity.⁷ The CIT sustained Commerce's remand redetermination as it pertained to Lavo

⁵ See Multilayered Wood Flooring from the People's Republic of China: Notice of Court Decision Not in Harmony With the Final Determination and Amended Final Determination of the Antidumping Duty Investigation, 79 FR 25109 (May 2, 2014) (Second Amended Final Determination).

⁶ See Final Results of Redetermination Pursuant to Court Order, Baroque Timber Industries (Zhongshan) Company, Limited, et al. v. United States, dated November 14, 2013 (First Remand Redetermination), at 2–3. ⁷ Id.

¹ See Multilayered Wood Flooring from the People's Republic of China: Final Determination of Sales at Less Than Fair Value, 76 FR 64318 (October 18, 2011) (Final Determination).

² See Multilayered Wood Flooring from the People's Republic of China: Amended Final Determination of Sales at Less Than Fair Value and Antidumping Duty Order, 76 FR 76690 (December 8, 2011) (First Amended Final Determination and Order).

³ Id.

⁴ The full names of those companies are Zheijiang Layo Wood Industry Co. Ltd. (Layo Wood) and Baroque Timber Industries (Zhongshan) Co., Ltd., Riverside Plywood Corporation, Samling Elegant Living Trading (Labuan) Limited, Samling Global USA, Inc., Samling Riverside Co., Ltd., and Suzhou Times Flooring Co., Ltd. (collectively Samling Group).

Wood and Samling Group^{.8} Consequently, pursuant to section 735(a)(4) of the Act and 19 CFR 351.204(e)(1), Commerce excluded Layo Wood and Samling Group from the *Order*.⁹

Commerce was subsequently remanded by the CIT¹⁰ and the CAFC¹¹ to revise its determination of the separate rate. Specifically, in its third remand redetermination, Commerce assigned seven of the eight separate rate respondents, which were plaintiffs in the litigation, an unspecified above de*minimis* rate.¹² In the fourth remand redetermination, Commerce assigned the eighth separate rate plaintiff, Changzhou Hawd Flooring Co., a cash deposit rate consistent with the other separate rate plaintiffs, until Changzhou Hawd's' new cash deposit and assessment rate was established in the final results of the second administrative review.13

The CIT sustained Commerce's determinations; however, the CAFC vacated the CIT's judgment and remanded back to the CIT with instructions to remand to Commerce to revise its determination of the separate rate and apply the "expected method" under section 735(c)(5) of the Act, or to justify any departure.¹⁴ In its fifth remand redetermination, Commerce was unable to make the necessary findings to justify departure from the expected method, and thus applied the expected method for the separate rate, averaging

the calculated rates for the mandatory respondents, resulting in a zero rate.¹⁵ Commerce further determined that the relevant statutory and regulatory provision, section 735(a)(4) of the Act and 19 CFR 351.204(e)(1), did not provide a basis for excluding from the order producers that were not individually investigated and assigned individual dumping margins. Commerce also denied a request to terminate the order completely for lack of any individually calculated dumping margins above *de minimis*.

On July 3, 2018, the CIT sustained, in part, Commerce's fifth remand redetermination.¹⁶ The CIT sustained Commerce's determination not to terminate the order because the order was imposed, in part, based on indirect evidence of dumping by the China-wide entity, a finding which was not challenged.¹⁷ With respect to the separate rate plaintiffs, the CIT ordered exclusion from the order for three separate respondents that sought voluntary examination in the investigation, but were denied: Dunhua City Jisen Wood Industry Co., Ltd., Fine Furniture (Shanghai) Limited, and Armstrong Wood Products (Kunshan) Co., Ltd. The CIT held that Commerce's application of the exclusion regulation, 19 CFR 351.204(e)(1), was arbitrary with respect to these respondents.¹⁸

Timken Notice

In its decision in *Timken*, as clarified by *Diamond Sawblades*, the CAFC held

that, pursuant to section 516A(e) of the Act, Commerce must publish a notice of a court decision that is not "in harmony" with Commerce's determination and must suspend liquidation of entries pending a "conclusive" court decision. The CIT's July 3, 2018, final judgment affirming the Fifth Remand Redetermination,19 sustaining the recalculated separate rate of zero (applicable to the separate rate plaintiffs), and ordering the exclusion of Dunhua City Jisen Wood Industry Co., Ltd., Fine Furniture (Shanghai) Limited, and Armstrong Wood Products (Kunshan) Co., Ltd. from the order constitutes a final decision of that court that is not in harmony with the Second Amended Final Determination. This notice is published in fulfillment of the publication requirements of *Timken*.

Third Amended Final Determination

There is now a final court decision with respect to the *Second Amended Final Determination* as it concerns the eight separate rate respondents listed below. As of the date of this notice, all eight companies have received updated cash deposit rates, and their rates will not change as a result of this litigation. Accordingly, Commerce is amending the *Second Amended Final Determination*. The revised weightedaverage dumping margins for these companies are as follows:

Exporter	Weighted- average dumping margin (percent)
Changzhou Hawd Flooring Co	0.00
Dunhua City Jisen Wood Industry Co., Ltd	0.00
Dunhua City Dexin Wood Industry Co., Ltd	0.00
Dalian Huilong Wooden Products Co., Ltd	0.00
Kunshan Yingy-Nature Wood Industry Co., Ltd	0.00

⁸ See also Baroque Timber Indus. (Zhongshan) Co. v. United States, 971 F.Supp.2d 1333, 1336 (Ct. Int'l Trade 2014).

⁹ See First Remand Redetermination, dated November 14, 2013. On May 23, 2014, Commerce provided liquidation instructions to U.S. Customs and Border Protection (CBP) for both Layo Wood and Samling Group explaining that Commerce has determined that merchandise produced and exported by Layo Wood and Samling Group are "excluded from the antidumping duty order on multilayered wood flooring from {China}". See CBP Message from Commerce, "Liquidation instructions for multilayered wood flooring from the People's Republic of China ("PRC") produced and exported by Zhejiang Layo Wood Industry Co., Ltd. (A–570– 970–001)," dated May 23, 3014, Message Number 4143303; see also CBP Message from Commerce, "Liquidation instructions for multilayered wood flooring from the People's Republic of China ("PRC") produced and exported by the Samling Group (A–570–970–002)," dated May 23, 3014, Message Number 4143304.

¹⁰ See Changzhou Hawd Flooring Co. v. United States, 77 F. Supp. 3d 1351 (Ct. Int'l Trade 2015) (Changzhou Hawd 2015).

¹¹ See Changzhou Hawd Flooring Co. v. United States, 848 F.3d 1006, 1008 (Fed. Cir. 2017) (Changzhou Hawd 2017).

¹² See Final Results of Redetermination Pursuant to Court Order, Changzhou Hawd Flooring Co., Ltd., et al. v. United States, dated October 16, 2014 (Third Remand Redetermination). Commerce inferred that the margins of the separate rate plaintiffs were above-de minimis in the second remand redetermination. Commerce based this inference on two primary considerations. First, Commerce observed that 110 companies did not respond to the quantity and value questionnaire, that certain of those companies could have been selected as mandatory respondents, and that it is reasonable to infer those companies would have received above-de minimis rates. Second, Commerce corroborated this inference using the intervening results of the first administrative

review, where Commerce found continued dumping. See Final Results of Redetermination Pursuant to Court Order, Baroque Timber Industries (Zhongshan) Company, Limited, et al. v. United States, dated May 30, 2014 (Second Remand Redetermination).

¹³ See Final Results of Redetermination Pursuant to Court Order, *Changzhou Hawd Flooring Co., Ltd., et al.* v. *United States,* dated March 24, 2015 (Fourth Remand Redetermination).

¹⁴ See Changzhou Hawd 2015, 77 F. Supp. 3d
 1351; Changzhou Hawd 2017, 848 F.3d 1006, 1008.
 ¹⁵ See Final Results of Redetermination Pursuant

to Court Order, Court No. 12–00020, dated February 15, 2017 (Fifth Remand Redetermination).

¹⁶ See Changzhou Hawd Flooring Co., et al. v. United States, Ct. No. 12–20, Slip Op. 18–82 (Ct. Int'l Trade July 3, 2018).

¹⁷ Id. at 11–12.

¹⁸ *Id.* at 16.

¹⁹ Id.

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Exporter	Weighted- average dumping margin (percent)
Karly Wood Product Limited	0.00
Fine Furniture (Shanghai) Limited	0.00
Armstrong Wood Products (Kunshan) Co., Ltd	0.00

Further, pursuant to the CIT's July 3, 2018, final judgment, Commerce is also excluding Dunhua City Jisen Wood Industry Co., Ltd., Fine Furniture (Shanghai) Limited, and Armstrong Wood Products (Kunshan) Co., Ltd., from the order. Section 735(c)(2)(A)-(B)of the Act instructs Commerce to terminate suspension of liquidation and to release any bond or other security, and refund any cash deposit, in the event of a negative determination. Here, suspension of liquidation must continue during the pendency of the appeals process (in accordance with *Timken* and as discussed above), and, therefore, we will continue to instruct CBP at this time to (A) continue suspension at a cash deposit rate of zero percent until instructed otherwise; and (B) release any bond or other security, and refund any cash deposit made pursuant to the order by Dunhua City Jisen Wood Industry Co., Ltd., Fine Furniture (Shanghai) Limited, and Armstrong Wood Products (Kunshan) Co., Ltd. In the event that the CIT's ruling is not appealed, or appealed and upheld by the CAFC, Commerce will instruct CBP to terminate the suspension of liquidation and to liquidate those unliquidated entries of subject merchandise without regard to antidumping duties.

Notification to Interested Parties

This notice serves as a reminder to 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 the destruction of APO materials or conversion to judicial protective order is hereby requested. Failure to comply with the regulations and the terms of the APO is a violation subject to sanction.

This notice is issued and published in accordance with sections 516A(e)(1), 735, and 777(i)(1) of the Act.

Dated: July 18, 2018. Gary Taverman,

Deputy Assistant Secretary for Antidumping and Countervailing Duty Operations, performing the non-exclusive functions and duties of the Assistant Secretary for Enforcement and Compliance. [FR Doc. 2018–15878 Filed 7–24–18; 8:45 am]

BILLING CODE 3510-DS-P

DEPARTMENT OF COMMERCE

National Oceanic and Atmospheric Administration

RIN 0648-XG367

NOAA's Implementation of the Department of Commerce 2018–2022 Strategic Plan; Public Meetings

AGENCY: National Oceanic and Atmospheric Administration (NOAA), Commerce.

ACTION: Notice of public meeting.

SUMMARY: The Office of Under Secretary of Commerce (USEC) for Oceans and Atmosphere is holding multiple listening sessions to provide information and receive stakeholder input regarding implementation of the Department of Commerce's 2018–2022 Strategic Plan. Focal topics will be implementation of the Weather Research and Forecasting Innovation Act of 2017, reducing the seafood trade deficit, supporting maritime commerce, fisheries, recreation and tourism. The listening sessions will include presentations and time for stakeholder input into the development of priority objectives. The meeting topics are described under the SUPPLEMENTARY **INFORMATION** section of the notice.

DATES: The meetings will be held between August and November 2018. For specific dates and times, see **SUPPLEMENTARY INFORMATION**.

ADDRESSES: Meeting address: The meetings will be held in Norman, OK; Juneau, AK; St. Petersburg, FL; Madison, WI; Charleston, SC; Seattle, WA; San Diego, CA and Durham, NC. For specific locations, see

SUPPLEMENTARY INFORMATION.

FOR FURTHER INFORMATION CONTACT: Julie Kay Roberts, Director of

Communications, National Oceanic and Atmospheric Administration; telephone: 202–482–6090.

SUPPLEMENTARY INFORMATION: The National Oceanic and Atmospheric Administration (NOAA) has several initiatives underway to support the Department of Commerce (DOC) 2018-2022 Strategic Plan. NOAA will address the priority of reducing extreme weather impacts through the implementation of the Weather Research and Forecasting Innovation Act (Act). Among other requirements, the Act directs NOAA to improve seasonal and sub-seasonal forecasts, an area of forecasting that presents significant opportunity for improvement. NOAA is also interested in ideas to expand marine aquaculture across the United States as a means of creating quality jobs in coastal communities and reducing the seafood trade deficit. Other aspects to support domestic fisheries include reducing regulatory burden for wild-caught fisheries, implementing and enforcing recent regulations that establish minimum standards for imported seafood, and increasing foreign market access for U.S. seafood products. NOAA is also interested in pursuing efforts to support commerce through expanding precision maritime navigation products, ecotourism through the National Marine Sanctuaries Program, and harnessing the deep sea through ocean exploration. NOAA also intends to re-energize the National Oceanographic Partnership Program—a federal program that facilitates public-private partnerships to fund marine research.

For the listening sessions, the Office of Under Secretary of Commerce (USEC) for Oceans and Atmosphere will present background on these ideas and solicit comment from stakeholders. The focus of each public meeting and structure of public comment will be at the discretion of the presenters and NOAA staff. The USEC schedule, location, and agenda for the following eight meetings are as follows with exact times and locations to be released at least 14 days in advance of the events at http:// www.noaa.gov/stories/noaa-startsnationwide-listening-sessions:

Meetings: Schedule, Location, and Agenda

1. Thursday, August 30, Norman, OK

Agenda: To discuss implementation of The Weather Act, including the development of a community-based weather model.

2. Friday, August 31, Juneau, Alaska

Agenda: To discuss opportunities to reduce the nation's seafood trade deficit, and promote marine commerce and tourism.

3. Monday, September 10, St. Petersburg, Florida

Agenda: To discuss advancing commercial and recreational fisheries, technology development and tourism.

4. Wednesday, September 12, Madison, Wisconsin

Agenda: To discuss implementation of The Weather Act, including the development of a community-based weather model.

5. Thursday, October 4, Seattle, Washington

Agenda: To discuss implementation of The Weather Act, including the development of a community-based weather model.

6. Tuesday, October 23, Charleston, SC

Agenda: To discuss opportunities to improve the efficiency of U.S. ports, reduce the seafood trade deficit, and expand exploration of the nation's Exclusive Economic Zone.

7. Thursday, November 1, Durham, NC

Agenda: To discuss implementation of The Weather Act, including the development of a community-based weather model, opportunities to reduce the nation's seafood trade deficit, and ocean exploration.

8. Friday, November 9, San Diego, California

Agenda: To discuss opportunities to improve the efficiency of U.S. ports, promote domestic aquaculture production, and expand exploration of the nation's Exclusive Economic Zone.

Special Accommodations

These meetings are physically accessible to people with disabilities. Requests for sign language interpretation or other auxiliary aids should be directed to Julie Kay Roberts; 202–482–6090, at least 10 working days prior to the meeting date.

Authority: 15 U.S.C. 8501 et seq.

Dated: July 20, 2018. Tim Gallaudet,

Assistant Secretary of Commerce for Oceans and Atmosphere and Acting Under Secretary of Commerce for Oceans and Atmosphere, National Oceanic and Atmospheric Administration.

[FR Doc. 2018–15937 Filed 7–24–18; 8:45 am] BILLING CODE 3510–12–P

DEPARTMENT OF COMMERCE

National Oceanic and Atmospheric Administration

RIN 0648-XG133

Takes of Marine Mammals Incidental to Specified Activities; Taking Marine Mammals Incidental to Port of Kalama Expansion Project on the Lower Columbia River

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

ACTION: Notice; proposed incidental harassment authorization; request for comments.

SUMMARY: NMFS received a request from the Port of Kalama (POK) to issue an incidental harassment authorization (IHA) previously issued to the POK to incidentally take three species of marine mammal, by Level B harassment only, during construction activities associated with an expansion project at the Port of Kalama on the Lower Columbia River, Washington. The current IHA was issued in 2017 and is in effect until August 31, 2018 (2017–2018 IHA). However, the project has been delayed such that none of the work covered by the 2017–2018 IHA has been initiated and, therefore, the POK requested that an IHA be issued to conduct their work beginning on or about September 1, 2018 (2018-2019 IHA). NMFS is seeking public comment on its proposal to issue the 2018–2019 IHA to cover the incidental take analyzed and authorized in the 2017-2018 IHA. Pursuant to the Marine Mammal Protection Act (MMPA), NMFS is requesting comments on its proposal to issue an IHA to POK to incidentally take, by Level B harassment, small numbers of marine mammals during the specified activities. The authorized take numbers and related analyses would be the same as for the 2017–2018 IHA, and the required mitigation, monitoring, and reporting would remain the same as authorized in the 2017–2018 IHA referenced above. NMFS will consider public comments prior to making any final decision on the issuance of the requested MMPA

authorization and agency responses will be summarized in the final notice of our decision.

DATES: Comments and information must be received no later than August 24, 2018.

ADDRESSES: An electronic copy of the final Authorization issued in 2017 and supporting material along with an updated IHA request memo from POK may be obtained by visiting *https://www.fisheries.noaa.gov/national/marine-mammal-protection/incidental-take-authorizations-construction-activities.* In case of problems accessing these documents, please call the contact listed below (see FOR FURTHER INFORMATION CONTACT).

FOR FURTHER INFORMATION CONTACT: Dale Youngkin, Office of Protected Resources, NMFS, (301) 427–8401. SUPPLEMENTARY INFORMATION:

Background

Sections 101(a)(5)(A) and (D) of the MMPA (16 U.S.C. 1361 *et seq.*) direct the Secretary of Commerce (as delegated to NMFS) to allow, upon request, the incidental, but not intentional, taking of small numbers of marine mammals by U.S. citizens who engage in a specified activity (other than commercial fishing) within a specified geographical region if certain findings are made and either regulations are issued or, if the taking is limited to harassment, a notice of a proposed authorization is provided to the public for review.

An authorization for incidental takings shall be granted if NMFS finds that the taking will have a negligible impact on the species or stock(s), will not have an unmitigable adverse impact on the availability of the species or stock(s) for subsistence uses (where relevant), and if the permissible methods of taking and requirements pertaining to the mitigation, monitoring and reporting of such takings are set forth.

NMFS has defined "negligible impact" in 50 CFR 216.103 as an impact resulting from the specified activity that cannot be reasonably expected to, and is not reasonably likely to, adversely affect the species or stock through effects on annual rates of recruitment or survival.

The MMPA states that the term "take" means to harass, hunt, capture, kill or attempt to harass, hunt, capture, or kill any marine mammal.

Except with respect to certain activities not pertinent here, the MMPA defines "harassment" as any act of pursuit, torment, or annoyance which (i) has the potential to injure a marine mammal or marine mammal stock in the wild (Level A harassment); or (ii) has the potential to disturb a marine mammal or marine mammal stock in the wild by causing disruption of behavioral patterns, including, but not limited to, migration, breathing, nursing, breeding, feeding, or sheltering (Level B harassment).

National Environmental Policy Act

In compliance with the National Environmental Policy Act of 1969 (42 U.S.C. 4321 *et seq.*), as implemented by the regulations published by the Council on Environmental Quality (40 CFR parts 1500-1508), NMFS prepared an Environmental Assessment (EA) to consider the direct, indirect and cumulative effects to the human environment resulting from the POK Expansion project. NMFS made the EA available to the public for review and comment in order to assess the impacts to the human environment of issuance of the 2017-2018 IHA to the POK. Also in compliance with NEPA and the CEQ regulations, as well as NOAA Administrative Order 216–6, NMFS signed a Finding of No Significant Impact (FONSI) on October 24, 2016 for issuance of the 2017-2018 IHA. These NEPA documents are available at https://www.fisheries.noaa.gov/ national/marine-mammal-protection/ incidental-take-authorizationsconstruction-activities.

Since this IHA covers the same work covered in the 2017–2018 IHA, NMFS has reviewed our previous EA and FONSI, and has preliminarily determined that this action is consistent with categories of activities identified in CE B4 of the Companion Manual for NOAA Administrative Order 216-6A, which do not individually or cumulatively have the potential for significant impacts on the quality of the human environment and for which we have not identified any extraordinary circumstances that would preclude this categorical exclusion. Accordingly, NMFS has preliminarily determined that the issuance of the proposed IHA qualifies to be categorically excluded from further NEPA review. We will review all comments submitted in response to this notice prior to concluding our NEPA process or making a final decision on the 2018–2019 IHA request.

History of Request

On September 28, 2015, we received a request from the POK for authorization of the taking, by Level B harassment only, of marine mammals incidental to the construction associated with the Port of Kalama Expansion Project, which involved construction of the

Kalama Marine Manufacturing and Export Facility including a new marine terminal for the export of methanol, and installation of engineered log jams, restoration of riparian wetlands, and the removal of existing wood piles in a side channel as mitigation activities. The specified activity is expected to result in the take of three species of marine mammals (harbor seals, California sea lions, and Steller sea lions). A final version of the application, which we deemed adequate and complete, was submitted on December 10, 2015. We published a notice of a proposed IHA and request for comments on March 21, 2016 (81 FR 715064). After the public comment period and before we issued the final IHA, POK requested that we issue the IHA for 2017 instead of the 2016 work season. We subsequently published the final notice of our issuance of the IHA on December 12, 2016 (81 FR 89436), effective from September 1, 2017-August 31, 2018. Inwater work associated with the project was expected to be completed within the one-year timeframe of the IHA.

On June 21, 2018, POK informed NMFS that work relevant to the specified activity considered in the MMPA analysis for the 2017–2018 IHA was postponed and would not be completed. POK requested that the IHA be issued to be effective for the period from September 1, 2018-August 31, 2019. In support of that request, POK submitted an application addendum affirming that no change in the proposed activities is anticipated and that no new information regarding the abundance of marine mammals is available that would change the previous analysis and findings.

Description of the Activity and Anticipated Impacts

The 2017–2018 IHA covered the construction of a marine terminal and dock/pier for the export of methanol, and associated compensatory mitigation activities for the purposes of offsetting habitat effects from the action. The marine terminal will be approximately 45,000 square feet in size, supported by 320 concrete piles (24-inch precast octagonal piles to be driven by impact hammer) and 16 steel piles (12 x 12inch and 4 x 18-inch anticipated to be driven by vibratory hammer, and impact hammering will only be done to drive/ proof if necessary). The compensatory mitigation includes installation of 8 engineered log jams (ELJs), which will be anchored by untreated wooden piles driven by impact hammer at low tides (not in water). The compensatory mitigation also includes removal of

approximately 320 untreated wooden piles from an abandoned U.S. Army Corps of Engineers (USACE) dike in a nearby backwater area. The piles will be removed either by direct pull or vibratory extraction. Finally, the compensatory mitigation includes wetland restoration and enhancement by removal of invasive species and replacement with native wetland species.

NMFS refers the reader to the documents related to the 2017–2018 IHA for more detailed description of the project activities. These previous documents include the **Federal Register** notice of the issuance of the 2017–2018 IHA for the POK's Port of Kalama Expansion Project (81 FR 89436, December 12, 2016), the **Federal Register** notice of the proposed IHA (81 FR 15064, March 21, 2016), POK's application (and 2018 application addendum), and all associated references.

Detailed Description of the Action—A detailed description of the pile driving activities at the Port of Kalama is found in these previous documents and the updated 2018–2019 IHA application addendum. The location, timing (*e.g.*, seasonality), and nature of the pile driving operations, including the type and size of piles and the methods of pile driving, are identical to those described in the previous **Federal Register** notices referenced above.

Description of Marine Mammals—A description of the marine mammals in the area of the activities is found in the previous documents referenced above, which remain applicable to this IHA as well. In addition, NMFS has reviewed recent Stock Assessment Reports, information on relevant Unusual Mortality Events, and recent scientific literature. Since the submittal of the 2015 IHA application, the USACE has published updated data on pinniped presence at the Bonneville Dam (Tidwell et al., 2017). This information reveals that in both 2016 and 2017 the numbers of pinnipeds present at Bonneville Dam were within the range of historical variability. The latest USACE data does not suggest a trend that would require a modification to the take estimates or to the effects analysis (see Table 1 below for a summary of monitoring data by year from Tidwell et al., 2017). Therefore, NMFS has preliminarily determined that the updated information does not affect our analysis of impacts for the 2018-2019 IHA.

TABLE 1-MINIMUM ESTIMATED NUMBER OF INDIVIDUAL PINNIPEDS OBSERVED AT BONNEVILLE DAM TAILRACE AREAS AND THE HOURS OF OBSERVATION DURING THE FOCAL SAMPLING PERIOD, 2002 TO 2017

[From Tidwell et al., 2017]

Year	Total hours observed	California sea lions	Steller sea lions	Harbor seals	Total pinnipeds
2002	662	30	0	1	31
2003	1,356	104	3	2	109
2004	516	99	3	2	104
2005 *	1,109	81	4	1	86
2006	3,650	72	11	3	86
2007	4,433	71	9	2	82
2008	5,131	82	39	2	123
2009	3,455	54	26	2	82
2010	3,609	89	75	2	166
2011	3,315	54	89	1	144
2012	3,404	39	73	0	112
2013	3,247	56	80	0	136
2014	2,947	71	65	1	137
2015	2,995	195	^a 69	0	264
2016	1,974	149	^a 54	0	203
2017	1,142	92	^a 63	1	156

* Observations did not begin until March 18 in 2005. a In 2015, 2016, and 2017 the minimum estimated number of Steller sea lions was 55, 41, and 32, respectively. These counts were less than the maximum number of Steller sea lions observed on one day, so Tidwell et al. (2017) used the maximum number observed on one day as the minimum number. This difference was driven by a focus on California sea lions and lack of branding or unique markers on Steller sea lions.

Potential Effects on Marine Mammals—A description of the potential effects of the specified activities on marine mammals and their habitat is found in the previous documents referenced above, and remain applicable to this proposed IHA. There is no new information on potential effects that would change our analyses or determinations under the 2018-2019 IHA.

Estimated Take—A description of the methods and inputs used to estimate take anticipated to occur and,

ultimately, the take that was authorized is found in the previous documents referenced above. The methods of estimating take for this proposed IHA are identical to those used in the 2017-2018 IHA, as is the density of marine mammals. The source levels, also remain unchanged from the 2017–2018 IHA, and NMFS' 2016 Technical Guidance for Assessing the Effects of Anthropogenic Sound on Marine Mammal Hearing (NMFS 2016) was used to address new acoustic thresholds in the notice of issuance of the 20172018 IHA. As stated above, since the submittal of the application for the 2017-2018 IHA (in effect from September 1, 2017 through August 31, 2018), the USACE has published updated data on pinniped presence at the Bonneville Dam, and this data does not suggest a trend that would require a modification to the take estimates or effects analysis. Consequently, the proposed authorized take for this proposed 2018–2019 IHA is identical to the 2017–2018 IHA, as presented in Table 2 below.

TABLE 2—ESTIMATED TAKE PROPOSED FOR AUTHORIZATION AND PROPORTION OF POPULATION POTENTIALLY AFFECTED

	Estimated take by Level B harassment	Abundance of stock	Percentage of stock potentially affected	Population trend
Harbor seal	1,530	24,732	6.2	Stable.
California sea lion	372	153,337	0.2	Stable.
Steller sea lion	372	59,968	0.6	Increasing.

Description of Mitigation, Monitoring and Reporting Measures—A description of mitigation, monitoring, and reporting measures is found in the previous documents referenced above, and remain unchanged for this proposed IHA. In summary, mitigation includes implementation of shut down procedures if any marine mammal approaches or enters the Level A harassment zone for impact pile driving. One trained observer shall monitor to implement shutdowns and collect information at each active impact pile driving location. In addition, two shorebased observers (one upstream of the project, and another downstream of the project), whose primary responsibility shall be to record pinnipeds in the disturbance zone and to alert bargebased observers to the presence of pinnipeds, thus creating a redundant alert system for prevention of injurious interaction as well as increasing the probability of detecting pinnipeds in the disturbance zone.

At least three observers shall be on duty during vibratory pile driving activity for the first two days, and thereafter on every third day to allow for

estimation of Level B takes. The first observer shall be positioned on a work platform or barge where the entirety of a 10 m shutdown zone can be monitored. Shore based observers shall be positioned to observe the disturbance zone from the bank of the river. Protocols will be implemented to ensure that coordinated communication of sightings occurs between observers in a timely manner.

Pile driving activities shall only be conducted during daylight hours. If the shutdown zone is obscured by fog or poor lighting conditions, pile driving

will not be initiated until the entire shutdown zone is visible. Work that has been initiated appropriately in conditions of good visibility may continue during poor visibility. The shutdown zone will be monitored for 30 minutes prior to initiating the start of pile driving, during the activity, and for 30 minutes after activities have ceased. If pinnipeds are present within the shutdown zone prior to pile driving, the start will be delayed until the animals leave the shutdown zone of their own volition, or until 15 minutes elapse without re-sighting the animal(s).

Soft start procedures shall be implemented at the start of each day's impact pile driving and at any time following cessation of impact driving for a period of thirty minutes or longer. If steel piles require impact installation or proofing, a bubble curtain will be used for sound attenuation.

Determinations

The POK proposes to conduct activities in 2018–2019 that are identical to those covered in the currently 2017–2018 IHA. As described above, the number of estimated takes of the same stocks of harbor seals (OR/WA Coast stock), California sea lion (U.S. stock), and Steller sea lion (Eastern DPS) is the same for this proposed IHA as those authorized in the 2017-2018 IHA, which were found to meet the negligible impact and small numbers standards. The authorized take of 1,200 harbor seals; 70 California sea lions, and 68 Steller sea lions represent 4.8 percent, >0.1 percent, and 0.1 percent of these stocks of marine mammals by Level B harassment, respectively. This proposed IHA includes identical required mitigation, monitoring, and reporting measures as the 2017–2018 IHA, and there is no new information suggesting that our prior analyses or findings should change.

Based on the information contained here and in the referenced documents, NMFS has preliminarily determined the following: (1) The authorized takes will have a negligible impact on the affected marine mammal species or stocks; (2) the required mitigation measures will effect the least practicable impact on marine mammal species or stocks and their habitat; (3) the authorized takes represent small numbers of marine mammals relative to the affected species or stock abundances; and (4) the POK's activities will not have an unmitigable adverse impact on taking for subsistence purposes, as no relevant subsistence uses of marine mammals are implicated by this action.

Endangered Species Act (ESA)

Section 7(a)(2) of the Endangered Species Act of 1973 (ESA: 16 U.S.C. 1531 *et seq.*) requires that each Federal agency insure that any action it authorizes, funds, or carries out is not likely to jeopardize the continued existence of any endangered or threatened species or result in the destruction or adverse modification of designated critical habitat. To ensure ESA compliance for the issuance of IHAs, NMFS consults internally whenever we propose to authorize take for endangered or threatened species.

No incidental take of ESA-listed species is expected to result from this activity, and none would be authorized. Therefore, NMFS has determined that consultation under section 7 of the ESA is not required for this action.

Proposed Authorization

NMFS proposes to issue an IHA to POK for in-water construction work activities beginning September 2018 through August 2019, with the proposed mitigation, monitoring, and reporting requirements. The proposed IHA language is provided next.

This section contains a draft of the IHA itself. The wording contained in this section is proposed for inclusion in the IHA (if issued).

The Port of Kalama (POK), 110 West Marine Drive, Kalama, Washington, 98625, is hereby authorized under section 101(a)(5)(D) of the Marine Mammal Protection Act (16 U.S.C. 1371(a)(5)(D)) and 50 CFR 216.107 to take marine mammals, by harassment, incidental to conducting in-water construction work for the Port of Kalama Expansion Project contingent upon the following conditions:

1. This Authorization is effective for one year from the date of issuance.

2. Timing of Activities

(a) Timing of activities anticipated to result in take of marine mammals shall be conducted between September 1, 2018 and January 31, 2019;

(b) Timing of Activities Not Anticipated to Result in Take of Marine Mammals;

(i) Dredging would be conducted between September 1, 2018 and December 31, 2018;

(ii) Construction/installation of engineered log jams (ELJ) may be conducted year-round;

(iii) Construction that will take place below the Ordinary High Water Mark (OHWM), but outside of the wetted perimeter of the river (in the dry) may be conducted year-round; and

(iv) Removal of wooden piles from former trestle in the freshwater intertidal backwater channel portion of the project site (compensatory mitigation measure of removal of 157 wooden piles) may be conducted yearround.

3. This Authorization is valid only for activities associated with in-water construction work for the Port of Kalama Expansion Project on approximately 100 acres (including uplands) at the northern end of the Port of Kalama's North Port site (Lat. 46.049, Long. – 122.874), located at approximately river mile 72 along the lower Columbia River along the east bank in Cowlitz County, Washington.

4. Briefings shall be conducted between construction supervisors, crews, marine mammal observer team, and Port of Kalama staff prior to the start of all pile driving/removal work and when new personnel join the work in order to explain responsibilities, communication procedures, marine mammal monitoring protocol, and operational procedures.

5. (a) The number and species authorized for taking are: 1,530 harbor seals (*Phoca vitulina richardsi*), 372 California sea lions (*Zalophus californianus*), and 372 Steller sea lions (*Eumatopius jubatus*).

(b) The Authorization for taking by harassment is limited to the following acoustic sources and activities:

(i) Impact pile driving; and
 (ii) Vibratory pile driving activities
 (including vibratory removal of

temporary construction piles (c) The taking of any marine mammal in a manner prohibited under this Authorization must be reported within 24 hours of the taking to the National Marine Fisheries Service (NMFS) West Coast Regional Administrator at (206) 526–6150 and the NMFS Chief of the Permits and Conservation Division at (301) 427–8401.

6. The taking, by Level B harassment only, is limited to the species listed, and by the numbers listed, under condition 4(a) above. The taking by Level A harassment or death of the species identified in 4(a) or any taking of any other species of marine mammal is prohibited and may result in the modification, suspension, or revocation of this Authorization.

7. Mitigation

(a) Activities authorized for take of marine mammals by this Authorization shall occur only during daylight hours.

(b) A bubble curtain shall be used for sound attenuation if steel piles require impact installation or proofing.

(c) Exclusion Zone and Level B Harassment Zones of Influence;

(i) Exclusion zones out to distances encompassing the Level A harassment zones shall be implemented to avoid Level A take of marine mammals (40 m (131 ft) for impact driving of concrete piles; 252 m (828 ft) for impact driving of steel piles; and 16.5 m (54 ft) for vibratory driving of steel piles); and

(ii) Disturbance zones shall be established as 117 m (384 ft) for impact driving of concrete piles; 1,848 m (6,063 ft) for impact driving of steel piles; and line of sight to nearest shoreline (5.7 km (18,700 ft) maximum) for vibratory driving of steel piles;

(d) Monitoring of marine mammals shall take place starting 30 minutes before pile driving begins and shall continue until 30 minutes after pile driving ends.

(e) Soft Start

(i) Soft start procedures shall be implemented at the start of each day's impact pile driving and at any time following cessation of impact pile driving for a period of 30 minutes or longer; and

(ii) Soft start procedures require that the contractor provides an initial set of three strikes at reduced energy followed by a 30-second waiting period, then two subsequent reduced energy strike sets.

(f) Shutdown Measures

(i) POK shall implement shutdown measures if a marine mammal is sighted within, or is perceived to be approaching, the exclusion zones identified in 5(c)(i) above and the associated construction or pile driving activities shall immediately cease. Pile driving or in-water construction work shall not be resumed until the exclusion zone has been observed as being clear of marine mammals for at least 15 minutes; and

(ii) If marine mammals are present within the exclusion zones established in 5(c)(i) above prior to the start of inwater construction activities, these activities would be delayed until the animals leave the exclusion zone of their own volition, or until 15 minutes elapse without resighting the animal, at which time it may be assumed that the animal(s) have left the exclusion zone.

8. Monitoring

Marine Mammal Observers—POK shall employ observers to conduct marine mammal monitoring for its construction project. Observers shall have the following minimum qualifications:

(i) Visual acuity in both eyes (correction is permissible) sufficient for discernment of moving targets at the water's surface with the ability to estimate target size and distance. Use of binoculars may be necessary to correctly identify the target;

(ii) Experience and ability to conduct field observations and collect data

according to assigned protocols (this may include academic experience);

(iii) Experience or training in the field identification of the marine mammals that could potentially be encountered;

(iv) Sufficient training, orientation, or experience with the construction operation to provide for personal safety during observations;

(v) Writing skills sufficient to prepare a report of observations that shall include such information as the number and types of marine mammals observed; the behavior of marine mammals in the project area during construction; the dates and times when observations were conducted; the dates and times when inwater construction activities were conducted; the dates and times when marine mammals were present at or within the defined disturbance zone; and the dates and times when in-water construction activities were suspended to avoid incidental harassment by disturbance from construction noise; and

(vi) Ability to communicate orally, by radio or in person, with project personnel to provide real time information on marine mammals observed in the area.

(b) Individuals meeting the minimum qualifications identified in 7(a), above, shall be present on site (on land or dock) at all times during pile driving activities conducted for the project.

(c) During all impact pile driving activities, observers shall be stationed to allow a clear line of sight of the exclusion zone (10 m (33 ft) except for steel piles, which shall be 18 m (59 ft)) and the entire disturbance zone as identified in Table 2 (attached).

(d) Marine mammal observers shall monitor for the first two days of vibratory pile driving, and thereafter on every third day of vibratory pile driving. Monitoring shall be conducted by three observers during vibratory pile driving activities. One observer shall be stationed in the general vicinity of the pile being driven and shall have clear line of sight views of the entire inner harbor. Another observer shall be stationed at an accessible location downstream (such as northern tip of Prescott Beach County Park) and would observe the northern (downstream) portion of the disturbance zone. A third observer shall be stationed at an accessible location upstream and would observe the southern (upstream) portion of the disturbance zone.

(e) Marine mammal observers shall scan the waters within each monitoring zone activity using binoculars (Vector 10 X 42 or equivalent), spotting scopes (Swarovski 20–60 zoom or equivalent; Washington Department of Fish and Wildlife 2000), and visual observation.

(f) Marine mammal presence within the Level B harassment zones of influence (disturbance zones) shall be monitored, but pile driving activity shall not be stopped if marine mammals are found present unless they enter or approach the exclusion zone. Any marine mammal observed within the disturbance zone shall be documented and counted as a Level B take. Monitoring during vibratory pile driving shall occur during the first two days of activity and during every three days thereafter to estimate the number of individuals present within the Level B harassment area.

(g) If waters exceed a sea-state which restrict the observers' ability to make observations within the Level A injury exclusion zone, relevant activities shall cease until conditions allow the resumption of monitoring. Vibratory pile installation would continue under these conditions.

(h) The waters shall be scanned 30 minutes prior to commencing pile driving activities and during all pile driving activities. If marine mammals enter or are observed within the designated exclusion zones during, or 15 minutes prior to, impact pile driving, the monitors shall notify the on-site construction manager to not begin, or cease, work until the animal(s) leave of their own volition, or have not been observed within the zone for 15 minutes.

9. Reporting

(a) POK shall provide NMFS with a draft monitoring report within 90 days of the expiration of this Authorization, or within conclusion of the construction work, whichever comes first. This report shall detail the monitoring protocol, summarize the data recorded during monitoring, and estimate the number of marine mammals that may have been harassed.

(b) If comments are received from NMFS (West Coast Regional Administrator or NMFS Office of Protected Resources) on the draft report within 30 days, a final report shall be submitted to NMFS within 30 days thereafter. If not comments are received from NMFS within 30 days after receipt of the draft report, the draft report shall be considered final.

(c) In the unanticipated event that the construction activities clearly cause the take of a marine mammal in a manner prohibited by this Authorization, such as an injury, serious injury, or mortality (Level A take), POK shall immediately cease all operations and immediately report the incident to the NMFS Chief of the Permits and Conservation Division, Office of Protected Resources and the NMFS West Coast Regional Stranding Coordinators. The report must include the following information:

(i) Time, date, and location (latitude and longitude) of the incident;

(ii) Description of the incident;

(iii) Status of all sound sources used

in the 24 hours preceding the incident; (iv) Environmental conditions (wind speed, wind direction, sea state, cloud cover, visibility, water depth);

(v) Description of the marine mammal observations in the 24 hours preceding the incident;

(vi) Species identification or description of the animal(s) involved;

(vii) The fate of the animal(s); and (viii) Photographs or video footage of

the animal(s), if equipment is available. (d) Activities shall not resume until NMFS is able to review the circumstances of the prohibited take. NMFS shall work with POK to determine what is necessary to minimize the likelihood of further prohibited take and ensure MMPA compliance. POK may not resume their activities until notified by NMFS via letter, email, or telephone.

(e) In the event that POK discovers an injured or dead marine mammal, and the marine mammal observer determines that the cause of injury or death is unknown and the death is relatively recent (less than a moderate state of decomposition), POK shall immediately report the incident to the NMFS Chief of Permits and Conservation Division, Office of Protected Resources, and the NMFS West Coast Regional Stranding Coordinator. The report must include the same information identified above. Activities may continue while NMFS reviews the circumstances of the incident. NMFS shall work with POK to determine whether modifications in the activities are appropriate

(f) In the event that POK discovers an injured or dead marine mammal, and the marine mammal observer determines that the injury or death is not associated with or related to the activities authorized in the IHA (previously wounded animal, carcass with moderate to advanced decomposition, or scavenger damage), POK shall report the incident to the NMFS Chief of Permits and Conservation Division, Office of Protected Resources, and the NMFS West Coast Regional Stranding Coordinator within 24 hours of the discovery. POK shall provide photographs or video footage (if available) or other documentation of the stranded animal(s) to NMFS and the Marine Mammal Stranding Network.

POK may continue its operations under such a case.

10. This Authorization may be modified, suspended, or withdrawn if the holder fails to abide by the conditions prescribed herein or if NMFS determines that the authorized taking is having more than a negligible impact on the species or stock of affected marine mammals.

Request for Public Comments

We request comment on our analyses, the draft authorization, and any other aspect of this Notice of Proposed IHA for the proposed POK construction activities. Please include with your comments any supporting data or literature citations to help inform our final decision on the request for MMPA authorization.

On a case-by-case basis, NMFS may issue a one-year renewal IHA without additional notice when (1) another year of identical or nearly identical activities as described in the Specified Activities section is planned, or (2) the activities would not be completed by the time the IHA expires and renewal would allow completion of the activities beyond that described in the Dates and Duration section, provided all of the following conditions are met:

• A request for renewal is received no later than 60 days prior to expiration of the current IHA;

• The request for renewal must include the following:

(1) An explanation that the activities to be conducted beyond the initial dates either are identical to the previously analyzed activities or include changes so minor (*e.g.*, reduction in pile size) that the changes do not affect the previous analyses, take estimates, or mitigation and monitoring requirements; and

(2) A preliminary monitoring report showing the results of the required monitoring to date and an explanation showing that the monitoring results do not indicate impacts of a scale or nature not previously analyzed or authorized;

• Upon review of the request for renewal, the status of the affected species or stocks, and any other pertinent information, NMFS determines that there are no more than minor changes in the activities, the mitigation and monitoring measures remain the same and appropriate, and the original findings remain valid.

Dated: July 19, 2018.

Donna S. Wieting,

Director, Office of Protected Resources, National Marine Fisheries Service. [FR Doc. 2018–15837 Filed 7–24–18; 8:45 am] BILLING CODE 3510–22–P

DEPARTMENT OF COMMERCE

National Oceanic and Atmospheric Administration

Submission for OMB Review; Comment Request

The Department of Commerce will submit to the Office of Management and Budget (OMB) for clearance the following proposal for collection of information under the provisions of the Paperwork Reduction Act.

Agency: National Oceanic and Atmospheric Administration (NOAA).

Title: Scientific Research, Exempted Fishing, and Exempted Educational Activity Submissions.

OMB Control Number: 0648–0309. Form Number(s): None. Type of Request: Regular (revision and extension of a currently approved

information collection).

Number of Respondents: 121. Average Hours per Response: Scientific research plans, 13 hours; scientific research reports, 6 hours; exempted fishing permit requests; 10 hours, exempted fishing permit reports, 4.5 hours; exempted educational requests, 5 hours; exempted educational reports, 2.5 hours.

Burden Hours: 2,141.

Needs and Uses: This request is for revision and extension of a currently approved information collection. Research permits already covered under other OMB Control Numbers have been removed.

Fishery regulations do not generally affect scientific research activities conducted by a scientific research vessel. Persons planning to conduct such research are encouraged to submit a scientific research plan to ensure that the activities are considered research and not fishing. The researchers are requested to submit reports of their scientific research activity after its completion. Eligible researchers on board federally permitted fishing vessels that plan to temporarily possess fish in a manner not compliant with applicable fishing regulations for the purpose of collecting scientific data on catch may submit a request for a temporary possession letter of authorization. The researchers are requested to submit reports of their scientific research activity after its completion. The National Marine Fisheries Service (NMFS) may also grant exemptions from fishery regulations for educational or other activities (e.g., using nonregulation gear). The applications for these exemptions must be submitted, as well as reports on activities.

Affected Public: Business or other forprofit organizations; not-for-profit institutions; state, local or tribal governments; individuals or households; federal government.

Frequency: Annually and on occasion. *Respondent's Obligation:* Mandatory.

This information collection request may be viewed at *reginfo.gov*. Follow the instructions to view Department of Commerce collections currently under review by OMB.

Written comments and recommendations for the proposed information collection should be sent within 30 days of publication of this notice to OIRA_Submission@ omb.eop.gov or fax to (202) 395–5806.

Dated: July 20, 2018.

Sarah Brabson,

NOAA PRA Clearance Officer. [FR Doc. 2018–15873 Filed 7–24–18; 8:45 am] BILLING CODE 3510–22–P

DEPARTMENT OF COMMERCE

National Oceanic and Atmospheric Administration

RIN 0648-XG219

Takes of Marine Mammals Incidental to Specified Activities; Taking Marine Mammals Incidental to Seattle Multimodal Project in Seattle, Washington

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

ACTION: Notice; issuance of an incidental harassment authorization.

SUMMARY: In accordance with the regulations implementing the Marine Mammal Protection Act (MMPA) as amended, notification is hereby given that we have issued an incidental harassment authorization (IHA) to Washington State Department of Transportation (WSDOT) to take small numbers of marine mammals, by harassment, incidental to Seattle Multimodal Project at Colman Dock in Seattle, Washington.

DATES: This authorization is effective from August 1, 2018, through July 31, 2019.

FOR FURTHER INFORMATION CONTACT:

Shane Guan, Office of Protected Resources, NMFS, (301) 427–8401. Electronic copies of the application and supporting documents, as well as the issued IHA, may be obtained online at: https://www.fisheries.noaa.gov/ national/marine-mammal-protection/ incidental-take-authorizationsconstruction-activities. In case of problems accessing these documents, please call the contact listed above. SUPPLEMENTARY INFORMATION:

Background

Sections 101(a)(5)(A) and (D) of the MMPA (16 U.S.C. 1361 *et seq.*) direct the Secretary of Commerce (as delegated to NMFS) to allow, upon request, the incidental, but not intentional, taking of small numbers of marine mammals by U.S. citizens who engage in a specified activity (other than commercial fishing) within a specified geographical region if certain findings are made and either regulations are issued or, if the taking is limited to harassment, a notice of a proposed authorization is provided to the public for review.

An authorization for incidental takings shall be granted if NMFS finds that the taking will have a negligible impact on the species or stock(s), will not have an unmitigable adverse impact on the availability of the species or stock(s) for subsistence uses (where relevant), and if the permissible methods of taking and requirements pertaining to the mitigation, monitoring and reporting of such takings are set forth.

NMFS has defined "negligible impact" in 50 CFR 216.103 as an impact resulting from the specified activity that cannot be reasonably expected to, and is not reasonably likely to, adversely affect the species or stock through effects on annual rates of recruitment or survival.

The MMPA states that the term "take" means to harass, hunt, capture, kill or attempt to harass, hunt, capture, or kill any marine mammal.

Except with respect to certain activities not pertinent here, the MMPA defines "harassment" as any act of pursuit, torment, or annoyance which (i) has the potential to injure a marine mammal or marine mammal stock in the wild (Level A harassment); or (ii) has the potential to disturb a marine mammal or marine mammal stock in the wild by causing disruption of behavioral patterns, including, but not limited to, migration, breathing, nursing, breeding, feeding, or sheltering (Level B harassment).

Summary of Request

On November 21, 2017, WSDOT submitted a request to NMFS requesting an IHA for the possible harassment of small numbers of marine mammal species incidental to Seattle Multimodal Project at Colman Dock in Seattle, Washington, from August 1, 2018 to July 31, 2019. After receiving the revised project description and the revised IHA application, NMFS determined that the IHA application was adequate and

complete on April 4, 2018. NMFS is authorizing the take by Level A and Level B harassment of the following marine mammal species: Harbor seal (Phoca vitulina); northern elephant seal (Mirounga angustirostris); California sea lion (Zalophus californianus); Steller sea lion (*Eumetopias jubatus*); killer whale (Orcinus orca); long-beaked common dolphin (Delphinus delphis), bottlenose dolphin (Tursiops truncatus), gray whale (*Eschrichtius robustus*); humpback whale (Megaptera novaeangliae), minke whale (*Balaenoptera acutorostrata*); harbor porpoise (*Phocoena phocoena*); and Dall's porpoise (Phocoenoides dalli). Neither WSDOT nor NMFS expect mortality to result from this activity and, therefore, an IHA is appropriate.

NMFS previously issued an IHA to WSDOT for the first year of this project (FR 21579; July 7, 2017). WSDOT complied with all the requirements (*e.g.,* mitigation, monitoring, and reporting) of the previous IHA and information regarding their monitoring results may be found in the Estimated Take section.

Description of Specified Activity

Overview

The purpose of the Seattle Multimodal Project at Colman Dock is to preserve the transportation function of an aging, deteriorating and seismically deficient facility to continue providing safe and reliable service. The project will also address existing safety concerns related to conflicts between vehicles and pedestrian traffic and operational inefficiencies.

Dates and Duration

Due to NMFS and the U.S. Fish and Wildlife Service (USFWS) in-water work timing restrictions to protect Endangered Species Act (ESA)-listed salmonids, planned WSDOT in-water construction is limited each year to July 16 through February 15.

Specific Geographic Region

The Seattle Ferry Terminal at Colman Dock is located on the downtown Seattle waterfront, in King County, Washington. The terminal services vessels from the Bainbridge Island and Bremerton routes, and is the most heavily used terminal in the Washington State Ferry system. The Seattle terminal is located in Section 6, Township 24 North, Range 4 East, and is adjacent to Elliott Bay, tributary to Puget Sound (Figure 1–2 of the IHA application). Land use in the area is highly urban, and includes business, industrial, the Port of Seattle container loading facility, residential, the Pioneer Square Historic District and local parks.

Detailed Description of the Seattle Multimodal Project at Colman Dock: Year 2

The project will reconfigure the Colman Dock while maintaining approximately the same vehicle holding capacity as current conditions. The construction began in August 2017. In the 2017–2018 season, the construction activities were focused on the South Trestle, Terminal Building Foundation, and the temporary and permanent Passenger Offloading Facility. In the 2018–2019 season, WSDOT plans to continue the project by constructing the North Trestle, and Slip 3 bridge seat, overhead loading, wingwall, and inner dolphin. Both impact pile driving and vibratory pile driving and pile removal will be conducted. A total of 37 days are estimated for pile driving and 77 days for pile removal.

In-water construction methods include:

• Installing 119 36-inch (in) permanent steel piles with a vibratory hammer, and then proofed with an impact hammer for the last 5–10 feet; • Installing six 36-in and (8) 30-in steel piles with a vibratory hammer;

• Installing one 108-in steel pile with a vibratory hammer;

• Removing all existing 12-in steel, 14-in timber, 14-in H, 24-in steel and 30-in steel piles with a vibratory hammer;

• Installing and then removing eight 24-in Slip 3 Overhead loading temporary piles with a vibratory hammer; and

• Installing and then removing 147 24-in temporary template piles with a vibratory hammer.

A list of pile driving and removal activities is provided in Table 1.

TABLE 1—SUMMARY OF IN-WATER	PILE DRIVING AND	REMOVAL ACTIVITIES
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Method	Pile type	Pile size (inch)	Pile number	Piles/day	Minutes/pile	Duration (days)
Vibratory drive	Steel (temporary)	24	147	8	20	18
Vibratory drive		24	8	8	20	1
Vibratory drive	Steel	30	8	8	20	1
Vibratory drive	Steel	36	6	6	20	1
Vibratory drive *		36	119	8	20	15
Impact drive (proof) *	Steel	36	119	8	** 300	15
Vibratory drive	Steel	108	1	1	120	1
Subtotal						37
Vibratory remove	Timber	14	925	20	15	47
Vibratory remove	Steel	12	22	11	20	2
Vibratory remove		14	19	10	20	2
Vibratory remove	Steel	24	35	8	20	5
Vibratory remove	Steel (Slip 3)	24	8	8	20	1
Vibratory remove		24	147	8	20	19
Vibratory remove		30	1	1	20	1
Subtotal						77

* These two activities occur on the same day.

** Strikes.

Prescribed mitigation, monitoring, and reporting measures are described in detail later in this document (please see "Mitigation" and "Monitoring and Reporting").

Comments and Responses

A notice of NMFS' proposal to issue an IHA was published in the **Federal Register** on May 25, 2018 (83 FR 24279). During the 30-day public comment period, NMFS received comment letters from the Marine Mammal Commission (Commission) and the Center for Biological Diversity (CBD). Specific comments and responses are provided below.

Comment 1: The Commission recommends that NMFS reduce the shut-down zone from 60 meters (m) to 15 m for harbor seals during vibratory installation/removal and/or impact installation of 24-, 30, 36, and 108-in piles and increase the number of Level A harassment takes for harbor seals, if necessary.

Response: NMFS reviewed WSDOT's Seattle Year 1 draft monitoring report and worked with WSDOT on the number of harbor seals that could be potentially taken by Level A harassment and the practicability of implementing shutdown measures. Based on the assessment, NMFS learned that during the construction window between August 1, 2017, and February 15, 2018, for the Seattle Year 1 project, a total of 23 harbor seals were taken by Level A harassment while implementing a 50-m shutdown distance. For the Seattle Year 1 project, a total of 77 days had Level A harassment zones beyond the 50-m shutdown distance, with the authorized Level A harassment take of harbor seal of 364 animals. This shows that the actual Level A takes during WSDOT's Seattle Year 1 activity were much less than authorized.

For the current IHA, WSDOT

estimated that a total of 17 days would have Level A harassment zones beyond the newly required 60-m shutdown distance. Level A harassment distance for the 24-in vibratory pile driving and removal is less than the 60-m shutdown distance due to fewer piles being driven per day. Finally, there is no indication that the environment in the project area has changed that there are more harbor seals in the region that warrant to increase take numbers.

In conclusion, based on the planned construction activity level for the Seattle Year 2 project, harbor seal abundance in the project area, harbor seal Level A harassment takes from Seattle Year 1 monitoring report, and the feasibility of WSDOT to implement a 60-m shutdown measure for harbor seals, we think that requiring WSDOT to implement a 60-m shutdown zone for harbor seal with an authorized Level A harassment take of 187 animals is feasible for WSDOT and beneficial to the resources. Therefore, NMFS does not agree with the Commission's recommendation to reduce shutdown distance to 15-m while increasing harbor seal Level A harassment takes.

Comment 2: The Commission recommends that NMFS more thoroughly assess the proposed shutdown zones that are to be implemented and the associated numbers of Level A harassment takes requested for each proposed incidental take authorization prior to publication in the **Federal Register**.

Response: NMFS agrees with the Commission's recommendation, and agrees that the proposed shutdown zones that are to be implemented and the associated numbers of Level A harassment hakes for this IHA as well as other incidental take authorizations should be thoroughly assessed at early review team meetings prior to drafting the proposed IHAs.

Comment 3: The Commission commented that the method NMFS used to estimate the numbers of takes during the proposed activities, which summed fractions of takes for each species across project days, does not account for and negates the intent of NMFS' 24-hour reset policy. The Commission also recommends that NMFS develop and share guidance on this issue.

Response: NMFS has provided the guidance to the Commission as recommended.

Comment 4: The Commission requested clarification of certain issues associated with NMFS's notice that onevear renewals could be issued in certain limited circumstances and expressed concern that the process would bypass the public notice and comment requirements. The Commission also suggested that NMFS should discuss the possibility of renewals through a more general route, such as a rulemaking, instead of notice in a specific authorization. The Commission further recommended that if NMFS did not pursue a more general route, that the agency provide the Commission and the public with a legal analysis supporting our conclusion that this process is consistent with the requirements of section 101(a)(5)(D) of the MMPA.

Response: The process of issuing a renewal IHA does not bypass the public notice and comment requirements of the MMPA. The notice of the proposed IHA expressly notifies the public that under certain, limited conditions an applicant could seek a renewal IHA for an additional year. The notice describes the conditions under which such a renewal

request could be considered and expressly seeks public comment in the event such a renewal is sought. Additional reference to this solicitation of public comment has recently been added at the beginning of FR notices that consider renewals. NMFS appreciates the streamlining achieved by the use of abbreviated FR notices and intends to continue using them for proposed IHAs that include minor changes from previously issued IHAs, but which do not satisfy the renewal requirements. However, we believe our proposed method for issuing renewals meets statutory requirements and maximizes efficiency. Importantly, such renewals would be limited to where the activities are identical or nearly identical to those analyzed in the proposed IHA, monitoring does not indicate impacts that were not previously analyzed and authorized, and the mitigation and monitoring requirements remain the same, all of which allow the public to comment on the appropriateness and effects of a renewal at the same time the public provides comments on the initial IHA. NMFS has, however, modified the language for future proposed IHAs to clarify that all IHAs, including renewal IHAs, are valid for no more than one year and that the agency would consider only one renewal for a project at this time. In addition, notice of issuance or denial of a renewal IHA would be published in the Federal Register, as are all IHAs. Last, NMFS will publish on our website a description of the renewal process before any renewal is issued utilizing the new process.

Comment 5: The CBD recommends that the authorization include mitigation measures on operation of the ferries that will result from construction activities. Specifically, the CBD recommends that NMFS find ways to support and accelerate transition of the Washington State ferry system to quieter designs and technologies.

Response: While NMFS shares the concerns with CBD regarding the elevated underwater noise from ferry operations and general shipping activities in the Puget Sound area, the specific recommendation raised by the CBD is irrelevant in evaluating the potential impacts from ferry terminal construction on marine mammals. For the issuance of the IHA to take marine mammals incidental to WSDOT's Seattle Multimodal Project at Colman Dock, we analyzed the impacts from construction related activities that may affect marine mammals, which are mostly from underwater noise generated during in-water pile driving and pile removal. Please see Potential Effects of Specified Activities on Marine Mammals and their Habitat section below for detailed analysis.

Description of Marine Mammals in the Area of Specified Activities

Sections 3 and 4 of the application summarize available information regarding status and trends, distribution and habitat preferences, and behavior and life history, of the potentially affected species. Additional information regarding population trends and threats may be found in NMFS's Stock Assessment Reports (SAR; https:// www.fisheries.noaa.gov/national/ marine-mammal-protection/marinemammal-stock-assessment-reportsregion#reports).

Table 2 lists all species with expected potential for occurrence in the lower Puget Sound area and summarizes information related to the population or stock, including regulatory status under the MMPA and ESA and potential biological removal (PBR), where known. For taxonomy, we follow Committee on Taxonomy (2017). PBR is defined by the MMPA as the maximum number of animals, not including natural mortalities, that may be removed from a marine mammal stock while allowing that stock to reach or maintain its optimum sustainable population (as described in NMFS's SARs). While no mortality is anticipated or authorized here, PBR and annual serious injury and mortality from anthropogenic sources are included here as gross indicators of the status of the species and other threats.

Marine mammal abundance estimates presented in this document represent the total number of individuals that make up a given stock or the total number estimated within a particular study or survey area. NMFS's stock abundance estimates for most species represent the total estimate of individuals within the geographic area, if known, that comprises that stock. For some species, this geographic area may extend beyond U.S. waters. All managed stocks in this region are assessed in NMFS's 2017 U.S. Pacific Marine Mammal SARs (Carretta et al., 2018). The 2017 SAR is available online at: https://www.fisheries.noaa.gov/ national/marine-mammal-protection/ marine-mammal-stock-assessmentreports-region#reports.

TABLE 2—MARINE MAMMALS WITH POTENTIAL PRESENCE WITHIN THE PROPOSED PROJECT AREA

Common name	Scientific name	Stock	ESA/ MMPA status; strategic (Y/N) ¹	Stock abun- dance ²	PBR	Annual M/SI ³
		a—Superfamily Mysticeti (baleen whal / Eschrichtiidae	es)			
Gray whale	Eschrichtius robustus	Eastern North Pacific	-; N	20,990	624	132
	Family	Balaenopteridae				
Humpback whale Minke whale	Megaptera novaneagliae Balaenoptera acutorostrata	California/Oregon/Washington California/Oregon/Washington	E/D; Y -; N	1,918 636	11.0 3.5	>6.5 >1.3
	Fami	ly Delphinidae				
Killer whale Long-beaked common dolphin Bottlenose dolphin	ng-beaked common dolphin Delphinus capensis		E/D; Y -; N -; N -; N	83 243 101,305 1,924	0.14 2.4 657 11	0 0 >35.4 >1.6
	Family Pho	coenidae (porpoises)				
Harbor porpoise Dall's porpoise				11,233 25,750	66 172	7.2 0.3
		—Superfamily Pinnipedia (eared seals and sea lions)				
California sea lion Steller sea lion	nia sea lion <i>Zalophus californianus</i> U.S		-; N -; N	296,750 41,638	9,200 2,498	389 108
	Family Pho	cidae (earless seals)				
Harbor seal Northern elephant seal	Phoca vitulina Mirounga angustirostris	Washington northern inland waters California breeding	-; N -; N	4 11,036 179,000	1,641 4,882	43 8.8

¹Endangered 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 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-assessmentreports-region#reports.

³These values, found in NMFS's SARs, represent annual levels of human-caused mortality plus serious injury 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. ⁴Harbor seal estimate is based on data that are greater than 8 years old, but this is the best available information for use here (Jeffries *et al.*, 2003; Carretta *et al.*,

2017).

All species that could potentially occur in the proposed construction areas are included in Table 2. However, the temporal and/or spatial occurrence of humpback whale and Southern Resident killer whale (SRKW) and the implementation of monitoring and mitigation measures are such that take is not expected to occur, and they are not discussed further beyond the explanation provided here. The occurrence of humpback whale in the WSDOT's Seattle Multimodal Project area is rare, and WSDOT's 2017 monitoring report showed no sighting of this species. Although the SRKW could occur in the vicinity of the project area, WSDOT is required to implement strict monitoring and mitigation measures with assistance from local marine mammal researchers and observers. Thus, the take of this marine mammal stock can be avoided (see details in Mitigation section).

In addition, the sea otter may be found in Puget Sound area. However, this species is managed by the USFWS and is not considered further in this document.

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 (2016) described generalized hearing ranges for these marine mammal hearing groups. Generalized hearing ranges were chosen based on the approximately 65 decibel (dB) threshold from the normalized composite audiograms, with the exception for lower limits for lowfrequency 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 hertz (Hz) and 35 kilohertz (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;

• 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).

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For more detail concerning these groups and associated frequency ranges, please see NMFS (2016) for a review of available information. Eleven marine mammal species (7 cetacean and 4 pinniped (2 otariid and 2 phocid) species) have the reasonable potential to co-occur with the proposed construction activities. Please refer to Table 2. Of the cetacean species that may be present, one species is classified as lowfrequency cetaceans (*i.e.*, gray whale), two are classified as high-frequency cetaceans (i.e., harbor porpoise and Dall's porpoise), and the rest of them mid-frequency cetaceans.

Potential Effects of Specified Activities on Marine Mammals and Their Habitat

This section includes a summary and discussion of the ways that components of the specified activity may impact marine mammals and their habitat. The "Estimated Take" section later in this document will include a quantitative analysis of the number of individuals that are expected to be taken by this activity. The "Negligible Impact Analysis and Determination" section will consider the content of this section, the "Estimated Take" section, and the Mitigation section, to draw conclusions regarding the likely impacts of these activities on the reproductive success or survivorship of individuals and how those impacts on individuals are likely to impact marine mammal species or stocks.

Potential impacts to marine mammals from the Seattle Multimodal Colman Dock project are from noise generated during in-water pile driving and pile removal activities.

Acoustic Effects

Here, we first provide background information on marine mammal hearing before discussing the potential effects of the use of active acoustic sources on marine mammals.

The WSDOT's Seattle Multimodal Project using in-water pile driving and pile removal could adversely affect marine mammal species and stocks by exposing them to elevated noise levels in the vicinity of the activity area.

Exposure to high intensity sound for a sufficient duration may result in auditory effects such as a noise-induced threshold shift (TS)—an increase in the auditory threshold after exposure to noise (Finneran et al., 2005). Factors that influence the amount of TS include the amplitude, duration, frequency content, temporal pattern, and energy distribution of noise exposure. The magnitude of hearing TS normally decreases over time following cessation of the noise exposure. The amount of TS just after exposure is the initial TS. If the TS eventually returns to zero (i.e., the threshold returns to the preexposure value), it is a temporary threshold shift (TTS) (Southall et al., 2007).

Threshold Shift (noise-induced loss of *hearing*)—When animals exhibit reduced hearing sensitivity (*i.e.*, sounds must be louder for an animal to detect them) following exposure to an intense sound or sound for long duration, it is referred to as a noise-induced TS. An animal can experience TTS or permanent threshold shift (PTS). TTS can last from minutes or hours to days (*i.e.*, there is complete recovery), can occur in specific frequency ranges (i.e., an animal might only have a temporary loss of hearing sensitivity between the frequencies of 1 and 10 kHz), and can be of varying amounts (for example, an animal's hearing sensitivity might be reduced initially by only 6 dB or reduced by 30 dB). PTS is permanent, but some recovery is possible. PTS can also occur in a specific frequency range and amount as mentioned above for TTS.

For marine mammals, published data are limited to the captive bottlenose dolphin, beluga, harbor porpoise, and Yangtze finless porpoise (Finneran, 2015). For pinnipeds in water, data are limited to measurements of TTS in harbor seals, an elephant seal, and California sea lions (Kastak *et al.*, 1999, 2005; Kastelein *et al.*, 2012b).

Lucke et al. (2009) found a TS of a harbor porpoise after exposing it to airgun noise with a received sound pressure level (SPL) at 200.2 dB (peakto-peak) re: 1 micropascal (µPa), which corresponds to a sound exposure level of 164.5 dB re: 1 µPa² s after integrating exposure. Because the airgun noise is a broadband impulse, one cannot directly determine the equivalent of root mean square (rms) SPL from the reported peak-to-peak SPLs. However, applying a conservative conversion factor of 16 dB for broadband signals from seismic surveys (McCauley, et al., 2000) to correct for the difference between peakto-peak levels reported in Lucke *et al.* (2009) and rms SPLs, the rms SPL for TTS would be approximately 184 dB re: 1 µPa, and the received levels associated with PTS (Level A harassment) would be higher. Therefore, based on these studies, NMFS recognizes that TTS of harbor porpoises is lower than other cetacean species empirically tested (Finneran & Schlundt, 2010; Finneran et al., 2002; Kastelein and Jennings, 2012).

Marine mammal hearing plays a critical role in communication with conspecifics, and 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 occurs 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 time when communication is critical for successful mother/calf interactions could have more serious impacts. Also, depending on the degree and frequency range, the effects of PTS on an animal could range in severity, although it is considered generally more serious 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 one can infer that strategies exist for coping with this condition to some degree, though likely not without cost.

In addition, chronic exposure to excessive, though not high-intensity, noise could cause masking at particular frequencies for marine mammals, which utilize sound for vital biological functions (Clark et al., 2009). Acoustic masking is when other noises such as from human sources interfere with animal detection of acoustic signals such as communication calls, echolocation sounds, and environmental sounds important to marine mammals. Therefore, under certain circumstances, marine mammals whose acoustical sensors or environment are being severely masked could also be impaired from maximizing their performance fitness in survival and reproduction.

Masking occurs at the frequency band that the animals utilize. Therefore, since noise generated from vibratory pile driving is mostly concentrated at low frequency ranges, it may have less effect on high frequency echolocation sounds by odontocetes (toothed whales). However, lower frequency man-made noises are more likely to affect detection of communication calls and other potentially important natural sounds such as surf and prey noise. It may also affect communication signals when they occur near the noise band and thus reduce the communication space of animals (e.g., Clark et al., 2009) and cause increased stress levels (e.g., Foote et al., 2004; Holt et al., 2009).

Unlike TS, masking, which can occur over large temporal and spatial scales, can potentially affect the species at population, community, or even ecosystem levels, as well as individual levels. Masking affects both senders and receivers of the signals and could have long-term chronic effects on marine mammal species and populations. Recent science suggests that 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, and most of these increases are from distant shipping (Hildebrand, 2009). For WSDOT's Seattle Multimodal at Colman Dock Project, noises from vibratory pile driving and pile removal contribute to the elevated ambient noise levels in the project area, thus increasing potential for or severity of masking. Baseline ambient noise levels in the vicinity of project area are high due to ongoing shipping, construction and other activities in the Puget Sound.

Finally, marine mammals' exposure to certain sounds could lead to behavioral

disturbance (Richardson *et al.*, 1995), such as changing durations of surfacing and dives, number of blows per surfacing, or moving direction and/or speed; reduced/increased vocal activities; changing/cessation of certain behavioral activities (such as socializing or feeding); visible startle response or aggressive behavior (such as tail/fluke slapping or jaw clapping); avoidance of areas where noise sources are located; and/or flight responses (*e.g.*, pinnipeds flushing into water from haulouts or rookeries).

The onset of behavioral disturbance from anthropogenic noise depends on both external factors (characteristics of noise sources and their paths) and the receiving animals (hearing, motivation, experience, demography) and is also difficult to predict (Southall et al., 2007). Currently NMFS uses a received level of 160 dB re 1 µPa (rms) to predict the onset of behavioral harassment from impulse noises (such as impact pile driving), and 120 dB re 1 µPa (rms) for continuous noises (such as vibratory pile driving). For the WSDOT's Seattle Multimodal Project at Colman Ferry Terminal, both 120-dB and 160-dB levels are considered for effects analysis because WSDOT plans to use both impact pile driving and vibratory pile driving and pile removal.

The biological significance of many of these behavioral disturbances is difficult to predict, especially if the detected disturbances appear minor. However, the consequences of behavioral modification could be biologically significant if the change affects growth, survival, and/or reproduction, which depends on the severity, duration, and context of the effects.

Potential Effects on Marine Mammal Habitat

The primary potential impacts to marine mammal habitat are associated with elevated sound levels produced by vibratory pile removal and pile driving in the area. However, other potential impacts to the surrounding habitat from physical disturbance are also possible.

With regard to fish as a prey source for cetaceans and pinnipeds, fish are known to hear and react to sounds and to use sound to communicate (Tavolga *et al.*, 1981) and possibly avoid predators (Wilson and Dill, 2002). Experiments have shown that fish can sense both the strength and direction of sound (Hawkins, 1981). Primary factors determining whether a fish can sense a sound signal, and potentially react to it, are the frequency of the signal and the strength of the signal in relation to the natural background noise level.

The level of sound at which a fish will react or alter its behavior is usually well above the detection level. Fish have been found to react to sounds when the sound level increased to about 20 dB above the detection level of 120 dB (Ona, 1988); however, the response threshold can depend on the time of year and the fish's physiological condition (Engas et al., 1993). In general, fish react more strongly to pulses of sound (such as noise from impact pile driving) rather than continuous signals (such as noise from vibratory pile driving) (Blaxter et al., 1981), and a quicker alarm response is elicited when the sound signal intensity rises rapidly compared to sound rising more slowly to the same level.

During the coastal construction, only a small fraction of the available habitat would be ensonified at any given time. Disturbance to fish species would be short-term and fish would return to their pre-disturbance behavior once the pile driving activity ceases. Thus, the proposed construction would have little, if any, impact on marine mammals' prey availability in the area where construction work is planned.

Finally, the time of the proposed construction activity would avoid the spawning season of the ESA-listed salmonid species.

Estimated Take

This section provides an estimate of the number of incidental takes authorized through this IHA, which will inform both NMFS' consideration of whether the number of takes is "small" and the negligible impact determination.

Harassment is the only type of take expected to result from these activities. Except with respect to certain activities not pertinent here, section 3(18) of the MMPA defines "harassment" as any act of pursuit, torment, or annoyance which (i) has the potential to injure a marine mammal or marine mammal stock in the wild (Level A harassment); or (ii) has the potential to disturb a marine mammal or marine mammal stock in the wild by causing disruption of behavioral patterns, including, but not limited to, migration, breathing, nursing, breeding, feeding, or sheltering (Level B harassment).

Authorized takes would be by Level A and Level B harassment.

As described previously, no mortality is anticipated or authorized for this activity. Below we describe how the take is estimated.

Described in the most basic way, we estimate take by considering: (1) Acoustic thresholds above which NMFS believes the best available science indicates marine mammals will be behaviorally harassed or incur some degree of permanent hearing impairment; (2) the area or volume of water that will be ensonified above these levels in a day; (3) the density or occurrence of marine mammals within these ensonified areas; and, (4) and the number of days of activities. Below, we describe these components in more detail and present the take estimate.

Acoustic Thresholds

Using the best available science, NMFS has developed acoustic thresholds that identify the received level of underwater sound above which exposed marine mammals would be reasonably expected to be behaviorally harassed (equated to Level B harassment) or to incur PTS of some degree (equated to Level A harassment).

Level B Harassment for non-explosive sources—Though significantly driven by received level, the onset of behavioral disturbance from anthropogenic noise exposure is also informed to varying degrees by other factors related to the source (*e.g.*, frequency, predictability,

duty cycle), the environment (e.g., bathymetry), and the receiving animals (hearing, motivation, experience, demography, behavioral context) and can be difficult to predict (Southall et al., 2007, Ellison et al., 2012). Based on what the available science indicates and the practical need to use a threshold based on a factor that is both predictable and measurable for most activities, NMFS uses a generalized acoustic threshold based on received level to estimate the onset of behavioral harassment. NMFS predicts that marine mammals are likely to be behaviorally harassed in a manner we consider Level B harassment when exposed to underwater anthropogenic noise above received levels of 120 dB re 1 µPa (rms) for continuous (e.g. vibratory piledriving, drilling) and above 160 dB re 1 µPa (rms) for non-explosive impulsive (e.g., seismic airguns) sources.

Applicant's proposed activity includes the generation of impulse (impact pile driving) and non-impulse (vibratory pile driving and removal) sources; and, therefore, both 160- and 120-dB re 1 μ Pa (rms) are used.

Level A harassment for non-explosive sources-NMFS' Technical Guidance for Assessing the Effects of Anthropogenic Sound on Marine Mammal Hearing (Technical Guidance, 2016) identifies dual criteria to assess auditory injury (Level A harassment) to five different marine mammal groups (based on hearing sensitivity) as a result of exposure to noise from two different types of sources (impulsive or nonimpulsive). Applicant's proposed activity would generate and nonimpulsive (vibratory pile driving and pile removal) noises. These thresholds were developed by compiling and synthesizing the best available science and soliciting input multiple times from both the public and peer reviewers to inform the final product and are provided in the table below. The references, analysis, and methodology used in the development of the thresholds are described in NMFS 2016 Technical Guidance, which may be accessed at: https://www.fisheries.noaa. gov/national/marine-mammalprotection/marine-mammal-acoustictechnical-guidance.

TABLE 3—CURRENT ACOUSTIC EXPOSURE CRITERIA FOR NON-EXPLOSIVE SOUND UNDERWATER

	PTS onset	thresholds	Behavioral thresholds		
Hearing group	Impulsive	Non-impulsive	Impulsive	Non-impulsive	
Low-Frequency (LF) Cetaceans	L _{pk,flat} : 219 dB L _{E.L.E.24b} : 183 dB	L _{E,LF,24h} : 199 dB.			
Mid-Frequency (MF) Cetaceans	L _{E,LF,24h} : 185 dB L _{pk,flat} : 230 dB L _{E.ME,24h} : 185 dB	L _{E,MF,24h} : 198 dB.			
High-Frequency (HF) Cetaceans	L _{pk,flat} : 202 dB L _{E,HE,24b} : 155 dB	L _{E,HF,24h} : 173 dВ	L _{rms,flat} : 160 dB	L _{rms,flat} : 120 dB	
Phocid Pinnipeds (PW) (Under- water).	L _{pk,flat} : 218 dB L _{E,PW,24b} : 185 dB	L _{E,PW,24h} : 201 dB.			
Otariid Pinnipeds (OW) (Underwater)	L _{pk,flat} : 232 dB	L _{E,OW,24h} : 219 dB.			

* Dual metric acoustic thresholds for impulsive sounds: Use whichever results in the largest isopleth for calculating PTS onset. If a non-impulsive sound has the potential of exceeding the peak sound pressure level thresholds associated with impulsive sounds, these thresholds should also be considered.

Note: Peak sound pressure (Lpk) has a reference value of 1 μ Pa, and cumulative sound exposure level (LE) has a reference value of 1 μ Pa2s. In this Table, thresholds are abbreviated to reflect American National Standards Institute standards (ANSI 2013). However, peak sound pressure is defined by ANSI as incorporating frequency weighting, which is not the intent for this Technical Guidance. Hence, the subscript "flat" is being included to indicate peak sound pressure should be flat weighted or unweighted within the generalized hearing range. The subscript associated with cumulative sound exposure level thresholds indicates the designated marine mammal auditory weighting function (LF, MF, and HF cetaceans, and PW and OW pinnipeds) and that the recommended accumulation period is 24 hours. The cumulative sound exposure level thresholds could be exceeded in a multitude of ways (*i.e.*, varying exposure levels and durations, duty cycle). When possible, it is valuable for action proponents to indicate the conditions under which these acoustic thresholds will be exceeded.

Ensonified Area

Here, we describe operational and environmental parameters of the activity that will feed into identifying the area ensonified above the acoustic thresholds.

Source Levels

The source level for vibratory pile driving and removal of the 24- and 30in steel pile is based on vibratory pile driving of the 30-in steel pile at Port Townsend (WSDOT, 2010). The unweighted SPLrms source level at 10 m from the pile is 174 dB re 1 re 1 μ Pa.

The source level for vibratory pile driving of the 36-in steel piles is based on vibratory test pile driving of 36-in steel piles at Port Townsend in 2010 (Laughlin 2011). Recordings of vibratory pile driving were made at a distance of 10 m from the pile. The results show that the unweighted SPL_{rms} for vibratory pile driving of 36-in steel pile was 177 dB re 1 μ Pa.

The source level for vibratory pile driving of the 108-in steel pile is based on measurements of 72-in steel piles vibratory driving conducted by CALTRANS. The unweighted SPL_{rms} source level ranged between 170 and 180 dB re 1 μ Pa at 10 m from the pile (CALTRANS 2015). The value of 180 dB is chosen to be more conservative.

The source level for impact pile driving of the 36-in steel pile is based on impact test pile driving for the 36-in steel pile at Mukilteo in November 2006 (WSDOT 2007). Recordings of the impact pile driving that were made at a distance of 10 m from the pile were analyzed using Matlab. The results show that the unweighted source levels are 178 dB re 1 μ Pa²-s for SEL_{ss} and 193 dB re 1 μ Pa for SPL_{rms}. The peak source level for impact pile driving of the 36-in steel pile is based on measurement conducted by CALTRANS for the same

type and dimension of the pile, which is 210 dB_{pk} re 1 μ Pa.

The source level for vibratory pile removal of 14-in timber pile is based measurements conducted at the Port Townsend Ferry Terminal during vibratory removal of a 12-in timber pile by WSDOT (Laughlin 2011). The recorded source level is 152 dB_{rms} re 1 μ Pa at 16 m from the pile, with an adjusted source level of 155 $dB_{\rm rms}$ re 1 μPa at 10 m.

The source levels for vibratory pile removal of 12-in steel and 14-in steel H piles are based on vibratory pile driving of 12-in steel pipe pile measured by CALTRANS. The unweighted source level is 155 dB_{rms} re 1 μ Pa at 10 m.

A summary of source levels is presented in Table 4.

TABLE 4—SUMMARY OF IN-WATER PILE DRIVING SOURCE LEVELS

[at 10 m from source]

Method	Pile type/size (inch)	SEL, dB re 1 µPa²-s	SPL _{rms} , dB re 1 μPa	SPL _{pk} , dB re 1 μPa
Vibratory driving/removal Vibratory driving/removal Vibratory driving Impact pile driving (proof) Vibratory driving Vibratory removal Vibratory removal Vibratory removal	Steel, 30-in Steel, 36-in Steel, 36-in Steel, 108-in Timber, 14-in Steel, 12-in	174 174 177 178 180 155 155 155	174 174 177 193 180 155 155 155	210

These source levels are used to compute the Level A harassment zones and to estimate the Level B harassment zones. For Level A harassment zones, since the peak source levels for both pile driving are below the injury thresholds, cumulative SEL were used to do the calculations using the NMFS acoustic guidance (NMFS 2016).

Estimating Harassment Zones

The Level B harassment ensonified areas for vibratory removal of the 14-in timber, 12-in steel, 14-in steel H, and 18-in concrete piles are based on the above source level of 155 dB_{rms} re 1μ Pa at 10 m, applying practical spreading

loss of 15*log(R) for transmission loss calculation. The derived distance to the 120-dB Level B zone is 2,54 m.

For Level B harassment ensonified areas for vibratory pile driving and removal of the 24-in, 30-in, 36-in, and 108-in steel piles, the distance is based on measurements conducted during the year 1 Seattle multimodal project at Colman. The result showed that pile driving noise of two 36-in steel piles being concurrently driven was no longer detectable at a range of 5.4 miles (8.69 km) (WSDOT 2017). Therefore, the distance of 8,690 m is selected as the Level B harassment distance for vibratory pile driving and removal of the 24-in, 30-in, 36-in and 108-in steel piles.

The Level B harassment ensonified area for impact pile driving of the 36in steel piles is based on the above source level of 193 dB_{rms} re 1 μ Pa at 10 m, applying practical spreading loss of 15*log(R) for transmission loss calculation. The derived distance to the 160-dB Level B zone is 1,585 m.

For Level A harassment, calculation is based on pile driving duration of each pile and the number of piles installed or removed per day, using NMFS optional spreadsheet.

TABLE 5—MODELED DISTANCES AND AREAS TO HARASSMENT ZONES

Pile driving activity	SL (10m)	Level A distance (m) Level A area (km ²)					Level B distance (m)
	SEL	LF	MF	HF			Level B area (km ²)
	ÖLL	Cetacean	Cetacean	Cetacean	Phocid	Otariid	All marine mammals
Vibratory drive/removal, 24" & 30" steel							
piles, 8 piles/day, 20 min/pile	174	96.7 0.03	8.6 0.00	143.0 0.00	58.8 0.00	4.1 0.00	8,690 74.29
Vibratory removal 30" steel pile, 1 pile/							
day, 20 min/pile	174	24.2 0.00	2.1 0.00	35.7 0.00	14.7 0.00	1.0 0.00	8,960 74.29
Vibratory drive 36" steel pile, 6 piles/day,							_
20 min/pile	177	126.4 0.05	11.2 0.00	186.9 0.11	76.8 0.02	5.4 0.00	8,960 74.29
Vibratory drive 36" steel pile, 8 piles/day,							
20 min/pile	177	153.3 0.07	13.6 0.00	226.6 0.16	93.2 0.03	6.5 0.00	8,960 74.29
Impact drive (proof) 36" steel pile, 8							
piles/day, 300 strikes/pile	178	830.9 2.17	29.6 0.00	989.7 3.08	444.7 0.62	32.4 0.00	1,585 7.89
Vibratory drive 108" steel pile, 1 pile/day,							
120 min/pile	180	200.3 0.13	17.8 0.00	296.2 0.28	121.8 0.05	8.5 0.00	8,690 74.29

	SL (10m)		Level B distance (m)				
Pile driving activity	SEL						Level B area (km ²)
	SEL	LF MF HF Phocid Cetacean Cetacean	Otariid	All marine mammals			
Vibratory remove 14" timber pile, 20							
piles/day, 15 min/pile	155	8.0 0.00	0.7 0.00	11.8 0.00	4.8 0.00	0.3 0.00	2,154 14.57
Vibratory remove 12" steel pile, 11 piles/							
day, 20 min/pile	155	6.5 0.00	0.6 0.00	9.6 0.00	3.9 0.00	0.3 0.00	2,154 14.57
Vibratory remove 14" steel H pile, 10		0.00	0.00		0.00	0.00	
piles/day, 20 min/pile	155	6.1 0.00	0.5 0.00	9.0 0.00	3.7 0.00	0.3 0.00	2,154 14.57

TABLE 5—MODELED DISTANCES AND AREAS TO HARASSMENT ZONES—Continued

Distances of ensonified area for different pile driving/removal activities for different marine mammal hearing groups is presented in Table 5.

Marine Mammal Occurrence

In this section we provide the information about the presence, density, or group dynamics of marine mammals that will inform the take calculations.

All marine mammal density data except harbor seal, California sea lion, harbor porpoise, bottlenose dolphin, and long-beaked common dolphin are from the U.S. Navy Marine Species Density Report. For harbor seal and California sea lion, because WSDOT has local distribution data based on recent survey in the area, local animal abundance are used to calculate the take numbers. Specifically, the occurrence of these two species are based on local seal abundance information off the Seattle area from Year One (2017/18) of WSDOT's Seattle Colman Project.

For bottlenose dolphin and longbeaked common dolphin, no density estimate is available. Therefore, take numbers for these two species are based on prior anecdotal observations and strandings in the action area (Shuster *et al.*, 2015; Huggins *et al.*, 2016).

Harbor porpoise density is based on a recent study by Smultea *et al.* (2017) for the Seattle area near the Colman Dock.

A summary of marine mammal density, days and Level A and Level B harassment areas from different pile driving and removal activities is provided in Table 6.

TABLE 6—MARINE MAMMAL DENSITY AND LOCAL OCCURRENCE IN THE WSDOT PROJECT AREA

Species	Density (#/km ²) or Animals/day
Gray whale	0.00051/km ² . 0.0003/km ² . 0.002/km ² . NA. NA. 0.54/km ² . 0.048/km ² . 14 animals/day. 0.04/km ² . 11 animals/day. 0.0001/km ² .

Take Calculation and Estimation

Here we describe how the information provided above is brought together to produce a quantitative take estimate.

In general, marine mammal takes were calculated as: Take = ensonified area \times average animal abundance in the area \times pile driving days. All Level A harassment takes were further adjusted by subtracting animals that would occur within the Level A harassment zone (except for harbor seal where a 60-m shutdown zone would be implemented), where pile driving activities that could cause Level A harassment for all marine mammals, except harbor seal, harbor porpoise, and Dall's porpoise, would be suspended when an animal is observed to approach such a zone. Further, the number of Level B harassment takes were adjusted to exclude those already counted for Level A harassment takes.

The harbor seal take estimate is based on local seal abundance information off the Seattle area from Year One (2017/18) of WSDOT's Seattle Colman Project. During 99 days of marine mammal visual monitoring, 813 harbor seals were observed, an average of 8.212 animals/ day, with a one-day high of 43 observations on 10/24/17 (WSDOT 2018b). By adjusting the averaged observation of harbor seals to 11 animals/day as a conservative estimate to account for possible missed observation, and based on a total of 114 pile driving days for the WSDOT Seattle

Colman Dock project, it is estimated that up to 1,254 harbor seals could be exposed to noise levels associated with "take." Since 17 days would involve vibratory/impact pile driving of 36-in steel piles (16 days) and vibratory driving of and 108-in steel pile (1 day) with Level A harassment zones beyond shutdown zones (445 m and 122 m, respectively, vs. the 60-m shutdown zone), we consider that 187 harbor seals exposed during these 17 days would experience Level A harassment. The difference between the 1,254 total takes and the 187 Level A harassment takes makes up the harbor seal Level B harassment takes, which is 1,067 animals.

The California sea lion take estimate is also based on local sea lion abundance information from the Seattle Colman Project). During 99 days of marine mammal visual monitoring 1.047 California sea lions were observed, an average of 11 animals/day, with a one-day high of 48 observations on 1/8/2018. (WSDOT 2018b). By adjusting the averaged observation of California sea lions to 14 animals/day as a conservative estimate to account for possible missed observation, and based on a total of 114 pile driving days for the WSDOT Seattle Colman Dock project, it is estimated that up to 1,596 California sea lions could be exposed to noise levels associated with "take". Although the Level A harassment zones of otariids are all very small (<33 m, Table 5) and WSDOT will implement strict shutdown measures if a sea lion is observed to be moving towards the Level A zone, it is still possible that in rare occasions an animal could enter the Level A zone undetected. We therefore, estimate that one California sea lion could be taken by Level A harassment on each of the 16 days that involve vibratory/impact pile driving of 36-in steel piles when the Level A zone is 32 m. Thus a total of 16 Level A harassment of California sea lion is estimated. The difference between the 1,596 total takes and the 16 Level A takes makes up the California sea lions Level B takes, which is 1,580 animals. The same reasoning is used for estimating Steller sea lion Level A takes, which results in an estimated 16 Level A takes and 215 Level B takes.

The common bottlenose dolphin estimate is based on sightings data from Cascadia Research Collective. Between September 2017 and March 2018, a group of up to five to six individuals was sighted in South Puget Sound (CRC 2017/18). It is assumed that this group is still present in the area.

Given how rare common bottlenose dolphins are in the area, it is unlikely they would be present on a daily basis. Instead it is assumed that they may be present in the Level B harassment zone once a month during the in-water work window (7 months), and adjusted for potential group size of 5–10 individuals with an average of 7 animals per group.

The long-beaked common dolphin estimate is based on sightings data from Cascadia Research Collective. Four to six Long-beaked Common dolphins have remained in Puget Sound since June 2016, and four animals with distinct markings have been seen multiple times and in every season of the year as of October 2017 (CRC 2017).

Given how rare long-beaked common dolphins are in the area, it is unlikely they would be present on a daily basis. Instead it is assumed that they may be present in the Level B harassment zone once a month during the in-water work window (7 months), and adjusted for potential group size of 5–10 individuals with an average of 7 animals per group.

For harbor porpoise, density based Level A harassment take calculation yields a total of 28 animals. However, due to the large Level A harassment distance during the 36-in pile driving (990 m) during 16 days and the 108-in

TABLE 7—ESTIMATED TAKE NUMBERS

pile driving (296 m) during one day, its Level A harassment take is readjusted to account for a typical animal group size of 3 multiplied by these 17 days with large Level A harassment zones. Therefore, we estimate that a total of 51 harbor porpoise could be taken by Level A harassment.

For Dall's porpoise, due to its relatively uncommon occurrence in comparison to harbor porpoise, the estimated Level A harassment take is scaled down by $\frac{1}{3}$ that of harbor porpoise, yielding 17 Level A harassment takes.

For calculated take number less than 15, such as northern elephant seals, transient killer whales, gray whales, and minke whales, takes numbers were adjusted to account for group encounter and the likelihood of encountering. Specifically, for northern elephant seal, take of 15 animals is estimated based on the likelihood of encountering this species during the project period. For transient killer whale, takes of 30 animals is estimated based on the group size and the likelihood of encountering in the area. For gray whale and minke whale, takes of 30 and 8 animals each are estimated, respectively, based on the likelihood of encountering.

For SRKWs, WSDOT will implement strict monitoring and mitigation measures and to suspend pile driving activities when such animal is detected in the vicinity of the action area (see Mitigation section below).

A summary of estimated takes based on the above analysis is listed in Table 7.

Species	Estimated level A take	Estimated level B take	Estimated total take	Abundance	Percentage
Pacific harbor seal	187	1,067	1,254	11,036	11
Northern elephant seal	0	15	15	81,368	0
California sea lion	16	1,580	1,596	296,750	1
Steller sea lion	16	215	231	41,638	1
Killer whale, transient	0	30	30	243	12
Killer whale, Southern Resident	0	0	0	83	0
Gray whale	0	30	30	20,990	0
Humpback whale	0	0	0	1,918	0
Minke whale	0	8	8	202	2
Harbor porpoise	51	3,069	3,120	11,233	*28
Dall's porpoise	17	260	277	25,750	1
Long-beaked common dolphin	0	49	49	101,305	0
Bottlenose dolphin	0	49	49	1,921	3

* The percentage of individual harbor porpoises take is estimated to be notably smaller than this, as described in the "Small Numbers" section.

Mitigation

In order to issue an IHA under section 101(a)(5)(D) of the MMPA, NMFS must set forth the permissible methods of taking pursuant to such activity, and other means of effecting the least practicable impact on such species or stock and its habitat, paying particular attention to rookeries, mating grounds, and areas of similar significance, and on the availability of such species or stock for taking for certain subsistence uses (latter not applicable for this action). NMFS regulations require applicants for incidental take authorizations to include information about the availability and feasibility (economic and technological) of equipment, methods, and manner of conducting such activity or other means of effecting the least practicable adverse impact upon the affected species or stocks and their habitat (50 CFR 216.104(a)(11)).

In evaluating how mitigation may or may not be appropriate to ensure the least practicable adverse impact on species or stocks and their habitat, as well as subsistence uses where applicable, we carefully consider two primary factors:

(1) The manner in which, and the degree to which, the successful implementation of the measure(s) is expected to reduce impacts to marine mammals, marine mammal species or stocks, and their habitat. This considers the nature of the potential adverse impact being mitigated (likelihood, scope, range). It further considers the likelihood that the measure will be effective if implemented (probability of accomplishing the mitigating result if implemented as planned) the likelihood of effective implementation (probability implemented as planned); and

(2) The practicability of the measures for applicant implementation, which may consider such things as cost, impact on operations, and, in the case of a military readiness activity, personnel safety, practicality of implementation, and impact on the effectiveness of the military readiness activity.

Mitigation for Marine Mammals and Their Habitat

1. Time Restriction. Work would occur only during daylight hours, when visual monitoring of marine mammals can be conducted.

2. Establishing and Monitoring Level A, Level B Harassment Zones, and Shutdown Zones.

WSDOT shall establish shutdown zones that encompass the distances within which marine mammals could be taken by Level A harassment (see Table 7 above) except for harbor seal. For Level A harassment zones that is less than 10 m from the source, a minimum of 10 m distance should be established as a shutdown zone. For harbor seal, a maximum of 60 m shutdown zone would be implemented if the actual Level A harassment zone exceeds 60 m. This is because there are a few habituated harbor seals that repeated occur within the larger Level A zone, which makes implementing a shutdown zone larger than 60 m infeasible.

A summary of exclusion zones is provided in Table 8.

TABLE 8—SHUTDOWN ZONES FOR VARIOUS PILE DRIVING ACTIVITIES AND MARINE MAMMAL HEARING GROUPS

Pilo type, size & pilo driving mothed	Shutdown zone (m)					
Pile type, size & pile driving method	LF cetacean	MF cetacean	HF cetacean	Phocid	Otariid	
Vibratory drive/removal, 24" & 30" steel piles, 8 piles/day, 20 min/pile	97	10	143	59	10	
Vibratory removal 30" steel pile, 1 pile/day, 20 min/pile	24	10	36	15	10	
Vibratory drive 36" steel pile, 8 piles/day, 20 min/pile	126	11	187	60	10	
Vibratory drive 36" steel pile, 8 piles/day, 20 min/pile Impact drive (proof) 36" steel pile, 8 piles/day, 300 strikes/	153	14	227	60	10	
pile	831	30	990	60	32	
Vibratory drive 108" steel pile, 1 pile/day, 120 min/pile	200	18	296	60	10	
Vibratory remove 14" timber pile, 20 piles/day, 15 min/pile	10	10	12	10	10	
Vibratory remove 12" steel pile, 11 piles/day, 20 min/pile	10	10	10	10	10	
Vibratory remove 14" steel H pile, 10 piles/day, 20 min/ pile.						

WSDOT shall also establish a Zone of Influence (ZOI) based on the Level B harassment zones for take monitoring where received underwater SPLs are higher than 160 dB_{rms} re 1 μ Pa for impulsive noise sources (impact pile driving) and 120 dB_{rms} re 1 μ Pa for non-impulsive noise sources (vibratory pile driving and pile removal).

NMFS-approved protected species observers (PSO) shall conduct an initial 30-minute survey of the exclusion zones to ensure that no marine mammals are seen within the zones before pile driving and pile removal of a pile segment begins. If marine mammals are found within the exclusion zone, pile driving of the segment would be delayed until they move out of the area. If a marine mammal is seen above water and then dives below, the contractor would wait 15 minutes. If no marine mammals are seen by the observer in that time it can be assumed that the animal has moved beyond the exclusion zone.

If pile driving of a segment ceases for 30 minutes or more and a marine mammal is sighted within the designated exclusion zone prior to commencement of pile driving, or if a shutdown occurs due to marine mammal sighting, the observer(s) must notify the pile driving operator (or other authorized individual) immediately and continue to monitor the exclusion zone. Operations may not resume until the marine mammal has exited the exclusion zone or 30 minutes have elapsed since the last sighting.

3. Soft-start.

A "soft-start" technique is intended to allow marine mammals to vacate the area before the impact pile driver reaches full power. Whenever there has been downtime of 30 minutes or more without impact pile driving, the contractor will initiate the driving with ramp-up procedures described below.

Soft start for impact hammers requires contractors to provide an initial set of three strikes from the impact hammer at 40 percent energy, followed by a 1minute waiting period, then two subsequent three-strike sets. Each day, WSDOT will use the soft-start technique at the beginning of impact pile driving, or if pile driving has ceased for more than 30 minutes.

4. Shutdown Measures.

WSDOT shall implement shutdown measures if a marine mammal is detected within an exclusion zone or is about to enter an exclusion zone listed in Table 8.

WSDOT shall also implement shutdown measures if SRKWs or humpback whales are sighted within the vicinity of the project area and are approaching the ZOI during in-water construction activities.

If a killer whale approaches the ZOI during pile driving or removal, and it is unknown whether it is a SRKW or a transient killer whale, it shall be assumed to be a SRKW and WSDOT shall implement the shutdown measure.

If a SRKW, an unidentified killer whale, or a humpback whale enters the ZOI undetected, in-water pile driving or pile removal shall be suspended until the whale exits the ZOI to avoid further Level B harassment.

Further, WSDOT shall implement shutdown measures if the number of authorized takes for any particular species reaches the limit under the IHA or if a marine mammal observed is not authorized for take under this IHA, if such marine mammals are sighted within the vicinity of the project area and are approaching the Level B harassment zone during in-water construction activities.

5. Coordination with Local Marine Mammal Research Network.

Prior to the start of pile driving for the day, the Orca Network and/or Center for Whale Research will be contacted by WSDOT to find out the location of the nearest marine mammal sightings. The Orca Sightings Network consists of a list of over 600 (and growing) residents, scientists, and government agency personnel in the United States and Canada. Sightings are called or emailed into the Orca Network and immediately distributed to other sighting networks including: the NMFS Northwest Fisheries Science Center, the Center for Whale Research, Cascadia Research, the Whale Museum Hotline and the British Columbia Sightings Network.

Sightings information collected by the Orca Network includes detection by hydrophone. The SeaSound Remote Sensing Network is a system of interconnected hydrophones installed in the marine environment of Haro Strait (west side of San Juan Island) to study orca communication, in-water noise, bottom fish ecology and local climatic conditions. A hydrophone at the Port Townsend Marine Science Center measures average in-water sound levels and automatically detects unusual sounds. These passive acoustic devices allow researchers to hear when different marine mammals come into the region. This acoustic network, combined with the volunteer (incidental) visual sighting network allows researchers to document presence and location of various marine mammal species.

With this level of coordination in the region of activity, WSDOT will be able to get real-time information on the presence or absence of whales before starting any pile driving.

Based on our evaluation of the required measures, NMFS has determined that the prescribed mitigation measures provide the means effecting the least practicable impact on the affected species or stocks and their habitat, paying particular attention to rookeries, mating grounds, and areas of similar significance.

Monitoring and Reporting

In order to issue an IHA for an activity, Section 101(a)(5)(D) of the MMPA states that NMFS must set forth, requirements pertaining to the monitoring and reporting of such taking. The MMPA implementing regulations at 50 CFR 216.104 (a)(13) indicate that requests for authorizations must include the suggested means of accomplishing the necessary monitoring and reporting that will result in increased knowledge of the species and of the level of taking or impacts on populations of marine mammals that are expected to be present in the proposed action area. Effective reporting is critical both to compliance as well as ensuring that the most value is obtained from the required monitoring.

Monitoring and reporting requirements prescribed by NMFS should contribute to improved understanding of one or more of the following:

• Occurrence of marine mammal species or stocks in the area in which take is anticipated (*e.g.*, presence, abundance, distribution, density);

• Nature, scope, or context of likely marine mammal exposure to potential stressors/impacts (individual or cumulative, acute or chronic), through better understanding of: (1) Action or environment (*e.g.*, source characterization, propagation, ambient noise); (2) affected species (*e.g.*, life history, dive patterns); (3) co-occurrence of marine mammal species with the action; or (4) biological or behavioral context of exposure (*e.g.*, age, calving or feeding areas);

• Individual marine mammal responses (behavioral or physiological) to acoustic stressors (acute, chronic, or cumulative), other stressors, or cumulative impacts from multiple stressors;

• How anticipated responses to stressors impact either: (1) Long-term fitness and survival of individual marine mammals; or (2) populations, species, or stocks;

• Effects on marine mammal habitat (e.g., marine mammal prey species, acoustic habitat, or other important physical components of marine mammal habitat); and

• Mitigation and monitoring effectiveness.

Monitoring Measures

WSDOT shall employ NMFSapproved PSOs to conduct marine mammal monitoring for the Seattle Multimodal Year 2 Project at Colman Dock. The purposes of marine mammal monitoring are to implement mitigation measures and learn more about impacts to marine mammals from WSDOT's construction activities. The PSOs will observe and collect data on marine mammals in and around the project area for 30 minutes before, during, and for 30 minutes after all pile removal and pile installation work. NMFS-approved PSOs shall meet the following requirements:

1. Independent observers (*i.e.*, not construction personnel) are required;

2. At least one observer must have prior experience working as an observer;

3. Other observers may substitute education (undergraduate degree in biological science or related field) or training for experience;

4. Where a team of three or more observers are required, one observer should be designated as lead observer or monitoring coordinator. The lead observer must have prior experience working as an observer; and

5. NMFS will require submission and approval of observer CVs.

Monitoring of marine mammals around the construction site shall be conducted using high-quality binoculars (e.g., Zeiss, 10 x 42 power). Due to the different sizes of ZOI from different pile types, three different ZOIs and different monitoring protocols corresponding to a specific pile type will be established.

• For Level B harassment zones with radii less than 1,600 m, 3 PSOs will be monitoring from land.

• For Level B harassment zones with radii larger than 1,600 m but smaller than 2,500 m, 4 PSOs will be monitoring from land.

• For Level B harassment zones with radii larger than 2,500 m, 4 PSOs will be monitoring from land with an additional 1 PSO monitoring from a ferry.

6. PSOs shall collect the following information during marine mammal monitoring:

• Date and time that monitored activity begins and ends for each day conducted (monitoring period);

• Construction activities occurring during each daily observation period, including how many and what type of piles driven;

• Deviation from initial proposal in pile numbers, pile types, average driving times, etc.;

• Weather parameters in each monitoring period (*e.g.*, wind speed, percent cloud cover, visibility);

• Water conditions in each

monitoring period (*e.g.*, sea state, tide state);

For each marine mammal sighting:
 Species, numbers, and, if possible,

sex and age class of marine mammals; • Description of any observable

marine mammal behavior patterns,

including bearing and direction of travel and distance from pile driving activity;

 Location and distance from pile driving activities to marine mammals and distance from the marine mammals to the observation point; and

 Estimated amount of time that the animals remained in the Level B zone;

• Description of implementation of mitigation measures within each monitoring period (*e.g.*, shutdown or delay); and

• Other human activity in the area within each monitoring period.

To verify the required monitoring distance, the exclusion zones and ZOIs will be determined by using a range finder or hand-held global positioning system device.

WSDOT will conduct noise field measurement to determine the actual Level B distance from the source during vibratory driving of the first 36-in pile. If the actual Level B harassment distance is less than modelled, the number of PSOs will be adjusted based on the criteria listed above.

Reporting Measures

WSDOT is required to submit a draft monitoring report within 90 days after completion of the construction work or the expiration of the IHA, whichever comes earlier. In the case if WSDOT intends to renew the IHA in a subsequent year, a monitoring report should be submitted 60 days before the expiration of the current IHA (if issued). This report would detail the monitoring protocol, summarize the data recorded during monitoring, and estimate the number of marine mammals that may have been harassed. NMFS would have an opportunity to provide comments on the report, and if NMFS has comments, WSDOT would address the comments and submit a final report to NMFS within 30 days.

In addition, NMFS would require WSDOT to notify NMFS' Office of Protected Resources and NMFS' West Coast Stranding Coordinator within 48 hours of sighting an injured or dead marine mammal in the construction site. WSDOT shall provide NMFS and the Stranding Network with the species or description of the animal(s), the condition of the animal(s) (including carcass condition, if the animal is dead), location, time of first discovery, observed behaviors (if alive), and photo or video (if available).

In the event that WSDOT finds an injured or dead marine mammal that is not in the construction area, WSDOT would report the same information as listed above to NMFS as soon as operationally feasible.

Negligible Impact Analysis and Determination

NMFS has defined negligible impact as an impact resulting from the specified activity that cannot be reasonably expected to, and is not reasonably likely to, adversely affect the species or stock through effects on annual rates of recruitment or survival (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., populationlevel effects). An estimate of the number of takes alone is not enough information on which to base an impact determination. In addition to considering estimates of the number of marine mammals that might be "taken' through harassment, NMFS considers other factors, such as the likely nature of any responses (e.g., intensity, duration), the context of any responses (e.g., critical reproductive time or location, migration), as well as effects on habitat, and the likely effectiveness of the mitigation. We also assess the number, intensity, and context of estimated takes by evaluating this information relative to population status. Consistent with the 1989 preamble for NMFS's implementing regulations (54 FR 40338; September 29, 1989), the impacts from other past and ongoing anthropogenic activities are incorporated into this analysis via their impacts on the environmental baseline (e.g., as reflected in the regulatory status of the species, population size and growth rate where known, ongoing sources of human-caused mortality, or ambient noise levels).

To avoid repetition, this introductory discussion of our analyses applies to all the species listed in Table 7, given that the anticipated effects of WSDOT's Seattle Multimodal at Colman Dock project involving pile driving and pile removal on marine mammals are expected to be relatively similar in nature. There is no information about the nature or severity of the impacts, or the size, status, or structure of any species or stock that would lead to a different analysis by species for this activity, or else species-specific factors would be identified and analyzed.

Although a few marine mammals (132 harbor seals, 12 harbor porpoises, and 1 Dall's porpoise) are estimated to experience Level A harassment in the form of PTS if they stay within the Level A harassment zone during the entire pile driving for the day, the degree of injury is expected to be mild and is not likely to affect the reproduction or survival of the individual animals. It is expected that, if hearing impairments occurs, most likely the affected animal would lose a few dB in its hearing sensitivity, which in most cases is not likely to affect its survival and recruitment. Hearing impairment that occur for these individual animals would be limited to the dominant frequency of the noise sources, *i.e.*, in the low-frequency region below 2 kHz. Therefore, the degree of PTS is not likely to affect the echolocation performance of the two porpoise species, which use frequencies mostly above 100 kHz. Nevertheless, for all marine mammal species, it is known that in general animals avoid areas where sound levels could cause hearing impairment. Therefore, it is not likely that an animal would stay in an area with intense noise that could cause severe levels of hearing damage. In addition, even if an animal receives a TTS, the TTS would be a one-time event from the exposure, making it unlikely that the TTS would evolve into PTS. Furthermore, Level A take estimates are based on the assumption that the animals are randomly distributed in the project area and would not avoid intense noise levels that could cause TTS or PTS. In reality, animals tend to avoid areas where noise levels are high (Richardson et al., 1995). Nonetheless, we evaluate the estimated take in this negligible impact analysis.

For these species except harbor seal, California sea lion, Steller sea lion, harbor porpoise and Dall's porpoise, takes that are anticipated and authorized are expected to be limited to short-term Level B harassment (behavioral and TTS). Marine mammals present in the vicinity of the action area and taken by Level B harassment would most likely show overt brief disturbance (startle reaction) and avoidance of the area from elevated noise levels during pile driving and pile removal and the implosion noise. A few marine mammals could experience TTS if they occur within the Level B TTS ZOI. However, as discussed earlier in this document, TTS is a temporary loss of hearing sensitivity when exposed to loud sound, and the hearing threshold is expected to recover completely within minutes to hours. Therefore, it is not considered an injury.

There are no other important areas for marine mammals, such as important feeding, pupping, or other areas.

The project also is not expected to have significant adverse effects on affected marine mammals' habitat, as analyzed in detail in the "Anticipated Effects on Marine Mammal Habitat" subsection. There is no ESA designated critical area in the vicinity of the Seattle Multimodal Project at Colman Dock area. The project activities would not permanently modify existing marine mammal habitat. The activities may kill some fish and cause other fish to leave the area temporarily, thus impacting marine mammals' foraging opportunities in a limited portion of the foraging range. However, because of the short duration of the activities and the relatively small area of the habitat that may be affected, the impacts to marine mammal habitat are not expected to cause significant or long-term negative consequences. Therefore, given the consideration of potential impacts to marine mammal prey species and their physical environment, WSDOT's proposed construction activity at Colman Dock would not adversely affect marine mammal habitat.

In summary and as described above, the following factors primarily support our determination that the impacts resulting from this activity are not expected to adversely affect the species or stock through effects on annual rates of recruitment or survival:

• No mortality is anticipated or authorized;

• Injury—only five species of marine mammals would experience Level A harassment in the form of mild PTS, which is expected to be of small degree; and

• Behavioral disturbance—eleven species/stocks of marine mammals would experience behavioral disturbance from the WSDOT's Seattle Colman Dock project. However, as discussed earlier, the area to be affected is small and the duration of the project is short. No other important habitat for marine mammals exist in the vicinity of the project area. Therefore, the overall impacts are expected to be insignificant.

Based on the analysis contained herein of the likely effects of the specified activity on marine mammals and their habitat, and taking into consideration the implementation of the monitoring and mitigation measures, NMFS finds that the total take from the proposed activity will have a negligible impact on all affected marine mammal species or stocks.

Small Numbers

As noted above, only small numbers of incidental take may be authorized under Section 101(a)(5)(D) of the MMPA for specified activities other than military readiness activities. The MMPA does not define small numbers and so, in practice, where estimated numbers are available, NMFS compares the number of individuals taken to the most appropriate estimation of abundance of the relevant species or stock in our determination of whether an authorization is limited to small numbers of marine mammals. Additionally, other qualitative factors may be considered in the analysis, such as the temporal or spatial scale of the activities.

The estimated takes are below 13 percent of the population for all marine mammals except harbor porpoise (Table 7). For harbor porpoise, the estimate of 3,120 incidences of takes would be 28 percent of the population, if each single take were a unique individual. However, this is highly unlikely because the harbor porpoise in Washington waters shows site fidelity to small areas for periods of time that can extend between seasons (Hanson et al., 1999; Hanson 2007a, 2007b). For example, Hanson et al. (1999) tracked a female harbor porpoise for 215 days, during which it remained exclusively within the southern Strait of Georgia region. Based on studies by Jefferson et al. (2016), harbor porpoise abundance in the southern Puget Sound region, which encompasses waters off Seattle, is 550. Therefore, if the estimated incidents of take accrued to all the animals expected to occur in the entire southern Puget Sound area (550 animals), it would be 4.90 percent of the Washington inland water stock of the harbor porpoise.

Based on the analysis contained herein of the proposed activity (including the prescribed mitigation and monitoring measures) and the anticipated take of marine mammals, NMFS finds that small numbers of each species or stock will be taken relative to the population size of the affected species or stocks.

Unmitigable Adverse Impact Determination

There are no relevant subsistence uses of the affected marine mammal stocks or species implicated by this action. Therefore, NMFS has determined that the total taking of affected species or stocks would not have an unmitigable adverse impact on the availability of such species or stocks for taking for subsistence purposes.

National Environmental Policy Act

To comply with the National Environmental Policy Act of 1969 (NEPA; 42 U.S.C. 4321 *et seq.*) and NOAA Administrative Order (NAO) 216–6A, NMFS must review our proposed action (*i.e.*, the issuance of an incidental harassment authorization) with respect to potential impacts on the human environment.

NMFS has determined the issuance of the IHA is consistent with categories of activities identified in CE B4 (issuance of incidental harassment authorizations under section 101(a)(5)(A) and (D) of the MMPA for which no serious injury or mortality is anticipated) of NOAA's Companion Manual for NAO 216–6A, and we have not identified any extraordinary circumstances listed in Chapter 4 of the Companion Manual for NAO 216–6A that would preclude this categorical exclusion under NEPA.

Endangered Species Act

Section 7(a)(2) of the ESA of 1973 (ESA: 16 U.S.C. 1531 *et seq.*) requires that each Federal agency insure that any action it authorizes, funds, or carries out is not likely to jeopardize the continued existence of any endangered or threatened species or result in the destruction or adverse modification of designated critical habitat.

The California-Oregon-Washington stock of humpback whale and the Southern Resident stock of killer whale are the only marine mammal species listed under the ESA that could occur in the vicinity of WSDOT's proposed construction projects. Two DPSs of humpback whales, the Mexico DPS and the Central America DPS, are listed as threatened and endangered under the ESA, respectively. NMFS worked with WSDOT to implement shutdown measures in the IHA that would avoid takes of both SR killer whale and humpback whales. Therefore, NMFS determined that no ESA-listed marine mammal species would be affected as a result of WSDOT's Seattle Colman Dock construction project.

Authorization

As a result of these determinations, NMFS has issued an IHA to the Washington State Department of Transportation for the Seattle Multimodal Project at Colman Dock in Washington State, provided the previously described mitigation, monitoring, and reporting requirements are incorporated.

Dated: July 20, 2018.

Donna S. Wieting,

Director, Office of Protected Resources, National Marine Fisheries Service. [FR Doc. 2018–15874 Filed 7–24–18; 8:45 am]

BILLING CODE 3510-22-P

DEPARTMENT OF COMMERCE

National Oceanic and Atmospheric Administration

Proposed Information Collection; Comment Request; National Oceanic and Atmospheric Administration's Bay Watershed Education and Training Program National Evaluation System

AGENCY: National Oceanic and Atmospheric Administration (NOAA), Commerce.

ACTION: Notice.

SUMMARY: The Department of Commerce, as part of its continuing effort to reduce paperwork and respondent burden, invites the general public and other Federal agencies to take this opportunity to comment on proposed and/or continuing information collections, as required by the Paperwork Reduction Act of 1995.

DATES: Written comments must be submitted on or before September 24, 2018.

ADDRESSES: Direct all written comments to Jennifer Jessup, Departmental Paperwork Clearance Officer, Department of Commerce, Room 6616, 14th and Constitution Avenue NW, Washington, DC 20230 (or via the internet at *pracomments@doc.gov*).

FOR FURTHER INFORMATION CONTACT: Requests for additional information or copies of the information collection instrument and instructions should be directed to Bronwen Rice, NOAA Office of Education, (202) 482–6797 or *Bronwen.Rice@noaa.gov.*

SUPPLEMENTARY INFORMATION:

I. Abstract

This request is for an extension of a currently approved information collection.

The NOAA Office of Education's Bay Watershed Education and Training (B-WET) program seeks to contribute to NOAA's mission by supporting education efforts to create an environmentally literate citizenry with the knowledge, attitudes, and skills needed to protect watersheds and related ocean, coastal, and Great Lakes ecosystems. B–WET currently funds projects in seven regions (California, Chesapeake Bay, Great Lakes, Gulf of Mexico, Hawaii, New England, and the Pacific Northwest). B–WET has created an across-region, internal evaluation system to provide ongoing feedback on program implementation and outcomes to ensure maximum quality and efficiency of the B-WET program. The evaluation system is sustained by B-

WET staff with occasional assistance from an outside contractor.

B–WET awardees and the awardees' professional development teacherparticipants are asked to voluntarily complete online survey forms to provide evaluation data. One individual from each awardee organization is asked to complete a form once per year of the award, and the teacher participants are asked to complete one form at the end of their professional development program and another form at the end of the following school year.

II. Method of Collection

Respondents submit their information electronically on web-based survey forms.

III. Data

OMB Control Number: 0648–0658. *Form Number:* None.

Type of Review: Regular submission (extension of a currently approved collection).

Affected Public: Not-for-profit organizations; state, local or tribal governments; individuals or households.

Estimated Number of Respondents: Given the funding levels of the past three fiscal years, NOAA B–WET estimates that approximately 115 awardees and 2,507 teachers will be invited to respond each year.

Estimated Time per Response: Awardee-respondents will complete an online survey in 60 minutes and teacher-respondents will complete two online surveys in 30 minutes each.

Estimated Total Annual Burden Hours: 1,040.

Estimated Total Annual Cost to Public: \$0 in recordkeeping/reporting costs.

IV. Request for Comments

Comments are invited on: (a) Whether the proposed collection of information is necessary for the proper performance of the functions of the agency, including whether the information shall have practical utility; (b) the accuracy of the agency's estimate of the burden (including hours and cost) of the proposed collection of information; (c) ways to enhance the quality, utility, and clarity of the information to be collected; and (d) ways to minimize the burden of the collection of information on respondents, including through the use of automated collection techniques or other forms of information technology.

Comments submitted in response to this notice will be summarized and/or included in the request for OMB approval of this information collection; they also will become a matter of public record.

Dated: July 20, 2018.

Sarah Brabson,

NOAA PRA Clearance Officer. [FR Doc. 2018–15872 Filed 7–24–18; 8:45 am] BILLING CODE 3510–12–P

DEPARTMENT OF COMMERCE

Patent and Trademark Office

Submission for OMB Review; Comment Request; "Rules for Patent Maintenance Fees"

Summary: The United States Patent and Trademark Office (USPTO) will submit to the Office of Management and Budget (OMB) for clearance the following proposal for collection of information under the provisions of the Paperwork Reduction Act.

Agency: United States Patent and Trademark Office, Commerce.

Title: Rules for Patent Maintenance Fees.

OMB Control Number: 0651–0016. Form Number(s):

- PTO/SB/45
- PTO/SB/47
- PTO/SB/66

Type of Request: Regular.

Number of Respondents: 533,910 responses per vear.

Average Hours per Response: The USPTO estimates it will take respondents from 0.006 hours (20 seconds) to 8 hours to complete the items in this collection, depending on the instrument(s) used.

Burden Hours: 13,878.89 hours per year.

Cost Burden: \$1,209,457,959.50. *Needs and Uses:* This information collection is necessary so that patent owners can maintain a utility patent in force and to ensure that the USPTO can properly credit maintenance fee payments. The USPTO offers forms to assist the public with providing the information covered by this collection, including maintenance fee payments, petitions to accept delayed maintenance fee payments, and fee address changes.

The public uses the Maintenance Fee Transmittal Form (PTO/SB/45) to determine and pay the correct amount due for a maintenance fee transaction. PTO/SB/45 may be mailed or faxed to the USPTO, but PTO/SB/45 may not be submitted electronically via EFS-Web. Customers may submit maintenance fees and six-month grace period surcharges paid before patent expiration electronically over the internet using the USPTO's Office of Finance Online Shopping Page (hereinafter, the "Electronic Maintenance Fee Form") provided through the USPTO website. To pay a maintenance fee after patent expiration, customers must submit the maintenance fee payment together with a Petition to Accept Unintentionally Delayed Payment (PTO/SB/66). A petition to accept delayed payment of a maintenance fee under the unintentional standard may be filed online. To designate or change a fee address, the customer must submit a Fee

Completion of these forms results in information collected, maintained, and used consistent with all applicable OMB and USPTO Information Quality Guidelines. This includes the basic information quality standards established in the Paperwork Reduction Act (44 U.S.C. chapter 35) (PRA), in OMB Circular A–130, and in the OMB information quality guidelines.

Address Indication Form (PTO/SB/47).

Frequency: On occasion.

Respondent's Obligation: Required to Obtain or Retain Benefits.

OMB Desk Officer: Nicholas A. Fraser, email: Nicholas_A._Fraser@ omb.eop.gov.

Once submitted, the request will be publicly available in electronic format through *reginfo.gov*. Follow the instructions to view Department of Commerce collections currently under review by OMB.

Further information can be obtained by:

• Email: InformationCollection@ uspto.gov. Include "0651–0016 comment" in the subject line of the message.

• *Mail:* Raul Tamayo, Senior Legal Advisor, Office of Patent Legal Administration,, United States Patent and Trademark Office, P.O. Box 1450, Alexandria, VA 22313–1450.

Written comments and recommendations for the proposed information collection should be sent on or before August 24, 2018 to Nicholas A. Fraser, OMB Desk Officer, via email to *Nicholas_A._Fraser@omb.eop.gov*, or by fax to 202–395–5167, marked to the attention of Nicholas A. Fraser.

Marcie Lovett,

Director, Records and Information Governance Division, Office of the Chief Technology Officer, United States Patent and Trademark Office.

[FR Doc. 2018–15877 Filed 7–24–18; 8:45 am]

BILLING CODE 3510-16-P

COMMODITY FUTURES TRADING COMMISSION

Order Granting Exemption From Certain Provisions of the Commodity Exchange Act Regarding Investment of Customer Funds and From Certain Related Commission Regulations

AGENCY: Commodity Futures Trading Commission.

ACTION: Order.

SUMMARY: The Commodity Futures Trading Commission ("CFTC" or "Commission") is issuing an order in response to a petition from ICE Clear Credit LLC, ICE Clear US, Inc., and ICE Clear Europe Limited (collectively, "the ICE DCOs" or "the Petitioners") seeking an exemption permitting the investment of futures and swap customer funds in certain categories of euro-denominated sovereign debt. The Commission is also granting exemptive relief to expand the universe of permissible counterparties and depositories that can be used in connection with these investments given the structure of the market for repurchase agreements in eurodenominated sovereign debt.

DATES: Applicable as of July 25, 2018.

FOR FURTHER INFORMATION CONTACT: Eileen A. Donovan, Deputy Director, (202) 418-5096, edonovan@cftc.gov, Division of Clearing and Risk, or Lihong McPhail, Research Economist, (202) 418-5722, lmcphail@cftc.gov, Office of the Chief Economist, Commodity Futures Trading Commission, Three Lafayette Centre, 1155 21st Street NW, Washington, DC 20581; or Tad Polley, Associate Director, (312) 596-0551, tpolley@cftc.gov, or Scott Sloan, Attorney-Advisor, (312) 596-0708, ssloan@cftc.gov, Division of Clearing and Risk, Commodity Futures Trading Commission, 525 West Monroe Street, Chicago, Illinois 60661.

SUPPLEMENTARY INFORMATION:

I. Background

By petition dated June 22, 2017, the Petitioners, all registered derivatives clearing organizations ("DCOs"), requested an exemptive order under section 4(c) of the Commodity Exchange Act ("CEA" or "Act") permitting the ICE DCOs to invest futures and cleared swap customer funds in certain categories of euro-denominated sovereign debt. On December 15, 2017, the Commission published a proposed order that would grant the requested exemption ("Proposed Order") and requested public comment on the Proposed Order.¹ Section 4d of the Act ² and Commission Regulation 1.25(a) ³ set out the permitted investments in which DCOs may invest customer funds.⁴ Section 4d limits investments of customer money to obligations of the United States ("U.S. Government Securities"), general obligations of any State or of any political subdivision thereof, and obligations fully guaranteed as to principal and interest by the United States.⁵ Regulation 1.25 expands the list of permitted investments but does not permit investment of customer funds in foreign sovereign debt.⁶

Regulation 1.25 previously included foreign sovereign debt as a permitted investment for customer funds.7 In 2011, the Commission removed this option from Regulation 1.25, but also acknowledged that the safety of sovereign debt issuances of one country may vary greatly from those of another, and stated that it was amenable to considering requests for section 4(c)exemptions from this restriction.⁸ Specifically, the Commission stated that it would consider permitting foreign sovereign debt investments (1) to the extent that the petitioner has balances in segregated accounts owed to customers or clearing member futures commission merchants in that country's currency and (2) to the extent that the sovereign debt serves to preserve principal and maintain liquidity of customer funds as

 $^{\rm 5}$ See 7 U.S.C. 6d(a)(2) (futures), (f)(4) (cleared swaps).

⁶Regulation 1.25 permits investment of customer funds in: (i) Obligations of the United States and obligations fully guaranteed as to principal and interest by the United States (U.S. government securities); (ii) General obligations of any State or of any political subdivision thereof (municipal securities); (iii) Obligations of any United States government corporation or enterprise sponsored by the United States government (U.S. agency obligations); (iv) Certificates of deposit issued by a bank (certificates of deposit) as defined in section 3(a)(6) of the Securities Exchange Act of 1934, or a domestic branch of a foreign bank that carries deposits insured by the Federal Deposit Insurance Corporation; (v) Commercial paper fully guaranteed as to principal and interest by the United States under the Temporary Liquidity Guarantee Program as administered by the Federal Deposit Insurance Corporation (commercial paper); (vi) Corporate notes or bonds fully guaranteed as to principal and interest by the United States under the Temporary Liquidity Guarantee Program as administered by the Federal Deposit Insurance Corporation (corporate notes or bonds); and (vii) Interests in money market mutual funds.

⁷ See 17 CFR 1.25(a) (2005).

⁸ Investment of Customer Funds and Funds Held in an Account for Foreign Futures and Foreign Options Transactions, 76 FR 78776, 78782 (Dec. 19, 2011).

¹82 FR 59586 (Dec. 15, 2017).

² 7 U.S.C. 6d.

³ 17 CFR 1.25(a) (2017).

⁴ Although Regulation 1.25 by its terms applies only to futures customer funds, Regulation 22.3(d) requires that a DCO investing cleared swap customer funds comply with the requirements of Regulation 1.25.

required for all other investments of customer funds under Regulation 1.25.⁹

In connection with their proposal to invest customer funds in foreign sovereign debt, the ICE DCOs have also requested an exemption from Regulations 1.25(d)(2) and (7). Regulation 1.25(d)(2) limits the counterparties with which a DCO can enter into a repurchase agreement involving customer funds to a bank as defined in section 3(a)(6) of the Securities Exchange Act of 1934, a domestic branch of a foreign bank insured by the Federal Deposit Insurance Corporation, a securities broker or dealer, or a government securities broker or government securities dealer registered with the Securities and Exchange Commission or which has filed notice pursuant to section 15C(a) of the Government Securities Act of 1986. Regulation 1.25(d)(7) requires a DCO to hold the securities transferred to the DCO under a repurchase agreement in a safekeeping account with a bank as referred to in Regulation 1.25(d)(2), a Federal Reserve Bank, a DCO, or the Depository Trust Company in an account that complies with the requirements of Regulation 1.26.

II. The ICE DCOs' Petition

The ICE DCOs request a limited exemption from section 4d of the Act and Commission Regulation 1.25(a) to invest euro-denominated customer funds in sovereign debt issued by the French Republic and the Federal Republic of Germany ("Designated Foreign Sovereign Debt") through both direct investment and repurchase agreements.¹⁰ The Petitioners also request an exemption from Regulation 1.25(d)(2) that would permit them to enter into reverse repurchase agreements with certain foreign banks, certain regulated securities dealers, or the European Central Bank and the central banks of Germany and France.¹¹ Lastly, the ICE DCOs request an exemption from Regulation 1.25(d)(7) that would permit them to hold the securities purchased through reverse repurchase agreements in a safekeeping account with a non-U.S. bank that qualifies as a depository under the requirements of Regulation 1.49.

III. Section 4(c) Analysis

In connection with the Proposed Order, the Commission preliminarily determined that granting the requested exemption would be consistent with Section 4(c) of the Act.¹² After reviewing the comments received in response to the Proposed Order, all of which supported an exemption, the Commission has determined that the exemption detailed below satisfies the requirements of Section 4(c)(2) of the Act.¹³

Specifically, the Commission has determined that the restriction on investments of customer funds by DCOs should not apply to Designated Foreign Sovereign Debt. As the Commission previously observed, the ICE DCOs demonstrated that the Designated Foreign Sovereign Debt has credit, liquidity, and volatility characteristics that are comparable to U.S. Government Securities, which are permitted investments under the Act and Regulation 1.25. For example, as evidence of the creditworthiness of France and Germany, the ICE DCOs provided data demonstrating that credit default swap spreads of France and Germany have historically been similar to those of the United States. To demonstrate the liquidity of the markets, the ICE DCOs pointed to, for example, the substantial amount of outstanding marketable French and German debt and the daily transaction value of the repo markets for their debt. And with respect to volatility, the ICE DCOs provided data on daily changes to sovereign debt yields demonstrating that the price stability of French and German debt is comparable to that of U.S. Government Securities.

The Commission also observed that the ICE DCOs demonstrated that investing in the Designated Foreign

¹³ Section 4(c)(2) of the Act provides that the Commission may grant exemptions under Section 4(c)(1) only when it determines that the requirements for which an exemption is being provided should not be applied to the agreements, contracts, or transactions at issue; that the exemption is consistent with the public interest and the purposes of the Act; that the agreements, contracts, or transactions will be entered into solely between appropriate persons; and that the exemption will not have a material adverse effect on the ability of the Commission or any contract market or derivatives transaction execution facility to discharge its regulatory or self-regulatory responsibilities under the Act.

Sovereign Debt poses less risk to customer funds than the current alternative of holding the funds at a commercial bank, on the basis that exposure to high-quality sovereign debt is preferable to facing the credit risk of commercial banks through unsecured bank demand deposit accounts. While investments through reverse repurchase agreements (as opposed to direct investments) still involve exposure to a commercial counterparty, a DCO would receive the additional benefit of receiving securities as collateral against that counterparty's credit risk. The ICE DCOs also represented that in the event a securities custodian enters insolvency proceedings, they would have a claim to specific securities rather than a general claim against the assets of the custodian.

Further, the Commission has determined that the exemption is consistent with the public interest and the purposes of the Act, which include ensuring the financial integrity of transactions and avoiding systemic risk.¹⁴ As noted above, investing customer funds in Designated Foreign Sovereign Debt is often a prudent alternative to holding cash at a commercial bank from a risk management perspective, and granting the exemption thus serves to protect market participants and the public. For the same reasons, granting the exemption may enhance the financial integrity of the DCO and thereby help to avoid systemic risk.

Finally, the Commission has determined that granting an exemption allowing investment of customer funds in instruments with risk characteristics comparable to currently permitted investments does not have a material adverse effect on the ability of the Commission or any contract market to discharge its regulatory or selfregulatory duties under the Act.¹⁵

Based on the foregoing, the Commission has determined that granting the exemption provided in the order below satisfies the requirements of section 4(c) of the Act.

IV. Proposed Order

The Commission proposed an exemption to permit the ICE DCOs, subject to certain conditions, to invest customer funds in Designated Foreign Sovereign Debt. The first condition required that the ICE DCOs only use customer euro cash to invest in the Designated Foreign Sovereign Debt. This restriction was previously included in

⁹ Id.

¹⁰ A copy of the petition is available on the Commission's website at http://www.cftc.gov/idc/ groups/public/@requestsandactions/documents/ ifdocs/icedcos4cappl6-22-17.pdf.

¹¹ The ICE DCOs have indicated they may not currently be able to enter into repurchase agreements with these central banks.

 $^{^{12}}$ Section 4(c)(1) of the Act empowers the Commission to promote responsible economic or financial innovation and fair competition by exempting any transaction or class of transactions (including any person or class of persons offering, entering into, rendering advice or rendering other services with respect to, the agreement, contract, or transaction), from any of the provisions of the Act, subject to exceptions not relevant here. 7 U.S.C. 6(c)(1).

¹⁴ See 7 U.S.C. 5(b).

¹⁵ The section 4(c)(2) factor of whether an agreement, contract or transaction is entered into solely between appropriate persons does not apply here.

Regulation 1.25 ¹⁶ when the rule permitted the investment of customer funds in foreign sovereign debt, and the Commission believes it is still an appropriate restriction on the amount that may be invested in these instruments.

Second, the Commission proposed to permit the ICE DCOs to invest in Designated Foreign Sovereign Debt only so long as the two-year credit default spread of the issuing sovereign is 45 basis points ("BPS") or less. The Commission explained that because the proposed order was not intended to expand the universe of permitted investments beyond instruments with a risk profile similar to those that are currently permitted, U.S. Government Securities provide an appropriate benchmark to confine permitted investments in foreign sovereign debt. The Commission proposed the cap of 45 BPS based on a historical analysis of the two-year credit default spread of the United States ("U.S. Spread"). Fortyfive BPS is approximately two standard deviations above the mean U.S. Spread over the past eight years and represents a risk level that the U.S. Spread has exceeded approximately 5% of the time over that period.¹⁷ The Proposed Order provided that if the spread exceeds 45 BPS, the ICE DCOs would not be permitted to make new investments in the relevant debt. They also would not need to immediately divest all current investments, however, due to risks associated with selling assets in a potentially volatile market. The Commission explained that prohibiting new investments, together with the length to maturity condition discussed immediately below, sufficiently protects customer funds in the event that a country's Designated Foreign Sovereign Debt were to exceed the 45 BPS spread limit.

Third, the Commission proposed to limit the length to maturity of direct investments in Designated Foreign

¹⁷ The Commission reviewed the daily U.S. Spread from July 3, 2009 to July 3, 2017. Over this time period, the U.S. Spread had a mean of approximately 26.5 BPS and a standard deviation of approximately 9.72 BPS. Over this same period, the two-year German spread exceeded 45 BPS approximately 6% of the time, and the two-year French spread exceeded 45 BPS approximately 25% of the time. Neither the German nor the French twoyear spread has exceeded 45 BPS since September 2012.

Sovereign Debt, to limit permitted investments to those with a lower risk profile. Specifically, the Proposed Order contained a requirement that each of the ICE DCOs ensure that the dollarweighted average of the time-to-maturity of their portfolio of direct investments in each type of Designated Foreign Sovereign Debt does not exceed 60 days. This restriction was modeled on Securities and Exchange Commission requirements for money market mutual funds,18 which have liquidity timing needs appropriately analogous to those of a DCO in this instance, and was designed to ensure that the investments will mature relatively quickly, providing the ICE DCOs with access to euro cash.

To provide the ICE DCOs with the ability to invest customer funds in the Designated Foreign Sovereign Debt, the Commission proposed to exempt the ICE DCOs from the counterparty and depository requirements of Regulation 1.25(d)(2) and (7), subject to conditions. As a practical matter, complying with these requirements would severely restrict the ICE DCOs' ability to enter into repurchase agreements for Designated Foreign Sovereign Debt.

Specifically the Commission proposed to exempt the ICE DCOs from the counterparty restrictions of Regulation 1.25(d)(2), subject to the condition that counterparties be limited to certain categories that are intended to limit the risk associated with reverse repurchase transactions. The ICE DCOs represented that the principal participants in the European sovereign debt repurchase markets are non-U.S. banks, non-U.S. securities dealers, and foreign branches of U.S. banks. As a result, the counterparty requirements under Regulation 1.25(d)(2) would significantly constrain the use of eurodenominated sovereign debt repurchase agreements. Additionally, the ICE DCOs represented that it would be impractical and inefficient to hold such securities at a U.S. custodian, and the Commission proposed to exempt the ICE DCOs from the depository requirement of Regulation 1.25(d)(7), so long as the depository qualifies as a permitted depository under Regulation 1.49. The Commission explained that the proposed restrictions on permitted counterparties and depositories are designed to ensure that the counterparties and depositories used by the ICE DCOs will be regulated entities comparable to those currently permitted under Regulation 1.25(d)(2) and (7).

V. Comments on the Proposed Order

The Commission published a request for comments regarding the Proposed Order in the **Federal Register** on December 15, 2017.¹⁹

The Commission received three comment letters.²⁰ Each of the commenters supported an exemption and suggested several changes to the Proposed Order. Both Eurex and FIA stated that the proposed exemption is consistent with the Regulation 1.25 objectives of preserving principle and maintaining liquidity.

All three commenters recommended that the Commission expand the scope of the order to grant relief to additional registrants. Eurex, a registered DCO, requested that it be included within the scope of the exemption. CME encouraged the Commission to include all DCOs in the scope of the exemption, and FIA recommended including all DCOs and their FCM clearing members.

CME and Eurex argued that expanding the scope of the order is consistent with the promotion of fair competition, which is one of the stated purposes of section 4(c) exemptions.²¹ They also highlighted the benefits of investing customer funds in Designated Foreign Sovereign Debt as justification for expanding the scope of the order. Eurex stated that investing in Designated Foreign Sovereign Debt is safer than holding euro cash at a commercial bank. Additionally, CME noted that investing in Designated Foreign Sovereign Debt promotes effective management of liquidity risk by aligning collateral types with potential liquidity obligations and by diversifying risk in the investment portfolio. CME further stated that investments in Designated Foreign Sovereign Debt allow DCOs to better mitigate collateral concentration risk and argued that these benefits are not unique to any particular DCO.

The Commission agrees that the benefits of the Proposed Order are not unique to the ICE DCOs and is accordingly expanding the scope of the Proposed Order to permit all DCOs to invest customer funds in Designated Foreign Sovereign Debt, subject to the conditions of the order. The Commission notes, however, that some DCOs have access to a central bank account for euro deposits and believes that such access can, in certain

¹⁶ See 17 CFR 1.25(b)(4)(D) (2005) (providing that sovereign debt is subject to the following limits: A futures commission merchant may invest in the sovereign debt of a country to the extent it has balances in segregated accounts owed to its customers denominated in that country's currency; a DCO may invest in the sovereign debt of a country to the extent it has balances in segregated accounts owed to its clearing member futures commission merchants denominated in that country's currency).

¹⁸ See 17 CFR 270.2a-7.

¹⁹82 FR 59586 (Dec. 15, 2017).

²⁰ Letters were submitted by CME Group, Inc ("CME"), Eurex Clearing AG ("Eurex"), and the Futures Industry Association ("FIA"). All comment letters are available through the Commission's website at: https://comments.cftc.gov/Public Comments/CommentList.aspx?id=2850. ²¹ See 7 U.S.C. 6(c)(1).

circumstances, reduce or eliminate the need for investing customer funds in Designated Foreign Sovereign Debt. The Commission therefore encourages DCOs to deposit customer euro with a central bank when it is practical to do so.²² The comments received did not provide support for an expansion of the exemption to FCMs,²³ a separate class of registrants subject to differing regulatory obligations that the Commission would need to carefully consider on their own terms. As a result, the Commission declines to expand the order to permit FCMs to invest customer funds in Designated Foreign Sovereign Debt at this time.

Both Eurex and FIA encouraged the Commission to expand the weighted average time-to-maturity limit beyond the proposed 60 days. Eurex recommended limiting portfolios, including repurchase agreements, to a two-year time-to-maturity requirement, consistent with the current limit in Regulation 1.25 for the overall portfolio of investments purchased with customer funds. It argued that because the Commission found the risk characteristics of German and French debt to be similar to those of U.S. Government Securities, the same timeto-maturity limit should apply. FIA recommended using a six month timeto-maturity limit.²⁴ Based on discussions with trading desks at several member firms, FIA suggested that the 60-day limit would be too restrictive. It explained that the new issuance supply of French and German sovereign debt that could be used to satisfy this restriction is limited and thinly traded and quoted, which could force participants to invest in less-liquid secondary market securities. Further, FIA noted that although the discussion of the proposed 60-day time-to-maturity limit noted the SEC's requirement for mutual funds as a point of reference, the SEC rule includes overnight repos in the calculation, which significantly reduces the average time-to-maturity of the portfolio as a whole.

The 60-day average time-to-maturity limitation as proposed to apply only to

²⁴ FIA did not specify whether repurchase agreements would be included in the calculation of the time-to-maturity limit it proposed.

direct investments may unduly limit investments in Designated Foreign Sovereign Debt, and the Commission is therefore amending the calculation of the limitation. Under the final order, the dollar-weighted average time-tomaturity of all investments in Designated Foreign Sovereign Debit, including repurchase agreements, may not exceed 60 days. The Commission is also, however, limiting individual direct investments in Designated Foreign Sovereign Debt to securities that have a remaining maturity of 180 days or less. While the risk characteristics of Designated Foreign Sovereign Debt are broadly comparable to those of U.S. Government Securities, Designated Foreign Sovereign Debt is somewhat less liquid than U.S. Government Securities and the cap on the time-tomaturity of individual investments is intended to address that reduced liquidity.

FIA recommended using the five-year credit default swap ("CDS") spread as the measure of credit quality for Designated Foreign Sovereign Debt, arguing that the two-year CDS is thinly traded and quoted compared to the fiveyear instrument. FIA recommended permitting investments in French and German debt when the five-year CDS spread is at 60 basis points or less.

The Commission understands that the five-year CDS is more commonly traded than the two-year, but believes that the two-year spread is more suitable for this purpose because it more closely tracks the duration of the investments that DCOs will make in Designated Foreign Sovereign debt. While liquidity of the two-year product may not match that of the five-year, the Commission believes that data and quotes on the two-year spread are adequately available for their intended use as a measure of creditworthiness.

FIA noted that under the proposed exemption from Regulation 1.25(d)(2) and (7), the ICE DCOs would be required to comply with the remaining provisions of Regulation 1.25(d). FIA stated that these requirements provide important protections for customer funds employed in repurchase agreements and should not be waived. The Commission agrees and confirms that DCOs must continue to comply with all requirements in Regulation 1.25 not exempted by the order.

Eurex requested the Commission clarify that like U.S. Government Securities, Foreign Sovereign Debt is not subject to an asset-based concentration limit. The Commission confirms that the order does not subject Designated Foreign Sovereign Debt to an assetbased concentration limit. Because investments of customer funds in Designated Foreign Sovereign Debt will be limited to the amount of euro cash held by DCOs, the Commission does not believe that an asset-based concentration limit is necessary.

In addition, the Commission is amending the Proposed Order to permit DCOs a reasonable amount of time after the two-year CDS spread of France or Germany exceeds 45 basis points to determine an appropriate alternative investment or depository for funds that had been invested in a repurchase agreement for the relevant Designated Foreign Sovereign Debt. The Commission does not believe it is prudent to immediately require DCOs to locate depositories for potentially large amounts of cash without notice. The order as revised will require DCOs to stop entering into repurchase agreements as soon as practicable under the circumstances while the French or German two-year CDS spread exceeds 45 basis points. The Commission is not amending the restriction that no new direct investments in the relevant debt may be made if the two-year spread is greater than 45 basis points.

The Commission is also making a change to the Proposed Order to clarify that the exemption to Regulation 1.25(d)(2) and (7) only applies to investments in Designated Foreign Sovereign Debt and not all securities purchased with customer funds.

The Commission does not intend this order to relieve a DCO of any obligation relating to investments in Designated Foreign Sovereign Debt that would apply if Designated Foreign Sovereign Debt were a permitted investment under Commission Regulation 1.25. The Commission is adding a new paragraph to the order to clarify that certain Commission regulations apply to investments made pursuant to this order.

VI. Order

After considering the above factors and the comment letters received in response to its request for comments, the Commission has determined to issue the following:

(1) The Commission, pursuant to its authority under section 4(c) of the Commodity Exchange Act ("Act") and subject to the conditions below, hereby grants registered derivatives clearing organizations ("DCOs") a limited exemption to section 4d of the Act and to Commission Regulation 1.25(a) to permit all registered DCOs to invest euro-denominated futures and cleared swap customer funds in eurodenominated sovereign debt issued by the French Republic and the Federal

²² See Comm. on Payment and Settlement Sys. and Technical Comm. of the Int'l Org. of Sec. Comm'ns [CPSS–IOSCO, now CPMI–IOSCO] *Principles for Financial Market Infrastructures*, Princ. 7 Key Consideration 8 (2012) ("An FMI with access to central bank accounts, payment services, or security services should use these services, where practical, to enhance its management of liquidity risk.").

²³ See FIA comment letter at 3 (providing only that "[w]e see no reason why the proposed relief should not be" available to FCMs holding eurodenominated segregated balances).

Republic of Germany ("Designated Foreign Sovereign Debt").

(2) The Commission, subject to the conditions below, additionally grants:

(a) A limited exemption to Commission Regulation 1.25(d)(2) to permit registered DCOs to use customer funds to enter into repurchase agreements for Designated Foreign Sovereign Debt with foreign banks and foreign securities brokers or dealers; and

(b) A limited exemption to Commission Regulation 1.25(d)(7) to permit registered DCOs to hold Designated Foreign Sovereign Debt purchased under a repurchase agreement in a safekeeping account at a foreign bank.

(3) This order is subject to the following conditions:

(a) Investments of customer funds in Designated Foreign Sovereign Debt by a DCO must be limited to investments made with euro customer cash.

(b) If the two-year credit default spread of an issuing sovereign of Designated Foreign Sovereign Debt is greater than 45 basis points:

(i) A DCO must discontinue investing customer funds in the relevant debt through repurchase transactions as soon as practicable under the circumstances;

(ii) A DCO may not make any new direct investments in the relevant debt using customer funds. Direct investment refers to purchases of Designated Foreign Sovereign Debt unaccompanied by a contemporaneous agreement to resell the securities.

(c) The dollar-weighted average of the time-to-maturity of a DCO's portfolio of investments in each sovereign's Designated Foreign Sovereign Debt may not exceed 60 days.

(d) A DCO may not make a direct investment in any Designated Foreign Sovereign Debt that has a remaining maturity of greater than 180 calendar days.

(e) A DCO may use customer funds to enter into repurchase agreements for Designated Foreign Sovereign Debt with a counterparty that does not meet the requirements of Commission Regulation 1.25(d)(2) only if the counterparty is:

(i) A foreign bank that qualifies as a permitted depository under Commission Regulation 1.49(d)(3) and that is located in a money center country (as defined in Commission Regulation 1.49(a)(1)) or in another jurisdiction that has adopted the euro as its currency;

(ii) A securities dealer located in a money center country as defined in Commission Regulation 1.49(a)(1) that is regulated by a national financial regulator such as the UK Prudential Regulation Authority or Financial Conduct Authority, the German

Bundesanstalt für

Finanzdienstleistungsaufsicht (BaFin), the French Autorité Des Marchés Financiers (AMF) or Autorité de Contrôle Prudentiel et de Résolution (ACPR), or the Italian Commissione Nazionale per le Società e la Borsa (CONSOB); or

(iii) The European Central Bank, the Deutsche Bundesbank, or the Banque de France.

(f) A DCO may hold customer Designated Foreign Sovereign Debt purchased under a repurchase agreement with a depository that does not meet the requirements of Commission Regulation 1.25(d)(7) only if the depository meets the location and qualification requirements contained in Commission Regulation 1.49(c) and (d) and if the account complies with the requirements of Commission Regulation 1.26.

(4) A DCO must continue to comply with all other requirements in Commission Regulation 1.25, including but not limited to the counterparty concentration limits in Commission Regulation 1.25(b)(3)(v), and other applicable Commission regulations.

(5) Investments made pursuant to this order will be considered "instruments described in § 1.25" for the purposes of Commission Regulation 1.29 and will be considered to be made "in accordance with § 1.25" for the purposes of Commission Regulation 22.3.

IV. Related Matters

A. Paperwork Reduction Act

The Paperwork Reduction Act ("PRA") imposes certain requirements on federal agencies (including the Commission) in connection with their conducting or sponsoring any collection of information as defined by the PRA. This exemptive order does not involve a collection of information. Accordingly, the PRA does not apply.

B. Cost-Benefit Analysis

Section 15(a) of the CEA requires the Commission to consider the costs and benefits of its action before issuing an order under the CEA. By its terms, section 15(a) does not require the Commission to quantify the costs and benefits of an order or to determine whether the benefits of the order outweigh its costs. Rather, section 15(a) simply requires the Commission to "consider the costs and benefits" of its action. The Commission did not receive any comments on its proposed costs and benefits.

1. Baseline

The Commission's baseline for consideration of the costs and benefits

of the exemptive order are the costs and benefits that DCOs and the public would face if the Commission does not grant the order, or in other words, the status quo. In that scenario, DCOs would be limited to investing customer funds in the instruments listed in Regulation 1.25.

2. Costs and Benefits

The costs and benefits of the order are not presently susceptible to meaningful quantification. Therefore, the Commission discusses costs and benefits in qualitative terms.

The Commission does not believe granting the exemption will impose additional costs on DCOs. The order permits but does not require DCOs to invest customer funds in Designated Foreign Sovereign Debt. Each DCO may therefore decide whether to accept any costs and benefits of an investment. The Commission also does not expect the order to impose additional costs on other market participants or the public, which do not face any direct costs from the order. While other market participants or the public could potentially face costs from riskier investment activity leading to financial instability at a DCO, the Commission believes that this is unlikely, because the order prescribes limits on investments of customer funds in Designated Foreign Sovereign Debt designed to preserve principal and maintain liquidity. In addition, the flexibility to hold customer funds in Designated Foreign Sovereign Debt rather than in euro cash at a commercial bank provides risk management benefits as described above.

The Commission believes that DCOs will benefit from the order. The exemption provides DCOs additional flexibility in how they manage and hold customer funds and allows them to improve the risk management of their customer accounts. Further, if DCOs invest customer funds in Designated Foreign Sovereign Debt, other participants in the relevant market may benefit from the additional liquidity. Moreover, as described above, it is safer from a risk management perspective to hold Foreign Sovereign Debt in a safekeeping account than to hold euro cash at a commercial bank. Therefore, market participants and the public may also benefit from the exemption.

3. Section 15(a) Factors

Section 15(a) of the CEA further specifies that costs and benefits shall be evaluated in light of five broad areas of market and public concern: protection of market participants and the public; efficiency, competitiveness, and financial integrity of futures markets; price discovery; sound risk management practices; and other public interest considerations. The Commission could in its discretion give greater weight to any one of the five enumerated areas and could in its discretion determine that, notwithstanding its costs, a particular order was necessary or appropriate to protect the public interest or to effectuate any of the provisions or to accomplish any of the purposes of the CEA. The Commission is considering the costs and benefits of this exemptive order in light of the specific provisions of section 15(a) of the CEA, as follows:

1. Protection of market participants and the public. As described above, investing in the Designated Foreign Sovereign Debt as requested by the Petitioners can provide risk management benefits relative to the current alternative of holding euro collateral in a commercial bank. Granting the exemption thus serves to protect market participants and the public.

2. Efficiency, competition, and financial integrity. Granting the exemption may increase efficiency by providing DCOs additional flexibility in how they manage customer funds. Making the investments permitted by the order is elective, within the discretion of each DCO, and thus does not impose additional costs. Further, as discussed in the above, DCOs can exercise prudent risk management by investing in the Designated Foreign Sovereign Debt, which may enhance the financial integrity of the DCO.

3. *Price discovery*. The exemption is unlikely to impact price discovery in the derivatives markets.

4. Sound risk management practices. As described above, investing customer funds in the Designated Foreign Sovereign Debt is intended to advance sound risk management practices, including by limiting custodian and collateral concentration risks.

5. Other public interest considerations. The Commission believes that the relevant cost-benefit considerations are captured in the four factors above. Issued in Washington, DC, on July 19, 2018, by the Commission.

Robert Sidman,

Deputy Secretary of the Commission.

Appendix To Order Granting Exemption From Certain Provisions of the Commodity Exchange Act Regarding Investment of Customer Funds and From Certain Related Commission Regulations—Commission Voting Summary

On this matter, Chairman Giancarlo and Commissioners Quintenz and Behnam voted in the affirmative. No Commissioner voted in the negative.

[FR Doc. 2018–15860 Filed 7–24–18; 8:45 am] BILLING CODE 6351–01–P

DEPARTMENT OF DEFENSE

Office of the Department of the Air Force

Board of Visitors of the U.S. Air Force Academy; Notice of Federal Advisory Committee Meeting

AGENCY: Board of Visitors of the U.S. Air Force Academy, Department of the Air Force.

ACTION: Notice of Federal Advisory Committee meeting.

SUMMARY: On Thursday, July 5, 2018, the Department of Defense published a notice to announce a Federal Advisory Committee meeting of the Board of Visitors of the U.S. Air Force Academy to be held on July 27, 2018. Subsequent to the publication of the notice, the meeting timeframe for opening and closing was changed, as well as part of the order of agenda topics. All other information in the July 5, 2018 notice remains the same.

DATES: Open to the public Friday July 27, 2018 from 7:30 a.m. to 3:00 p.m. (Mountain Time).

ADDRESSES: United States Air Force Academy, Blue and Silver Club, Colorado Springs, CO.

FOR FURTHER INFORMATION CONTACT: Jean R. Love, (703) 692–7757 (Voice), 703– 693–4244 (Facsimile), *jean.r.love.civ@ mail.mil* (Email). Mailing address is SAF/MRM, 1660 Air Force Pentagon, Washington, DC 20330–1660. Website: *https://www.usafa.edu/about/bov/*.

Čaptain Natalie Campos, Officer of the Deputy Assistant Secretary of the Air Force, SAF/MRM, Executive Officer and Force Management Action Officer, 1660 Air Force Pentagon, Washington, DC 20330, (703) 697–7058,

natalie.m.campos.mil@mail.mil.

SUPPLEMENTARY INFORMATION: Due to circumstances beyond the control of the

Department of Defense (DoD) and the Designated Federal Officer, the meeting schedule for the previously announced meeting of the Board of Visitors of the U.S. Air Force Academy on July 27, 2018 was changed and the Designated Federal Officer to the Board of Visitors of the U.S. Air Force Academy was unable to provide sufficient public notification of this change as required by 41 CFR 102–3.150(a). Accordingly, the Advisory Committee Management Officer for the Department of Defense, pursuant to 41 CFR 102–3.150(b), waives the 15-calendar day notification requirement. This meeting is being held under the provisions of the Federal Advisory Committee Act (FACA) of 1972 (5 U.S.C., Appendix, as amended), the Government in the Sunshine Act of 1976 (5 U.S.C. 552b, as amended), and

- 41 CFR 102–3.140 and 102–3.150. Purpose of the Meeting: No change. Agenda:
- 0730–0735 Introductions & opening remarks by Designated Federal Officer (Ms. Love)
- 0735–0740 Call to Order and Agenda Overview, BoV Chairman: Gen (Ret) Rice
- 0740–0745 Chairman's Opening Comments
- 0745-0845 Superintendent's Update
- 0845–0900 Comfort Break
- 0900–0945 Commandant's Update
- 0945-1030 Dean's Update
- 1030–1100 SAPR Update
- 1100–1130 CCLD's Update
- 1130–1215 BREAK: Group Photo, Lunch served
- 1215–1315 Admissions Update
- 1315–1330 Comfort Break
- 1330–1400 Athletic Director's Update
- 1400–1430 Superintendent's Summary Remarks
- 1430–1500 Chairman's Concluding Remarks
- 1500 Public Comment/Adjourn (DFO)

Meeting Accessibility: Open to the public subject to the availability of space. Registration of members of the public who wish to attend the meeting will begin upon publication of this meeting notice and end three business days (24 July) prior to the start of the meeting. All members of the public must contact Capt Campos at the phone number or email listed in the **FOR**

FURTHER INFORMATION CONTACT. Seating is limited and is on a first-to-arrive basis. Attendees will be asked to provide their name, title, affiliation, and contact information to include email address and daytime telephone number to the POC listed in the **FOR FURTHER INFORMATION CONTACT** section. Any interested person may attend the meeting, file written comments or statements with the committee, or make verbal comments from the floor during the public meeting, at the times, and in the manner, permitted by the BoV.

Written Statements: Pursuant to 41 CFR 102-3.105(j) and 102-3.140 and section 10(a)(3) of the Federal Advisory Committee Act, the public or interested organizations may submit written comments or statements to the BoV about its mission and/or the topics to be addressed in this public meeting. Written comments or statements should be submitted to Capt Campos, via electronic mail, the preferred mode of submission, at the email address listed in the FOR FURTHER INFORMATION **CONTACT** section in the following formats: Adobe Acrobat or Microsoft Word. The comment or statement must include the author's name, title, affiliation, address, and daytime telephone number. Written comments or statements being submitted in response to the agenda set forth in this notice must be received by the committee DFO at least five (5) business days (20 July) prior to the meeting so that they may be made available to the BoV Chairman for their consideration prior to the meeting. Written comments or statements received after this date (20 July) may not be provided to the BoV until its next meeting. Please note that because the BoV operates under the provisions of the Federal Advisory Committee Act, as amended, all written comments will be treated as public documents and will be made available for public inspection.

Verbal Comments: Members of the public will be permitted to make verbal comments during the meeting only at the time and in the manner allowed herein. If a member of the public is interested in making a verbal comment at the open meeting, that individual must submit a request, with a brief statement of the subject matter to be addressed by the comment, at least three (3) business days (24 July) in advance, via electronic mail, the preferred mode of submission, at the email address listed in the FOR FURTHER INFORMATION CONTACT section. The BoV DFO will log each request to make a comment, in the order received, and the DFO and BoV Chairman will determine whether the subject matter of each comment is relevant to the BoV's mission and/or the topics to be addressed in this public meeting. A period near the end of the meeting will be available for verbal public comments. Members of the public who have requested to make a verbal comment and whose comments have been deemed relevant under the process described in this paragraph, will be allotted no more than five (5) minutes during this period, and will be

invited to speak in the order in which their requests were received by the DFO. For the benefit of the public, rosters that list the names of BoV members and any releasable materials presented during the BoV meeting shall be made available upon request.

Henry Williams,

Acting Air Force Federal Register Liaison Officer, Department of Defense. [FR Doc. 2018–15898 Filed 7–24–18; 8:45 am] BILLING CODE 5001–10–P

DEPARTMENT OF DEFENSE

Department of the Air Force

Exchange of Air Force Real Property for Non-Air Force Real Property

AGENCY: Air Force Civil Engineer Center, United States Air Force, DoD. **ACTION:** Notice of intent.

SUMMARY: The Air Force is publishing this Notice to identify Federal real property that it intends to exchange for property that is needed by the Air Force to limit encroachment and other constraints on military operations at Melrose Air Force Range (MAFR), NM.

FOR FURTHER INFORMATION CONTACT: Mr. Joe Weathersby, Air Force Civil Engineer Center (AFCEC/CIUB), 2261 Hughes Avenue, Suite 155, Joint Base San Antonio (JBSA) Lackland, TX 78236–9853; telephone (210) 395–9516. SUPPLEMENTARY INFORMATION: MAFR is a long established training range, consisting of some 70,000 acres, 25 miles west of Cannon Air Force Base, New Mexico. Operations on Melrose Range also cover an area of 2,500 square miles of airspace. Melrose is used for training such as air to ground, small arms, and electronic combat.

Description of the Air Force Property: Approximately 1,240 acres of undeveloped rangeland located on the southern perimeter of MAFR in Township 1S, Ranges 29E and 30E, in Roosevelt County, New Mexico. This undeveloped land is adjacent to private ranchlands owned by Davis Mesa Ranch, LLC, Davis Arch Ranch, LLC, and Davis Spear Ranch, LLC. The ranchland properties represent ideal conditions for the commercial development of wind energy generation. For the exchange of 1,240 acres of Air Force real property the owner of these properties has agreed to convey 160 acres of ranchland on the eastern perimeter of the range utilizing 10 U.S.C. 2869 authority.

In conjunction with the exchange, the same landowner has agreed to convey a perpetual restrictive use easement on 29,319 acres to protect those acres adjoining MAFR from incompatible land uses. 10 U.S.C. 2869 authorizes the Air Force to convey real property at an installation in exchange for property interests to be acquired under the terms of an encroachment protection agreement executed in accordance with Title 10 U.S.C. 2684a. The Air Force executed an encroachment management agreement with The Conservation Fund on July 21, 2017.

The Air Force has notified the appropriate Congressional committees of the terms and conditions of the proposed exchange pursuant to 10 U.S.C. 2869(d)(2).

Authority: 10 U.S.C. 2869(d)(1) and 10 U.S.C. 2684a(d)(4)(B).

Dated: July 19, 2018.

Henry Williams,

Acting Air Force Federal Register Liaison Officer.

[FR Doc. 2018–15901 Filed 7–24–18; 8:45 am] BILLING CODE P

DEPARTMENT OF EDUCATION

Applications for New Awards; Technical Assistance and Dissemination To Improve Services and Results for Children With Disabilities—Center on Dispute Resolution

AGENCY: Office of Special Education and Rehabilitative. Services, Department of Education.

ACTION: Notice.

SUMMARY: The Department of Education is issuing a notice inviting applications for new awards for fiscal year (FY) 2018 for Technical Assistance and Dissemination to Improve Services and Results for Children With Disabilities— Center on Dispute Resolution, Catalog of Federal Domestic Assistance (CFDA) number 84.326X.

DATES:

Applications Available: July 25, 2018. Deadline for Transmittal of

Applications: August 24, 2018. ADDRESSES: For the addresses for obtaining and submitting an application, please refer to our Common Instructions for Applicants to Department of Education Discretionary Grant Programs, published in the Federal Register on February 12, 2018 (83 FR 6003) and available at www.gpo.gov/fdsys/pkg/FR-2018-02-12/ pdf/2018-02558.pdf.

FOR FURTHER INFORMATION CONTACT: Tina Diamond, U.S. Department of Education, 400 Maryland Avenue SW, Room 5136, Potomac Center Plaza, Washington, DC 20202–5108. Telephone: (202) 245–6674.

If you use a telecommunications device for the deaf (TDD) or a text telephone (TTY), call the Federal Relay Service (FRS), toll free, at 1–800–877– 8339.

SUPPLEMENTARY INFORMATION:

Full Text of Announcement

I. Funding Opportunity Description

Purpose of Program: The purpose of the Technical Assistance and Dissemination to Improve Services and Results for Children with Disabilities program is to promote academic achievement and to improve results for children with disabilities by providing technical assistance, supporting model demonstration projects, disseminating useful information, and implementing activities that are supported by scientifically based research.

Priority: In accordance with 34 CFR 75.105(b)(2)(v), this priority is from allowable activities specified in the statute (see sections 663 and 681(d) of the Individuals with Disabilities Education Act (IDEA); 20 U.S.C. 1463 and 1481(d)).

Absolute Priority: For FY 2018 and any subsequent year in which we make awards from the list of unfunded applications from this competition, this priority is an absolute priority. Under 34 CFR 75.105(c)(3), we consider only applications that meet this priority.

This priority is:

Center on Dispute Resolution. Background: The mission of the Office of Special Education and Rehabilitative Services (OSERS) is to improve early childhood, educational, and employment outcomes and raise expectations for all people with disabilities, their families, their communities, and the Nation. This priority is consistent with Supplemental Priority 1 in the Secretary's Final Supplemental Priorities and Definitions for Discretionary Grant Programs, published in the Federal Register on March 2, 2018 (83 FR 9096) (Supplemental Priorities)—Empowering Families and Individuals To Choose a **High-Quality Education That Meets** Their Unique Needs; and Supplemental Priority 5—Meeting the Unique Needs of Students and Children With Disabilities and/or Those With Unique Gifts and Talents.

IDEA includes procedural safeguards that are designed to protect the rights of children with disabilities and their parents and to provide parents with mechanisms for resolving, at the earliest point in time, disputes with those who provide services to children with

disabilities (State educational agencies (SEAs), local educational agencies (LEAs), schools, Part C State lead agencies, and early intervention service (EIS) providers). The procedural safeguards include the opportunity to seek a timely resolution of disputes about establishing a child's eligibility under IDEA and providing a free appropriate public education (FAPE) to an eligible child or the appropriate EIS to infants and toddlers with disabilities. Thus, IDEA encourages constructive relationships between parents of children with disabilities and those who provide services to children with disabilities by facilitating open communication between the parents and these entities and encouraging early resolution of disputes so that disagreements do not escalate and become adversarial and result in a delay in identifying, and providing needed services to, eligible children. IDEA's dispute resolution procedures include provisions for State complaints, mediation, due process complaints, and resolution sessions, as described below.

State Complaints. IDEA's State complaint procedures permit parents and other interested individuals or organizations to file a complaint with the SEA or Part C State lead agency to seek resolution of any alleged violations of IDEA. The goal of the State complaint procedures is to resolve disputes while avoiding costly or time-consuming due process hearings (34 CFR 300.151 through 300.153—Part B regulations; 34 CFR 303.432 through 303.434—Part C regulations). The State complaint procedures provide an important means of ensuring that the educational or early intervention needs of children with disabilities are met (34 CFR 300.151 and 303.432).

Mediation. In response to increasing numbers of due process complaints under Part B of IDEA, Congress amended IDEA in 1997 to require SEAs and Part C State lead agencies to make mediation available, at a minimum, whenever a due process complaint is filed. In 2004, Congress further amended section 615(e) of IDEA to allow parties to use mediation to resolve disputes involving any matter under IDEA, not just those matters that are the subject of a due process complaint, thus making mediation available at any time and on any matter under IDEA. (This amendment also applies to Part C through section 639(a)(8) of IDEA.) In mediation, the goal is for a neutral third party to facilitate the resolution of disputes without the need for an adversarial hearing. Thus, mediation is more likely than due process hearings to foster positive relationships between

families and educators and EIS providers (Government Accountability Office, 2003).

Due Process Hearings. In due process hearings, IDEA requires that an impartial, knowledgeable decisionmaker resolve disputes. While due process hearings are an important protection, they can be costly, timeconsuming, and contentious, and they may damage relationships between the parties involved in the dispute.

Resolution Session. The 2004 amendments to IDEA added a requirement for a resolution session prior to a due process hearing. The resolution session requirement applies to all IDEA Part B due process complaints and to those IDEA Part C due process complaints filed in a State that has elected to adopt the Part B-type due process hearing procedures in 34 CFR 303.440 through 303.449. Under section 615(f)(1)(B) of IDEA, the LEA (or in the case of IDEA Part C, under 34 CFR 303.442, the State lead agency) must convene a meeting with the parents and relevant members of the child's individualized education program (IEP) or individualized family service plan (IFSP) team who have specific knowledge of the facts identified in the complaint. This provides the parents and the agency responsible for providing service to a child with an opportunity to resolve the complaint and avoid a due process hearing.

Early Resolution Practices. In addition to these methods of dispute resolution specifically required under IDEA, there are a variety of informal or "early resolution" practices that can be used to resolve disputes at the school or district level and avoid time-consuming and costly litigation.

Each SEA and Part C State lead agency is responsible for annually reporting data on dispute resolution activity to the Office of Special Education Programs (OSEP) to help determine the extent to which States effectively implement dispute resolution practices. The data collected by OSEP include information on the timeliness of State complaint reports and due process hearing decisions, the percentage of due process complaints that were resolved through settlement agreements, and mediations resulting in agreements.

An analysis of national data trends in dispute resolution conducted by the Center for Appropriate Dispute Resolution in Special Education (CADRE) shows declines in processes, such as written State complaints and due process complaints, and increases in the use of collaborative approaches, such as mediation and IEP facilitation (CADRE, 2017). However, OSEP's most recent analysis of Annual Performance Reports (APRs) shows that States continue to fall short of their targets for agreement rates in resolution sessions. A survey of State officials indicated that a lack of public awareness about early resolution practices presents a challenge to expanding their use, which demonstrates a need for additional technical assistance (TA), dissemination of information, and coordination with parent organizations (Government Accountability Office, 2014). OSEPfunded parent TA providers have noted that this lack of awareness is prevalent among vulnerable populations due to language, informational, or economic barriers.

Priority: The purpose of this priority is to fund a cooperative agreement to establish and operate a Center on Dispute Resolution (Center). This Center will provide TA to SEAs, Part C State lead agencies, and OSEP-funded parent centers to improve the implementation of all of the dispute resolution practices required under IDEA, along with any optional early resolution strategies that may be available. The Center must achieve, at a minimum, the following expected outcomes:

(a) Increased capacity of SEAs and Part C State lead agencies to support local implementation of effective early resolution practices to resolve disputes and thereby decrease State complaints and due process complaints;

(b) Increased capacity of SEAs and Part C State lead agencies to collect, report, and use high-quality dispute resolution data;

(c) Increased body of knowledge on dispute prevention and exemplary dispute resolution practices to meet the dispute resolution needs of parents and families, including those from vulnerable populations who may be less likely to access dispute resolution due to language, informational, or economic barriers;

(d) Improved access for hearing officers to information on emerging issues related to special education and early intervention dispute resolution;

(e) Improved ability of SEAs and Part C State lead agencies to implement a range of dispute resolution options, including methods of dispute resolution required under IDEA and early resolution practices and to support SEAs and Part C State lead agencies in ensuring that dispute resolution options are not affected by administrative constraints (*e.g.*, staffing or target agreement rates for mediation agreements and resolution sessions); (f) Improved capacity of OSEP-funded parent centers to provide TA on the range of effective dispute resolution options;

(g) Increased knowledge of OSEPfunded parent centers, parents, and families about school choice as it relates to due process and procedural safeguards under IDEA; and

(h) An annual analysis of State and national trends and other data about dispute resolution to determine the extent to which SEAs and Part C State lead agencies have—

(i) Met the required timelines when resolving State complaints and issuing due process hearing decisions;

(ii) Used resolution meetings and mediation to successfully resolve disputes between parents and LEAs or EIS providers; and

(iii) Implemented effective methods of early dispute resolution.

In addition to these programmatic requirements, to be considered for funding under this priority, applicants must meet the application and administrative requirements in this priority, which are:

(a) Demonstrate, in the narrative section of the application under "Significance of the Project," how the proposed project will—

(1) Address gaps or weaknesses in State or local dispute resolution performance and compliance to meet the dispute resolution needs of SEA and Part C State lead agency personnel, as well as the needs of parents and families, including those from vulnerable populations who may be less likely to access dispute resolution due to language, informational, or economic barriers. To meet this requirement the applicant must—

(i) Demonstrate knowledge of exemplary dispute resolution practices that will assist SEAs and Part C State lead agencies in improving dispute resolution, especially practices that will assist agencies in meeting compliance and performance targets and implementing effective early resolution practices;

(ii) Present information about the current level of implementation of exemplary dispute resolution practices in SEAs and Part C State lead agencies, especially practices that will assist agencies in meeting compliance and performance targets and implementing effective early resolution practices; and

(iii) Present national, State, or local data on the financial and administrative burden of involvement in dispute resolution and discuss strategies for minimizing these burdens for all parties involved. (2) Improve outcomes in dispute resolution compliance and performance for SEAs and Part C State lead agencies and increase the implementation of early resolution practices.

(3) Improve communication between parents and families and education professionals to minimize conflict and increase the use of collaborative problem-solving and dispute resolution practices.

(b) Demonstrate, in the narrative section of the application under "Quality of the Project Services," how the proposed project will—

(1) Ensure equal access and treatment for members of groups that have traditionally been underrepresented based on race, color, national origin, gender, age, or disability. To meet this requirement, the applicant must describe how it will—

(i) Identify the needs of the intended recipients for TA and information; and

(ii) Ensure that services and products meet the needs of the intended recipients of the grant;

(2) Achieve its goals, objectives, and intended outcomes. To meet this requirement, the applicant must provide—

(i) Measurable intended project outcomes; and

(ii) In Appendix A, the logic model (as defined in this notice) by which the proposed project will achieve its intended outcomes that depicts, at a minimum, the goals, activities, outputs, and intended outcomes of the proposed project;

(3) Use a conceptual framework (and provide a copy in Appendix A) to develop project plans and activities, describing any underlying concepts, assumptions, expectations, beliefs, or theories, as well as the presumed relationships or linkages among these variables, and any empirical support for this framework;

Note: The following websites provide more information on logic models and conceptual frameworks: www.osepideasthatwork.org/logicModel and www.osepideasthatwork.org/ resources-grantees/program-areas/ta-ta/ tad-project-logic-model-and-conceptualframework.

(4) Be based on current research on effective dispute resolution practices, provide services that assist SEAs and Part C State lead agencies to comply with IDEA requirements, and draw from the knowledge base of effective early resolution evidence-based (as defined in this notice) practices (EBPs). To meet this requirement, the applicant must describe(i) The current research on effective dispute resolution practices, including early resolution EBPs;

(ii) The current research about adult learning principles and implementation science that will inform the proposed TA; and

(iii) How the proposed project will incorporate current research and EBPs in the development and delivery of its products and services;

(5) Develop products and provide services that are of high quality and sufficient intensity and duration to achieve the intended outcomes of the proposed project. To address this requirement, the applicant must describe—

(i) How it proposes to identify or develop the knowledge base in special education dispute resolution;

(ii) Its proposed approach to universal, general TA,¹ which must identify the intended recipients, including the type and number of recipients, that will receive the products and services, a description of the products and services that the Center proposes to make available, and the expected impact of those products and services under this approach;

(iii) Its proposed approach to targeted, specialized TA,² which must identify—

(A) The intended recipients, including the type and number of recipients, that will receive the products and services, a description of the products and services that the Center proposes to make available, and the expected impact of those products and services under this approach; and

(B) Its proposed approach to measure the dispute resolution needs and readiness of potential TA recipients to work with the project, assessing, at a minimum, their current infrastructure,

² "Targeted, specialized TA" means TA services based on needs common to multiple recipients and not extensively individualized. A relationship is established between the TA recipient and one or more TA center staff. This category of TA includes one-time, labor-intensive events, such as facilitating strategic planning or hosting regional or national conferences. It can also include episodic, less laborintensive events that extend over a period of time, such as facilitating a series of conference calls on single or multiple topics that are designed around the needs of the recipients. Facilitating communities of practice can also be considered targeted, specialized TA. available resources, and ability to build capacity at the local level; and

(iv) Its proposed approach to intensive, sustained TA,³ which must identify—

(A) The intended recipients, including the type and number of recipients, that will receive the products and services, a description of the products and services that the Center proposes to make available, and the expected impact of those products and services under this approach;

(B) Its proposed approach to measure the dispute resolution needs and readiness of SEAs, Part C State lead agencies, and parent centers to work with the project, including their commitment to the initiative, alignment of the initiative to their needs, current infrastructure, available resources, and ability of the SEAs, Part C State lead agencies, and parent centers to build capacity at the local school district or program level;

(Č) Its proposed plan for assisting SEAs and Part C State lead agencies to build or enhance training systems related to special education dispute resolution that include professional development based on adult learning principles and coaching; and

(D) Its proposed plan for working with appropriate levels of the education system (*e.g.*, SEAs, Part C State lead agencies, regional TA providers, parents and families) to ensure that there is communication between each level and that there are systems in place to support the use of effective dispute resolution practices, including early resolution EBPs;

(6) Develop products and implement services that are impartial and maximize efficiency. To address this requirement, the applicant must describe—

(i) How the proposed project will use technology to achieve the intended project outcomes;

(ii) With whom the proposed project will collaborate and the intended outcomes of this collaboration; and

(iii) How the proposed project will use non-project resources to achieve the intended project outcomes.

(c) In the narrative section of the application under "Quality of the Evaluation Plan," include an evaluation plan for the project as described in the following paragraphs. The evaluation plan must describe: Measures of progress in implementation, including the criteria for determining the extent to which the project's products and services have met the goals for reaching its target population; measures of intended outcomes or results of the project's activities in order to evaluate those activities; and how well the goals or objectives of the proposed project, as described in its logic model, have been met.

The applicant must provide an assurance that, in designing the evaluation plan, it will—

(1) Designate, with the approval of the OSEP project officer, a project liaison staff person with sufficient dedicated time, experience in evaluation, and knowledge of the project to work in collaboration with the Center to Improve Program and Project Performance (CIP3),⁴ the project director, and the OSEP project officer on the following tasks:

(i) Revise, as needed, the logic model submitted in the application to provide for a more comprehensive measurement of implementation and outcomes and to reflect any changes or clarifications to the model discussed at the kick-off meeting;

(ii) Refine the evaluation design and instrumentation proposed in the application consistent with the logic model (*e.g.*, prepare evaluation questions about significant program processes and outcomes; develop quantitative or qualitative data collections that permit both the collection of progress data, including fidelity of implementation, as appropriate, and the assessment of project outcomes; and identify analytic strategies); and

(iii) Revise, as needed, the evaluation plan submitted in the application such that it clearly—

(A) Specifies the measures and associated instruments or sources for data appropriate to the evaluation questions, suggests analytic strategies for those data, provides a timeline for conducting the evaluation, and includes staff assignments for completing the plan;

¹ "Universal, general TA" means TA and information provided to independent users through their own initiative, resulting in minimal interaction with TA center staff and including onetime, invited or offered conference presentations by TA center staff. This category of TA also includes information or products, such as newsletters, guidebooks, or research syntheses, downloaded from the TA center's website by independent users. Brief communications by TA center staff with recipients, either by telephone or email, are also considered universal, general TA.

³ "Intensive, sustained TA" means TA services often provided on-site and requiring a stable, ongoing relationship between the TA center staff and the TA recipient. "TA services" are defined as negotiated series of activities designed to reach a valued outcome. This category of TA should result in changes to policy, program, practice, or operations that support increased recipient capacity or improved outcomes at one or more systems levels.

⁴ The major tasks of CIP3 are to guide, coordinate, and oversee the design of formative evaluations for every large discretionary investment (*i.e.*, those awarded \$500,000 or more per year and required to participate in the 3+2 process) in OSEP's Technical Assistance and Dissemination; Personnel Development; Parent Training and Information Centers; and Educational Technology, Media, and Materials programs. The efforts of CIP3 are expected to enhance individual project evaluation plans by providing expert and unbiased TA in designing the evaluations with due consideration of the project's budget. CIP3 does not function as a third-party evaluator.

(B) Delineates the data expected to be available by the end of the second project year for use during the project's evaluation (3+2 review) for continued funding described under the heading *Fourth and Fifth Years of the Project;* and

(C) Can be used to assist the project director and the OSEP project officer, with the assistance of CIP3, as needed, to specify the performance measures to be addressed in the project's Annual Performance Report;

(2) Cooperate with CIP3 staff in order to accomplish the tasks described in paragraph (1) of this section; and

(3) Dedicate sufficient funds in each budget year to cover the costs of carrying out the tasks described in paragraphs (1) and (2) of this section and implementing the evaluation plan.

(d) Demonstrate, in the narrative section of the application under "Adequacy of Project Resources," how—

(1) The proposed project will encourage applications for employment from persons who are members of groups that have traditionally been underrepresented based on race, color, national origin, gender, age, or disability, as appropriate;

(2) The proposed key project personnel, consultants, and subcontractors have the qualifications and experience to carry out the proposed activities and achieve the project's intended outcomes;

(3) The applicant and any key partners have adequate resources to carry out the proposed activities; and

(4) The proposed costs are reasonable in relation to the anticipated results and benefits.

(e) Demonstrate, in the narrative section of the application under "Quality of the Management Plan," how—

(1) The proposed management plan will ensure that the project's intended outcomes will be achieved on time and within budget. To address this requirement, the applicant must describe—

(i) Clearly defined responsibilities for key project personnel, consultants, and subcontractors, as applicable; and

(ii) Timelines and milestones for accomplishing the project tasks;

(2) Key project personnel and any consultants and subcontractors will be allocated and how these allocations are appropriate and adequate to achieve the project's intended outcomes;

(3) The proposed management plan will ensure that the products and services provided are of high quality, relevant, and useful to recipients; and (4) The proposed project will benefit from a diversity of perspectives, including those of families, educators, TA providers, researchers, and policy makers, among others, in its development and operation.

(f) Address the following application requirements. The applicant must—

(1) Include, in Appendix A, personnel-loading charts and timelines, as applicable, to illustrate the management plan described in the narrative;

(2) Include, in the budget, attendance at the following:

(i) A one and one-half day kick-off meeting in Washington, DC, after receipt of the award, and an annual planning meeting, with the OSEP project officer and other relevant staff during each subsequent year of the project period.

Note: Within 30 days of receipt of the award, a post-award teleconference must be held between the OSEP project officer and the grantee's project director or other authorized representative;

(ii) A two and one-half day project directors' conference in Washington, DC, during each year of the project period;

(iii) Two annual two-day trips to attend Department briefings, Department-sponsored conferences, and other meetings, as requested by OSEP; and

(iv) A one-day intensive 3+2 review meeting during the last half of the second year of the project period;

(3) Include, in the budget, a line item for an annual set-aside of five percent of the grant amount to support emerging needs that are consistent with the proposed project's intended outcomes, as those needs are identified in consultation with, and approved by, the OSEP project officer. With approval from the OSEP project officer, the project must reallocate any remaining funds from this annual set-aside no later than the end of the third quarter of each budget period;

(4) Maintain a high-quality website, with an easy-to-navigate design, that meets government or industryrecognized standards for accessibility; and

(5) Include, in Appendix A, an assurance to assist OSEP with the transfer of pertinent resources and products and to maintain the continuity of services to TA recipients during the transition to this new award period and at the end of this award period, as appropriate.

Fourth and Fifth Years of the Project:

In deciding whether to continue funding the project for the fourth and fifth years, the Secretary will consider the requirements of 34 CFR 75.253(a), as well as—

(a) The recommendation of a 3+2 review team consisting of experts selected by the Secretary. This review will be conducted during a one-day intensive meeting that will be held during the last half of the second year of the project period;

(b) The timeliness with which, and how well, the requirements of the negotiated cooperative agreement have been or are being met by the project; and

(c) The quality, relevance, and usefulness of the project's products and services and the extent to which the project's products and services are aligned with the project's objectives and likely to result in the project achieving its intended outcomes.

References

- Center for Appropriate Dispute Resolution in Special Education (CADRE). (2017). Trends in dispute resolution under the Individuals with Disabilities Education Act (IDEA). Eugene, OR: CADRE. Retrieved from www.cadreworks.org/ sites/default/files/TrendsinDispute Resolution%20DEC17.pdf.
- Government Accountability Office. (2003). Numbers of formal disputes are generally low and States are using mediation and other strategies to resolve conflicts (GAO Publication No. 03–897). Washington, DC: Government Printing Office.
- Government Accountability Office. (2014). Improved performance measures could enhance oversight of dispute resolution (GAO Publication No. 14–390). Washington, DC: Government Printing Office.

Definitions: The following definitions are from 34 CFR 77.1:

Demonstrates a rationale means a key project component included in the project's logic model is informed by research or evaluation findings that suggest the project component is likely to improve relevant outcomes.

Evidence-based means the proposed project component is supported by one or more of strong evidence, moderate evidence, promising evidence, or evidence that demonstrates a rationale.

Experimental study means a study that is designed to compare outcomes between two groups of individuals (such as students) that are otherwise equivalent except for their assignment to either a treatment group receiving a project component or a control group that does not. Randomized controlled trials, regression discontinuity design studies, and single-case design studies are the specific types of experimental studies that, depending on their design and implementation (*e.g.*, sample attrition in randomized controlled trials and regression discontinuity design studies), can meet What Works Clearinghouse (WWC) standards without reservations as described in the WWC Handbook:

(i) A randomized controlled trial employs random assignment of, for example, students, teachers, classrooms, or schools to receive the project component being evaluated (the treatment group) or not to receive the project component (the control group).

(ii) A regression discontinuity design study assigns the project component being evaluated using a measured variable (*e.g.*, assigning students reading below a cutoff score to tutoring or developmental education classes) and controls for that variable in the analysis of outcomes.

(iii) A single-case design study uses observations of a single case (*e.g.*, a student eligible for a behavioral intervention) over time in the absence and presence of a controlled treatment manipulation to determine whether the outcome is systematically related to the treatment.

Logic model (also referred to as a theory of action) means a framework that identifies key project components of the proposed project (*i.e.*, the active "ingredients" that are hypothesized to be critical to achieving the relevant outcomes) and describes the theoretical and operational relationships among the key project components and relevant outcomes.

Moderate evidence means that there is evidence of effectiveness of a key project component in improving a relevant outcome for a sample that overlaps with the populations or settings proposed to receive that component, based on a relevant finding from one of the following:

(i) A practice guide prepared by the WWC using version 2.1 or 3.0 of the WWC Handbook reporting a "strong evidence base" or "moderate evidence base" for the corresponding practice guide recommendation;

(ii) An intervention report prepared by the WWC using version 2.1 or 3.0 of the WWC Handbook reporting a "positive effect" or "potentially positive effect" on a relevant outcome based on a "medium to large" extent of evidence, with no reporting of a "negative effect" or "potentially negative effect" on a relevant outcome; or

(iii) A single experimental study or quasi-experimental design study reviewed and reported by the WWC using version 2.1 or 3.0 of the WWC Handbook, or otherwise assessed by the Department using version 3.0 of the WWC Handbook, as appropriate, and that(A) Meets WWC standards with or without reservations;

(B) Includes at least one statistically significant and positive (*i.e.*, favorable) effect on a relevant outcome;

(C) Includes no overriding statistically significant and negative effects on relevant outcomes reported in the study or in a corresponding WWC intervention report prepared under version 2.1 or 3.0 of the WWC Handbook; and

(D) Is based on a sample from more than one site (*e.g.*, State, county, city, school district, or postsecondary campus) and includes at least 350 students or other individuals across sites. Multiple studies of the same project component that each meet requirements in paragraphs (iii)(A), (B), and (C) of this definition may together satisfy this requirement.

Project component means an activity, strategy, intervention, process, product, practice, or policy included in a project. Evidence may pertain to an individual project component or to a combination of project components (*e.g.*, training teachers on instructional practices for English learners and follow-on coaching for these teachers).

Promising evidence means that there is evidence of the effectiveness of a key project component in improving a relevant outcome, based on a relevant finding from one of the following:

(i) A practice guide prepared by WWC reporting a "strong evidence base" or "moderate evidence base" for the corresponding practice guide recommendation;

(ii) An intervention report prepared by the WWC reporting a "positive effect" or "potentially positive effect" on a relevant outcome with no reporting of a "negative effect" or "potentially negative effect" on a relevant outcome; or

(iii) A single study assessed by the Department, as appropriate, that—

(A) Is an experimental study, a quasiexperimental design study, or a welldesigned and well-implemented correlational study with statistical controls for selection bias (*e.g.*, a study using regression methods to account for differences between a treatment group and a comparison group); and

(B) Includes at least one statistically significant and positive (*i.e.*, favorable) effect on a relevant outcome.

Quasi-experimental design study means a study using a design that attempts to approximate an experimental study by identifying a comparison group that is similar to the treatment group in important respects. This type of study, depending on design and implementation (*e.g.*, establishment of baseline equivalence of the groups being compared), can meet WWC standards with reservations, but cannot meet WWC standards without reservations, as described in the WWC Handbook.

Relevant outcome means the student outcome(s) or other outcome(s) the key project component is designed to improve, consistent with the specific goals of the program.

Strong evidence means that there is evidence of the effectiveness of a key project component in improving a relevant outcome for a sample that overlaps with the populations and settings proposed to receive that component, based on a relevant finding from one of the following:

(i) A practice guide prepared by the WWC using version 2.1 or 3.0 of the WWC Handbook reporting a "strong evidence base" for the corresponding practice guide recommendation;

(ii) An intervention report prepared by the WWC using version 2.1 or 3.0 of the WWC Handbook reporting a "positive effect" on a relevant outcome based on a "medium to large" extent of evidence, with no reporting of a "negative effect" or "potentially negative effect" on a relevant outcome; or

(iii) A single experimental study reviewed and reported by the WWC using version 2.1 or 3.0 of the WWC Handbook, or otherwise assessed by the Department using version 3.0 of the WWC Handbook, as appropriate, and that—

(A) Meets WWC standards without reservations;

(B) Includes at least one statistically significant and positive (*i.e.*, favorable) effect on a relevant outcome;

(C) Includes no overriding statistically significant and negative effects on relevant outcomes reported in the study or in a corresponding WWC intervention report prepared under version 2.1 or 3.0 of the WWC Handbook; and

(D) Is based on a sample from more than one site (*e.g.*, State, county, city, school district, or postsecondary campus) and includes at least 350 students or other individuals across sites. Multiple studies of the same project component that each meet requirements in paragraphs (iii)(A), (B), and (C) of this definition may together satisfy this requirement.

What Works Clearinghouse Handbook (WWC Handbook) means the standards and procedures set forth in the WWC Procedures and Standards Handbook, Version 3.0 or Version 2.1 (incorporated by reference, see 34 CFR 77.2). Study findings eligible for review under WWC standards can meet WWC standards without reservations, meet WWC standards with reservations, or not meet WWC standards. WWC practice guides and intervention reports include findings from systematic reviews of evidence as described in the Handbook documentation.

Waiver of Proposed Rulemaking: Under the Administrative Procedure Act (APA) (5 U.S.C. 553) the Department generally offers interested parties the opportunity to comment on proposed priorities and requirements. Section 681(d) of IDEA, however, makes the public comment requirements of the APA inapplicable to the priority in this notice.

Program Authority: 20 U.S.C. 1463 and 1481.

Applicable Regulations: (a) The Education Department General Administrative Regulations in 34 CFR parts 75, 77, 79, 81, 82, 84, 86, 97, 98, and 99. (b) The Office of Management and Budget Guidelines to Agencies on Governmentwide Debarment and Suspension (Nonprocurement) in 2 CFR part 180, as adopted and amended as regulations of the Department in 2 CFR part 3485. (c) The Uniform Administrative Requirements, Cost Principles, and Audit Requirements for Federal Awards in 2 CFR part 200, as adopted and amended as regulations of the Department in 2 CFR part 3474.

Note: The regulations in 34 CFR part 79 apply to all applicants except federally recognized Indian Tribes.

Note: The regulations in 34 CFR part 86 apply to institutions of higher education (IHEs) only.

II. Award Information

Type of Award: Cooperative agreement.

Estimated Available Funds: \$750,000. Contingent upon the availability of funds and the quality of applications, we may make additional awards in FY 2019 from the list of unfunded applications from this competition.

Maximum Award: We will not make an award exceeding \$750,000 for a single budget period of 12 months.

Estimated Number of Awards: 1. *Note:* The Department is not bound by

any estimates in this notice. *Project Period:* Up to 60 months.

III. Eligibility Information

1. *Eligible Applicants:* SEAs; LEAs, including public charter schools that operate as LEAs under State law; IHEs; other public agencies; private nonprofit organizations; freely associated States and outlying areas; Indian Tribes or Tribal organizations; and for-profit organizations.

2. *Cost Sharing or Matching:* This program does not require cost sharing or matching.

3. Subgrantees: Under 34 CFR 75.708(b) and (c) a grantee under this competition may award subgrants—to directly carry out project activities described in its application—to the following types of entities: IHEs and private nonprofit organizations suitable to carry out the activities proposed in the application. The grantee may award subgrants to entities it has identified in an approved application.

4. *Other:* (a) Recipients of funding under this competition must make positive efforts to employ and advance in employment qualified individuals with disabilities (see section 606 of IDEA).

(b) Applicants for, and recipients of, funding must, with respect to the aspects of their proposed project relating to the absolute priority, involve individuals with disabilities, or parents of individuals with disabilities ages birth through 26, in planning, implementing, and evaluating the project (see section 682(a)(1)(A) of IDEA).

IV. Application and Submission Information

1. Application Submission Instructions: For information on how to submit an application please refer to our Common Instructions for Applicants to Department of Education Discretionary Grant Programs, published in the **Federal Register** on February 12, 2018 (83 FR 6003) and available at www.gpo.gov/fdsys/pkg/FR-2018-02-12/ pdf/2018-02558.pdf.

2. Intergovernmental Review: This competition is subject to Executive Order 12372 and the regulations in 34 CFR part 79. However, under 34 CFR 79.8(a), we waive intergovernmental review in order to make an award by the end of FY 2018.

3. Funding Restrictions: We reference regulations outlining funding restrictions in the Applicable Regulations section of this notice.

4. *Recommended Page Limit:* The application narrative (Part III of the application) is where you, the applicant, address the selection criteria that reviewers use to evaluate your application. We recommend that you (1) limit the application narrative to no more than 70 pages and (2) use the following standards:

• A "page" is 8.5" x 11", on one side only, with 1" margins at the top, bottom, and both sides.

• Double space (no more than three lines per vertical inch) all text in the application narrative, including titles, headings, footnotes, quotations, reference citations, and captions, as well as all text in charts, tables, figures, graphs, and screen shots.

• Use a font that is 12 point or larger.

• Use one of the following fonts: Times New Roman, Courier, Courier New, or Arial.

The recommended page limit does not apply to Part I, the cover sheet; Part II, the budget section, including the narrative budget justification; Part IV, the assurances and certifications; or the abstract (follow the guidance provided in the application package for completing the abstract), the table of contents, the list of priority requirements, the resumes, the reference list, the letters of support, or the appendices. However, the recommended page limit does apply to all of the application narrative, including all text in charts, tables, figures, graphs, and screen shots.

V. Application Review Information

1. *Selection Criteria:* The selection criteria for this competition are from 34 CFR 75.210 and are as follows:

(a) Significance (10 points).

(1) The Secretary considers the significance of the proposed project.

(2) In determining the significance of the proposed project, the Secretary considers the following factors:

(i) The extent to which specific gaps or weaknesses in services, infrastructure, or opportunities have been identified and will be addressed by the proposed project, including the nature and magnitude of those gaps or weaknesses.

(ii) The importance or magnitude of the results or outcomes likely to be attained by the proposed project.

(b) Quality of project services (35 points).

(1) The Secretary considers the quality of the services to be provided by the proposed project.

(2) In determining the quality of the services to be provided by the proposed project, the Secretary considers the quality and sufficiency of strategies for ensuring equal access and treatment for eligible project participants who are members of groups that have traditionally been underrepresented based on race, color, national origin, gender, age, or disability.

(3) In addition, the Secretary considers the following factors:

(i) The extent to which the goals, objectives, and outcomes to be achieved by the proposed project are clearly specified and measurable.

(ii) The extent to which there is a conceptual framework underlying the proposed research or demonstration activities and the quality of that framework.

(iii) The extent to which the services to be provided by the proposed project reflect up-to-date knowledge from research and effective practice.

(iv) The extent to which the training or professional development services to be provided by the proposed project are of sufficient quality, intensity, and duration to lead to improvements in practice among the recipients of those services.

(v) The extent to which the technical assistance services to be provided by the proposed project involve the use of efficient strategies, including the use of technology, as appropriate, and the leveraging of non-project resources.

(vi) The adequacy of mechanisms for ensuring high-quality products and services from the proposed project.

(c) Quality of the project evaluation (20 points).

(1) The Secretary considers the quality of the evaluation to be conducted of the proposed project.

(2) In determining the quality of the evaluation, the Secretary considers the following factors:

(i) The extent to which the methods of evaluation are thorough, feasible, and appropriate to the goals, objectives, and outcomes of the proposed project.

(ii) The extent to which the methods of evaluation provide for examining the effectiveness of project implementation strategies.

(iii) The extent to which the methods of evaluation will provide performance feedback and permit periodic assessment of progress toward achieving intended outcomes.

(iv) The extent to which the methods of evaluation include the use of objective performance measures that are clearly related to the intended outcomes of the project and will produce quantitative and qualitative data to the extent possible.

(d) Adequacy of resources and quality of project personnel (15 points).

(1) The Secretary considers the adequacy of resources for the proposed project and the quality of the personnel who will carry out the proposed project.

(2) In determining the quality of project personnel, the Secretary considers the extent to which the applicant encourages applications for employment from persons who are members of groups that have traditionally been underrepresented based on race, color, national origin, gender, age, or disability.

(3) In addition, the Secretary considers the following factors:

(i) The qualifications, including relevant training and experience, of the

project director or principal investigator.

(ii) The qualifications, including relevant training and experience, of key project personnel.

(iii) The qualifications, including relevant training and experience, of project consultants or subcontractors.

(iv) The qualifications, including relevant training, experience, and independence, of the evaluator.

(v) The adequacy of support, including facilities, equipment, supplies, and other resources, from the applicant organization or the lead applicant organization.

(vi) The relevance and demonstrated commitment of each partner in the proposed project to the implementation and success of the project.

(vii) The extent to which the budget is adequate to support the proposed project.

(viii) The extent to which the costs are reasonable in relation to the objectives, design, and potential significance of the proposed project.

(e) *Quality of the management plan* (20 points).

(1) The Secretary considers the quality of the management plan for the proposed project.

(2) In determining the quality of the management plan for the proposed project, the Secretary considers the following factors:

(i) The adequacy of the management plan to achieve the objectives of the proposed project on time and within budget, including clearly defined responsibilities, timelines, and milestones for accomplishing project tasks.

(ii) The extent to which the time commitments of the project director and principal investigator and other key project personnel are appropriate and adequate to meet the objectives of the proposed project.

(iii) The adequacy of mechanisms for ensuring high-quality products and services from the proposed project.

(iv) How the applicant will ensure that a diversity of perspectives are brought to bear in the operation of the proposed project, including those of parents, teachers, the business community, a variety of disciplinary and professional fields, recipients or beneficiaries of services, or others, as appropriate.

2. *Review and Selection Process:* We remind potential applicants that in reviewing applications in any discretionary grant competition, the Secretary may consider, under 34 CFR 75.217(d)(3), the past performance of the applicant in carrying out a previous award, such as the applicant's use of

funds, achievement of project objectives, and compliance with grant conditions. The Secretary may also consider whether the applicant failed to submit a timely performance report or submitted a report of unacceptable quality.

In addition, in making a competitive grant award, the Secretary requires various assurances, including those applicable to Federal civil rights laws that prohibit discrimination in programs or activities receiving Federal financial assistance from the Department of Education (34 CFR 100.4, 104.5, 106.4, 108.8, and 110.23).

3. Additional Review and Selection Process Factors: In the past, the Department has had difficulty finding peer reviewers for certain competitions because so many individuals who are eligible to serve as peer reviewers have conflicts of interest. The standing panel requirements under section 682(b) of IDEA also have placed additional constraints on the availability of reviewers. Therefore, the Department has determined that for some discretionary grant competitions, applications may be separated into two or more groups and ranked and selected for funding within specific groups. This procedure will make it easier for the Department to find peer reviewers by ensuring that greater numbers of individuals who are eligible to serve as reviewers for any particular group of applicants will not have conflicts of interest. It also will increase the quality, independence, and fairness of the review process, while permitting panel members to review applications under discretionary grant competitions for which they also have submitted applications.

4. Risk Assessment and Specific Conditions: Consistent with 2 CFR 200.205, before awarding grants under this competition the Department conducts a review of the risks posed by applicants. Under 2 CFR 3474.10, the Secretary may impose specific conditions and, in appropriate circumstances, high-risk conditions on a grant if the applicant or grantee is not financially stable; has a history of unsatisfactory performance; has a financial or other management system that does not meet the standards in 2 CFR part 200, subpart D; has not fulfilled the conditions of a prior grant; or is otherwise not responsible.

5. Integrity and Performance System: If you are selected under this competition to receive an award that over the course of the project period may exceed the simplified acquisition threshold (currently \$150,000), under 2 CFR 200.205(a)(2) we must make a judgment about your integrity, business ethics, and record of performance under Federal awards—that is, the risk posed by you as an applicant—before we make an award. In doing so, we must consider any information about you that is in the integrity and performance system (currently referred to as the Federal Awardee Performance and Integrity Information System (FAPIIS)), accessible through the System for Award Management. You may review and comment on any information about yourself that a Federal agency previously entered and that is currently in FAPIIS.

Please note that, if the total value of your currently active grants, cooperative agreements, and procurement contracts from the Federal Government exceeds \$10,000,000, the reporting requirements in 2 CFR part 200, Appendix XII, require you to report certain integrity information to FAPIIS semiannually. Please review the requirements in 2 CFR part 200, Appendix XII, if this grant plus all the other Federal funds you receive exceed \$10,000,000.

VI. Award Administration Information

1. *Award Notices:* If your application is successful, we notify your U.S. Representative and U.S. Senators and send you a Grant Award Notification (GAN); or we may send you an email containing a link to access an electronic version of your GAN. We may notify you informally, also.

If your application is not evaluated or not selected for funding, we notify you. 2. Administrative and National Policy

2. Administrative and National Policy Requirements: We identify administrative and national policy requirements in the application package and reference these and other requirements in the Applicable Regulations section of this notice.

We reference the regulations outlining the terms and conditions of an award in the *Applicable Regulations* section of this notice and include these and other specific conditions in the GAN. The GAN also incorporates your approved application as part of your binding commitments under the grant.

3. Open Licensing Requirements: Unless an exception applies, if you are awarded a grant under this competition, you will be required to openly license to the public grant deliverables created in whole, or in part, with Department grant funds. When the deliverable consists of modifications to pre-existing works, the license extends only to those modifications that can be separately identified and only to the extent that open licensing is permitted under the terms of any licenses or other legal restrictions on the use of pre-existing works. Additionally, a grantee or subgrantee that is awarded competitive grant funds must have a plan to disseminate these public grant deliverables. This dissemination plan can be developed and submitted after your application has been reviewed and selected for funding. For additional information on the open licensing requirements please refer to 2 CFR 3474.20.

4. *Reporting:* (a) If you apply for a grant under this competition, you must ensure that you have in place the necessary processes and systems to comply with the reporting requirements in 2 CFR part 170 should you receive funding under the competition. This does not apply if you have an exception under 2 CFR 170.110(b).

(b) At the end of your project period, you must submit a final performance report, including financial information, as directed by the Secretary. If you receive a multiyear award, you must submit an annual performance report that provides the most current performance and financial expenditure information as directed by the Secretary under 34 CFR 75.118. The Secretary may also require more frequent performance reports under 34 CFR 75.720(c). For specific requirements on reporting, please go to www.ed.gov/ fund/grant/apply/appforms/ appforms.html.

5. Performance Measures: Under the Government Performance and Results Act of 1993, the Department has established a set of performance measures, including long-term measures, that are designed to yield information on various aspects of the effectiveness and quality of the Technical Assistance and Dissemination to Improve Services and Results for Children With Disabilities program. These measures are:

• Program Performance Measure #1: The percentage of Technical Assistance and Dissemination products and services deemed to be of high quality by an independent review panel of experts qualified to review the substantive content of the products and services.

• Program Performance Measure #2: The percentage of Special Education Technical Assistance and Dissemination products and services deemed by an independent review panel of qualified experts to be of high relevance to educational and early intervention policy or practice.

• *Program Performance Measure #3:* The percentage of all Special Education Technical Assistance and Dissemination products and services deemed by an independent review panel of qualified experts to be useful in improving educational or early intervention policy or practice.

• Program Performance Measure #4: The cost efficiency of the Technical Assistance and Dissemination Program includes the percentage of milestones achieved in the current annual performance report period and the percentage of funds spent during the current fiscal year.

• Long-term Program Performance Measure: The percentage of States receiving Special Education Technical Assistance and Dissemination services regarding scientifically or evidencebased practices for infants, toddlers, children, and youth with disabilities that successfully promote the implementation of those practices in school districts and service agencies.

The measures apply to projects funded under this competition, and grantees are required to submit data on these measures as directed by OSEP.

Grantees will be required to report information on their project's performance in annual and final performance reports to the Department (34 CFR 75.590).

6. Continuation Awards: In making a continuation award under 34 CFR 75.253, the Secretary considers, among other things: Whether a grantee has made substantial progress in achieving the goals and objectives of the project; whether the grantee has expended funds in a manner that is consistent with its approved application and budget; and, if the Secretary has established performance measurement requirements, the performance targets in the grantee's approved application.

In making a continuation award, the Secretary also considers whether the grantee is operating in compliance with the assurances in its approved application, including those applicable to Federal civil rights laws that prohibit discrimination in programs or activities receiving Federal financial assistance from the Department (34 CFR 100.4, 104.5, 106.4, 108.8, and 110.23).

VII. Other Information

Accessible Format: Individuals with disabilities can obtain this document and a copy of the application package in an accessible format (*e.g.*, braille, large print, audiotape, or compact disc) by contacting the Management Support Services Team, U.S. Department of Education, 400 Maryland Avenue SW, Room 5113, Potomac Center Plaza, Washington, DC 20202–2500. Telephone: (202) 245–7363. If you use a TDD or a TTY, call the FRS, toll free, at 1–800–877–8339.

Electronic Access to This Document: The official version of this document is

the document published in the **Federal Register**. You may access the official edition of the **Federal Register** and the Code of Federal Regulations via the Federal Digital System at: *www.gpo.gov/ fdsys*. At this site you can view this document, as well as all other documents of this Department published in the **Federal Register**, in text or Portable Document Format (PDF). To use PDF you must have Adobe Acrobat Reader, which is available free at the site.

You may also access documents of the Department published in the **Federal Register** by using the article search feature at: *www.federalregister.gov.* Specifically, through the advanced search feature at this site, you can limit your search to documents published by the Department.

Dated: July 19, 2018.

Johnny W. Collett,

Assistant Secretary for Special Education and Rehabilitative Services.

[FR Doc. 2018–15932 Filed 7–24–18; 8:45 am] BILLING CODE 4000–01–P

DEPARTMENT OF EDUCATION

[Docket No. ED-2018-ICCD-0077]

Agency Information Collection Activities; Comment Request; High School Longitudinal Study of 2009 (HSLS: 09) Panel Maintenance 2018 and 2021

AGENCY: National Center for Education Statistics (NCES), Department of Education (ED). **ACTION:** Notice.

ACTION. NOLICE.

SUMMARY: In accordance with the Paperwork Reduction Act of 1995, ED is proposing a revision of an existing information collection.

DATES: Interested persons are invited to submit comments on or before September 24, 2018.

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-2018–ICCD–0077. Comments submitted in response to this notice should be submitted electronically through the Federal eRulemaking Portal at http:// www.regulations.gov by selecting the Docket ID number or via postal mail, commercial delivery, or hand delivery. Please note that comments submitted by fax or email and those submitted after the comment period will not be accepted. Written requests for information or comments submitted by postal mail or delivery should be

addressed to the Director of the Information Collection Clearance Division, U.S. Department of Education, 550 12th Street, SW, PCP, Room 9089, Washington, DC 20202–0023.

FOR FURTHER INFORMATION CONTACT: For specific questions related to collection activities, please contact Kashka Kubzdela, 202–502–7411 or email NCES.Information.Collections@ed.gov.

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: High School Longitudinal Study of 2009 (HSLS: 09) Panel Maintenance 2018 and 2021.

OMB Control Number: 1850–0852. Type of Review: A revision of an existing information collection.

Respondents/Affected Public: Individuals or Households.

Total Estimated Number of Annual Responses: 9,326.

Total Estimated Number of Annual Burden Hours: 778.

Abstract: The High School Longitudinal Study of 2009 (HSLS:09) is a nationally representative, longitudinal study of more than 20,000 9th graders in 944 schools in 2009 who are being followed through their secondary and postsecondary years. The study focuses on understanding students' trajectories from the beginning of high school into postsecondary education or the

workforce and beyond. What students decide to pursue when, why, and how are crucial questions for HSLS:09, especially, but not solely, in regards to science, technology, engineering, and math (STEM) courses, majors, and careers. HSLS:09 measured math achievement gains in the first 3 years of high school and, like past studies, surveyed students, their parents, school administrators, school counselors, and teachers. After the initial 2009 data collection, the main study students were re-surveyed in 2012 when most were high school 11th-graders, then again in 2013 when most had just graduated from high school, and lastly in 2016. The 2016 second follow-up data collection consisted of a survey, postsecondary transcript collection, financial aid records collection, and file matching to extant data sources. It focused on postsecondary attendance patterns, field of study selection processes with particular emphasis on STEM, the postsecondary academic and social experience, education financing, employment history including instances of unemployment and underemployment, job characteristics including income and benefits, job values, family formation, and civic engagement. The HSLS:09 data elements are designed to support research that speaks to the underlying dynamics and education processes that influence student achievement, growth, and personal development over time. This request is to conduct the HSLS:09 panel maintenance to keep sample members' contact information up-to-date for future follow-up activities.

Dated: July 20, 2018.

Stephanie Valentine,

Acting Director, Information Collection Clearance Division, Office of the Chief Privacy Officer, Office of Management. [FR Doc. 2018–15871 Filed 7–24–18; 8:45 am] BILLING CODE 4000–01–P

BILLING CODE 4000-01-P

DEPARTMENT OF EDUCATION

Applications for New Awards; Technical Assistance and Dissemination To Improve Services and Results for Children With Disabilities, School Safety National Activities, and Student Support and Academic Enrichment (SSAE) Grants Programs—National Technical Assistance Center on Positive Behavioral Interventions and Supports

AGENCY: Office of Special Education and Rehabilitative Services, Office of Elementary and Secondary Education, Department of Education.

ACTION: Notice.

SUMMARY: The Department of Education (Department) is issuing a notice inviting applications for new awards for fiscal year (FY) 2018 for Technical Assistance and Dissemination to Improve Services and Results for Children With Disabilities, School Safety National Activities, and Student Support and Academic Enrichment (SSAE) Grants Programs—National Technical Assistance Center on Positive Behavioral Interventions and Supports, Catalog of Federal Domestic Assistance (CFDA) number 84.326S.

DATES:

Applications Available: July 25, 2018. Deadline for Transmittal of Applications: August 24, 2018.

ADDRESSES: For the addresses for obtaining and submitting an application, please refer to our Common Instructions for Applicants to Department of Education Discretionary Grant Programs, published in the Federal Register on February 12, 2018 (83 FR 6003) and available at www.gpo.gov/fdsys/pkg/FR-2018-02-12/ pdf/2018-02558.pdf.

FOR FURTHER INFORMATION CONTACT: Renee Bradley, U.S. Department of Education, 400 Maryland Avenue SW, Room 5161, Potomac Center Plaza, Washington, DC 20202–5076. Telephone: (202) 245–7277. Email: *Renee.Bradley@ed.gov.*

If you use a telecommunications device for the deaf (TDD) or a text telephone (TTY), call the Federal Relay Service (FRS), toll free, at 1–800–877– 8339.

SUPPLEMENTARY INFORMATION:

Full Text of Announcement

I. Funding Opportunity Description

Purpose of Program: The purpose of the Technical Assistance and Dissemination to Improve Services and Results for Children with Disabilities program is to promote academic achievement and to improve results for children with disabilities by providing technical assistance (TA), supporting model demonstration projects, disseminating useful information, and implementing activities that are supported by scientifically based research.

The School Safety National Activities Program provides support to State educational agencies (SEAs) and local educational agencies (LEAs) for activities to improve student safety and well-being.

The Student Support and Academic Enrichment (SSAE) Grants Program is intended to improve student academic achievement by increasing the capacity of States, LEAs, schools, and communities to (1) provide all students with access to a well-rounded education, (2) improve school conditions for student learning, and (3) improve the use of technology in order to improve academic achievement and digital literacy.

Priorities: This notice includes three absolute priorities. Applicants must address all three absolute priorities, and we will make one award as a comprehensive investment designed to enhance local and State efforts to improve school climate, conditions for learning, and access to and engagement in the instructional environment, with a focus on students with behavioral challenges, by implementing comprehensive positive behavioral interventions and supports (PBIS) frameworks.

In accordance with 34 CFR 75.105(b)(2)(v), Absolute Priority 1 is from allowable activities specified in the statute (see sections 663 and 681(d) of the Individuals with Disabilities Education Act (IDEA); 20 U.S.C. 1463 and 1481(d)). We are establishing Absolute Priority 2 under title IV, part F, subpart 3, section 4631 of the Elementary and Secondary Education Act of 1965, as amended (ESEA) (20 U.S.C. 7281), and, for the FY 2018 grant competition and any subsequent year in which we make awards from the list of unfunded applications for this competition, in accordance with section 437(d)(1) of the General Education Provisions Act (GEPA) (20 U.S.C. 1232(d)(1)). We are establishing Absolute Priority 3 under title IV, part A, subpart 1 of the ESEA (20 U.S.C. 7101 et seq.) and, for the FY 2018 grant competition and any subsequent year in which we make awards from the list of unfunded applications for this competition, in accordance with section 437(d)(1) of GEPA (20 U.S.C. 1232(d)(1)).

Absolute Priorities: These priorities are absolute priorities. Under 34 CFR 75.105(c)(3), we consider only applications that meet all three of these priorities.

These priorities are:

Absolute Priority 1—Technical Assistance and Dissemination To Improve Services and Results for Children With Disabilities—National Technical Assistance Center on Positive Behavioral Interventions and Supports

Background

The mission of the Office of Special Education and Rehabilitative Services (OSERS) is to improve early childhood, educational, and employment outcomes and raise expectations for all people with disabilities, their families, their communities, and the Nation.

PBIS is a framework or approach for assisting school personnel in adopting and organizing evidence-based behavioral interventions and supports into an integrated continuum that enhances academic and social behavior outcomes for all students. The Department provided additional background about the term PBIS in a notice inviting applications published in the Federal Register on July 5, 2013 (78 FR 40459).¹ The term "positive behavioral interventions and supports" was first used in the 1997 reauthorization of IDEA. PBIS was also included in the 2004 reauthorization of IDEA (e.g., sections 601(c)(5)(F), 611(e)(2)(C)(iii), 614(d)(3)(B)(i), 662(b)(2)(A)(v), and 665), as well as the ESEA.

Evidence supports the positive outcomes associated with the effective implementation of PBIS frameworks (Bradshaw, Waasdorp, & Leaf, 2015). When there is fidelity in implementing PBIS frameworks, studies have found the following statistically significant results in schools as compared to schools without PBIS implementation: Improved student perception of school safety and reductions in overall problem behaviors, bullying behaviors, office discipline referrals, chronic absenteeism, and suspensions (Waasdorp, Bradshaw, & Leaf, 2012). Studies have also found a correlation between the use of PBIS procedures and improved social skills and academic achievement (McIntosh, Filter, Bennett, Ryan, & Sugai, 2010; Bradshaw et al., 2009).

Projects funded by the Office of Special Education Programs (OSEP) to date have succeeded in developing and refining the multi-tiered behavioral framework, developing resources for educators, policy makers, students, and families, and building SEA, LEA, and school capacity for implementation of PBIS with fidelity at the universal or primary tier of support and, to some extent, at the more intensive tiers for students with disabilities. Although these projects have documented successful implementation of PBIS and positive outcome data in over 25,000 schools, additional TA is needed to focus on students with more intensive needs and those most likely to be excluded from the learning environment due to behavior that interferes with instruction. In addition, SEAs and LEAs

¹ Available at: www.gpo.gov/fdsys/pkg/FR-2013-07-05/pdf/2013-16191.pdf.

need further assistance to develop and sustain school-wide behavior frameworks and build the capacity and expertise of SEAs and LEAs to address the technical and training needs of their personnel.

Accordingly, the National Technical Assistance Center on PBIS (TA Center) will enable SEAs and LEAs to continue to further develop, expand, and sustain comprehensive, systemic PBIS frameworks that (1) improve students' school behavior; (2) prevent bullying, violence, or disruptive actions that detract from a high-quality education; (3) address exclusionary practices and other disciplinary issues that detract from a high-quality learning environment; and (4) improve overall school climate by facilitating national, regional, State, and district implementation networks.

This priority is consistent with four priorities from the Secretary's Final Supplemental Priorities and Definitions for Discretionary Grant Programs, published in the Federal Register on March 2, 2018 (83 FR 9096) (Supplemental Priorities): Priority 1-**Empowering Families and Individuals** To Choose a High-Quality Education That Meets Their Unique Needs; Priority 5—Meeting the Unique Needs of Students and Children With Disabilities and/or Those With Unique Gifts and Talents; Priority 8-Promoting Effective Instruction in Classrooms and Schools; and Priority 10-Protecting Freedom of Speech and Encouraging **Respectful Interactions in a Safe** Educational Environment.

Priority

The purpose of this priority is to fund a cooperative agreement to establish and operate a National Technical Assistance Center for Positive Behavioral Interventions and Supports (PBIS) (TA Center) to assist SEAs and LEAs and national and regional networks, including professional networks and private school associations, to successfully implement and sustain evidence-based (as defined in this notice) PBIS practices and policies, especially for, but not limited to, students with the most significant behavioral challenges that interfere with their ability to fully participate in, and benefit from, a high-quality learning environment in public, private, parochial, alternative, charter, and other educational settings. This investment is needed to continue to assist SEAs and LEAs to enhance their capacity to develop, implement, scale-up, and sustain school-wide frameworks for PBIS to improve behavior and climate and to enable all students to fully

participate in, and benefit from, instruction. The applicant must propose to achieve, at a minimum, the following expected outcomes:

(a) Improved infrastructure at the national, regional, State, and district levels to support, develop, and sustain local PBIS implementation efforts;

(b) Improved capacity at the SEA and LEA levels to implement the components of a PBIS framework (i.e., policies, funding, professional development, coaching, data collection, analysis, and use) and develop more tools for selecting and aligning multiple initiatives within the State or district with a special focus on tiers beyond universal (i.e., beyond strategies and supports provided to all students to include strategies that are provided to selected groups of students or individual students) in order to increase the number of schools effectively implementing a PBIS framework;

(c) Improved capacity of SEA and LEA personnel to enhance the knowledge and skills of members of school leadership teams and Individualized Education Program (IEP) Teams to implement PBIS practices and policies to support positive school behavior and respond to behaviors that interfere with a student's ability to fully participate in, and benefit from, a highquality learning environment (*e.g.*, insubordination, leaving class without permission, chronic absenteeism, and aggression);

(d) Increased use and promulgation by SEAs and LEAs, as well as charter management organizations and private school organizations, of interventions, accommodations, and reliable and valid tools and processes for implementing a behavioral framework, developing local capacity, and measuring fidelity of implementation and outcomes (e.g., reductions in the use of discipline referrals, suspensions, expulsions, restrictive placements, chronic absenteeism, and restraints and seclusion; and improvements in school climate, time engaged in instruction, and overall academic achievement); and

(e) Increased body of knowledge to enhance implementation of PBIS in schools identified for comprehensive support and improvement under section 1111(d)(1) of the ESEA, schools identified for targeted support and improvement under section 1111(d)(2) of the ESEA, rural schools, high schools, alternative public schools, charter schools, mental health settings, private schools, parochial schools, and juvenile correction settings; and develop and improve the quality of information, tools, and resources to address these environments. Absolute Priority 2—Technical Assistance for Grantees Under the School Safety National Activities Program—National Technical Assistance Center on Positive Behavioral Interventions and Supports

Background

In FY 2014, under Safe and Drug-Free Schools and Communities National Programs (the predecessor ESEA authority to School Safety National Activities) the Department awarded five-year grants to a cohort of SEAs and to a cohort of LEAs under a competition for School Climate Transformation Grants (SCTGs). The grants enabled these SEAs and LEAs to develop, adapt, or expand a multi-tiered decisionmaking framework that guides the selection, integration, and implementation of the best evidencebased behavioral practices aimed at improving school climate and behavioral outcomes for all students.

The current National Technical Assistance Center on Positive Behavioral Interventions and Supports continues to provide TA to the recipients of SCTGs but began its fiveyear project period one year earlier than the FY 2014 cohort of SCTGs. As a result, there is a need for the National Technical Assistance Center on Positive Behavioral Interventions and Supports to provide TA to recipients of SCTGs during their fifth and final year, as well as to one or more new cohorts of SCTGs, if additional funds for SCTGs become available.

Priority

The purpose of this priority is to assist SEAs and LEAs that received or will receive SCTGs with developing and implementing PBIS frameworks that are designed to keep students engaged in instruction and improve academic outcomes. To meet this priority, the applicant must at a minimum propose to achieve for School Climate Transformation Grantees the following intended outcomes that support implementing a PBIS framework:

(a) Improved skills of SEA personnel to organize the components of a PBIS framework, such as policies, funding, professional development, coaching, data collection and analysis, and interagency coordination for service provision with State justice, mental health, and other youth services agencies.

(b) Improved skills of LEA personnel to (1) implement the evidence-based practices and skills that comprise the PBIS behavioral framework; (2) collect and use data to inform behavioral decision-making; and (3) develop, including through collaboration with mental health and juvenile justice agencies, the local capacity and expertise needed to implement, scale up, and sustain a PBIS framework and demonstrate the effects of the implementation within the school and the larger school community.

(c) Increased body of knowledge of researchers and practitioners on implementing, scaling up, and sustaining a PBIS framework to provide the behavioral supports to prevent violence and the illegal use of drugs among, and promote safety and discipline for, students.

(d) Increased use by SEAs and LEAs of reliable and valid tools and processes for evaluating the fidelity of the implementation of a PBIS framework and for measuring its outcomes, including reductions in violence and the illegal use of drugs, discipline referrals, suspensions, expulsions, and the use of restraints and seclusion, and improvements in school climate, time spent in instruction, and overall academic achievement.

(e) Increased body of knowledge on the processes to effectively implement PBIS in high-need LEAs ²—including those with schools identified for comprehensive support and improvement under section 1111(d)(1) of the ESEA and schools identified for targeted support and improvement under section 1111(d)(2) of the ESEA to develop and improve the quality of information, tools, and products to assist initial and sustained implementation of a PBIS framework in these LEAs;

(f) Expanded use of the lessons learned from implementing a PBIS framework to: (1) Inform other Federal, State, and district efforts to reduce incidents of violence and illegal drug use by students (including bullying), the use of restraint and seclusion, and the disproportionate application of disciplinary procedures such as suspension and expulsion to minority students and students with disabilities; (2) reduce inappropriate referrals of students to law enforcement; and (3) inform school climate and school mental health initiatives that are supported or will be supported by the Department and other Federal agencies.

Funds under this priority must be used to meet the absolute priority with regard to serving recipients of SCTGs that do not receive assistance under Absolute Priority 3.

Absolute Priority 3—Technical Assistance for Grantees Under the Student Support and Academic Enrichment (SSAE) Grants Program— National Technical Assistance Center on Positive Behavioral Interventions and Supports

Background

Authorized under title IV, part A, subpart 1 of the ESEA, the SSAE Grants Program is intended to improve student academic achievement by increasing the capacity of States, LEAs, schools, and communities to (1) provide all students with access to a well-rounded education, (2) improve school conditions for student learning, and (3) improve the use of technology in order to improve academic achievement and digital literacy. State capacity-building under this priority could include, for example, assisting States in developing or refining PBIS frameworks for implementation by their LEAs.

Priority

The purpose of this priority is to build the capacity of States to assist LEAs that seek to use SSAE funds to improve school conditions for student learning by implementing PBIS frameworks. To meet this priority the applicant must propose to build the capacity of States to assist such LEAs in a manner that achieves, at a minimum, the following intended outcomes that support implementing a PBIS framework:

(a) Improved skills of SEA personnel to organize the components of a PBIS framework, such as policies, funding, professional development, coaching, data collection and analysis, and interagency coordination for service provision with State justice, mental health, and other youth services agencies.

(b) Increased body of knowledge on implementing, scaling up, and sustaining a PBIS framework to provide the behavioral supports to prevent violence and illegal use of drugs among, and promote safety and discipline for, students.

(c) Increased use of reliable and valid tools and processes for evaluating the fidelity of the implementation of a PBIS framework and for measuring its outcomes, including reductions in violence and the illegal use of drugs, discipline referrals, suspensions, expulsions, and the use of restraints and seclusion, and improvements in school climate, time spent on instruction, and overall academic achievement.

(d) Increased body of knowledge on the processes to effectively implement PBIS in high-need schools, high-poverty schools, schools identified for comprehensive support and improvement under section 1111(d)(1) of the ESEA, schools identified for targeted support and improvement under section 1111(d)(2) of the ESEA, or schools identified as persistently dangerous public elementary or secondary schools under section 8532 of the ESEA, to develop and improve the quality of information, tools, and products to assist initial and sustained implementation of a PBIS framework.

(e) Expanded use of the lessons learned from implementing a PBIS framework to (1) inform other Federal, State, and district efforts to reduce incidents of illegal drug use and violence by students (including bullying), the use of restraint and seclusion, and the disproportionate application of disciplinary procedures such as suspension and expulsion to minority students and students with disabilities; and (2) reduce inappropriate referrals of students to law enforcement.

Funds received under this priority must be used to build the capacity of States to assist only LEAs that: (1) Seek to use SSAE funds to improve school conditions for student learning by implementing PBIS frameworks; and (2) are not receiving assistance under Absolute Priority 2.

Requirements: We are establishing the following application and administrative requirements for FY 2018 and any subsequent year in which we make awards from the list of unfunded applications from this competition, in accordance with section 437(d)(1) of GEPA:

(a) Demonstrate, in the narrative section of the application under "Significance," how the proposed project will—

(1) Improve SEAs' and LEAs' implementation, scaling, and sustainability of evidence-based PBIS practices and policies that are designed to improve school climate and, as needed, to provide additional behavioral supports for students whose behavior interferes with their ability to fully participate in, and benefit from, a high-quality learning environment, including students with disabilities. To meet this requirement, the applicant must—

(i) Present applicable State, regional, or local data demonstrating SEAs' and LEAs' needs related to (A) high-quality implementation of evidence-based PBIS practices and policies and (B) increasing students' ability to fully participate in, and benefit from, a high-quality learning environment, particularly for students

² High-need LEA means an LEA (a) that serves not fewer than 10,000 children from families with incomes below the poverty line; or (b) for which not less than 20 percent of the children served by the LEA are from families with incomes below the poverty line.

with the most significant behavioral challenges;

(ii) Demonstrate knowledge of current educational issues and policy initiatives relating to PBIS and school climate practices and policies for students whose behavioral challenges interfere with their ability to fully participate in, and benefit from, a high-quality learning environment, including students with disabilities; and

(iii) Present information about the current level of implementation of PBIS practices and policies, as well as students' access to more positive school climates that supports their ability to fully participate in, and benefit from, a high-quality learning environment;

(2) Improve outcomes for students with behavioral challenges that interfere with their ability or the ability of their peers to fully participate in, and benefit from, a high-quality learning environment through the implementation of PBIS frameworks, and indicate the likely magnitude or importance of the improvements.

(b) Demonstrate, in the narrative section of the application under "Quality of Project Services," how the proposed project will—

(1) Ensure equal access and treatment for members of groups that have traditionally been underrepresented based on race, color, national origin, gender, age, or disability. To meet this requirement, the applicant must describe how it will—

(i) Identify the needs of the intended recipients for TA and information; and

(ii) Ensure that services and products meet the needs of the intended recipients of the grant;

(2) Achieve its goals, objectives, and intended outcomes. To meet this requirement, the applicant must provide—

(i) Measurable intended project outcomes; and

(ii) In Appendix A, the logic model (as defined in this notice) by which the proposed project will achieve its intended outcomes that depicts, at a minimum, the goals, activities, outputs, and intended outcomes of the proposed project;

(3) Use a conceptual framework (and provide a copy in Appendix A) to develop project plans and activities, describing any underlying concepts, assumptions, expectations, beliefs, or theories, as well as the presumed relationships or linkages among these variables, and any empirical support for this framework;

Note: The following websites provide more information on logic models and conceptual frameworks: www.osepideasthatwork.org/ logicModel and www.osepideasthatwork.org/ resources-grantees/program-areas/ta-ta/tadproject-logic-model-and-conceptualframework.

(4) Be based on current research and make use of evidence-based practices (EBPs). To meet this requirement, the applicant must describe—

(i) The current research on the assessment of the implementation of PBIS frameworks and related EBPs;

(ii) The current research about adult learning principles and implementation science that will inform the proposed TA; and

(iii) How the proposed project will incorporate current research and EBPs in the development and delivery of its products and services;

(5) Develop products and provide services that are of high quality and sufficient intensity and duration to achieve the intended outcomes of the proposed project. To address this requirement, the applicant must describe—

(i) How it proposes to further develop the knowledge base of PBIS;

(ii) Its proposed approach to universal, general TA,³ which must identify the intended recipients, including the type and number of recipients, that will receive the products and services under this approach;

(iii) Its proposed approach to targeted, specialized TA,⁴ which must identify—

(A) The intended recipients, including the type and number of recipients, that will receive the products and services under this approach; and

(B) Its proposed approach to measure the readiness of potential TA recipients to work with the project, assessing, at a minimum, their current infrastructure, available resources, and ability to build capacity at the local level; and

⁴ "Targeted, specialized TA" means TA services based on needs common to multiple recipients and not extensively individualized. A relationship is established between the TA recipient and one or more TA center staff. This category of TA includes one-time, labor-intensive events, such as facilitating strategic planning or hosting regional or national conferences. It can also include episodic, less laborintensive events that extend over a period of time, such as facilitating a series of conference calls on single or multiple topics that are designed around the needs of the recipients. Facilitating communities of practice can also be considered targeted, specialized TA. (iv) Its proposed approach to intensive, sustained TA,⁵ which must identify—

(A) The intended recipients, including the type and number of recipients, that will receive the products and services under this approach;

(B) Its proposed approach to measure the readiness of State- and local-level personnel to work with the project, including their commitment to the initiative, alignment of the initiative to their needs, current infrastructure, available resources, and ability to build capacity at the local level;

(C) Its proposed plan for assisting SEAs, LEAs, charter management organizations, and private school organizations to build or enhance training systems that include professional development based on adult learning principles and coaching; and

(D) Its proposed plan for working with appropriate levels of the education system (*e.g.*, SEAs, regional TA providers, districts, schools, families) to ensure that there is communication between each level and that there are systems in place to support the use of PBIS;

(6) Develop products and implement services that maximize efficiency. To address this requirement, the applicant must describe—

(i) How the proposed project will use technology to achieve the intended project outcomes;

(ii) With whom the proposed project will collaborate and the intended outcomes of this collaboration; and

(iii) How the proposed project will use non-project resources to achieve the intended project outcomes.

(c) In the narrative section of the application under "Quality of the project evaluation," include an evaluation plan for the project developed in consultation with and implemented by a third-party evaluator.⁶ The evaluation plan must—

(1) Articulate formative and summative evaluation questions,

³ "Universal, general TA" means TA and information provided to independent users through their own initiative, resulting in minimal interaction with TA center staff and including onetime, invited or offered conference presentations by TA center staff. This category of TA also includes information or products, such as newsletters, guidebooks, or research syntheses, downloaded from the TA center's website by independent users. Brief communications by TA center staff with recipients, either by telephone or email, are also considered universal, general TA.

⁵ "Intensive, sustained TA" means TA services often provided on-site and requiring a stable, ongoing relationship between the TA center staff and the TA recipient. "TA services" are defined as negotiated series of activities designed to reach a valued outcome. This category of TA should result in changes to policy, program, practice, or operations that support increased recipient capacity or improved outcomes at one or more systems levels.

⁶ A "third-party" evaluator is an independent and impartial program evaluator who is contracted by the grantee to conduct an objective evaluation of the project. This evaluator must not have participated in the development or implementation of any project activities, except for the evaluation activities, nor have any financial interest in the outcome of the evaluation.

including important process and outcome evaluation questions. These questions should be related to the project's proposed logic model required in paragraph (b)(2)(ii) of these requirements;

(2) Describe how progress in and fidelity of implementation, as well as project outcomes, will be measured to answer the evaluation questions by, at a minimum:

(i) Specifying the measures and associated instruments or sources for data appropriate to the evaluation questions; and

(ii) Including information regarding reliability and validity of measures where appropriate;

(3) Describe strategies for analyzing data and how data collected as part of this plan will be used to inform and improve service delivery over the course of the project and to refine the proposed logic model and evaluation plan, including subsequent data collection;

(4) Provide a timeline for conducting the evaluation, and include staff assignments for completing the plan. The timeline must indicate that the data will be available annually for the Annual Performance Report (APR) and at the end of Year 2 for the review process described under the heading, Fourth and Fifth Years of the Project; and

(5) Dedicate sufficient funds in each budget year to cover the costs of developing or refining the evaluation plan in consultation with a "thirdparty" evaluator, as well as the costs associated with the implementation of the evaluation plan by the third-party evaluator.

(d) Demonstrate, in the narrative section of the application under "Adequacy of resources," how—

(1) The proposed project will encourage applications for employment from persons who are members of groups that have traditionally been underrepresented based on race, color, national origin, gender, age, or disability, as appropriate;

(2) The proposed key project personnel, consultants, and subcontractors have the qualifications and experience to carry out the proposed activities and achieve the project's intended outcomes;

(3) The applicant and any key partners have adequate resources to carry out the proposed activities; and

(4) The proposed costs are reasonable in relation to the anticipated results and benefits.

(e) Demonstrate, in the narrative section of the application under "Quality of the management plan," how(1) The proposed management plan will ensure that the project's intended outcomes will be achieved on time and within budget. To address this requirement, the applicant must describe—

(i) Clearly defined responsibilities for key project personnel, consultants, and subcontractors, as applicable; and

(ii) Timelines and milestones for accomplishing the project tasks;

(2) Key project personnel and any consultants and subcontractors will be allocated and how these allocations are appropriate and adequate to achieve the project's intended outcomes;

(3) The proposed management plan will ensure that the products and services provided are of high quality, relevant, and useful to recipients; and

(4) The proposed project will benefit from a diversity of perspectives, including those of families, educators, TA providers, researchers, and policy makers, among others, in its development and operation.

(f) Address the following application requirements. The applicant must—

(1) Include, in Appendix A, personnel-loading charts and timelines, as applicable, to illustrate the management plan described in the narrative;

(2) Include, in the budget, attendance at the following:

(i) A one and one-half day kick-off meeting in Washington, DC, after receipt of the award, and an annual planning meeting in Washington, DC, with the OSEP project officer and other relevant staff during each subsequent year of the project period.

Note: Within 30 days of receipt of the award, a post-award teleconference must be held between the OSEP project officer and the grantee's project director or other authorized representative;

(ii) A two and one-half day project directors' conference in Washington, DC, during each year of the project period;

(iii) Three annual two-day trips to attend Department briefings, Department-sponsored conferences, and other meetings, as requested by OSEP; and

(iv) A one-day intensive 3+2 review meeting in Washington, DC, during the last half of the second year of the project period;

(3) Include, in the budget, a line item for an annual set-aside of five percent of the grant amount to support emerging needs that are consistent with the proposed project's intended outcomes, as those needs are identified in consultation with, and approved by, the OSEP project officer. With approval from the OSEP project officer, the project must reallocate any remaining funds from this annual set-aside no later than the end of the third quarter of each budget period;

(4) Maintain a high-quality website, with an easy-to-navigate design, that meets government or industryrecognized standards for accessibility; and

(5) Include, in Appendix A, an assurance to assist OSEP with the transfer of pertinent resources and products and to maintain the continuity of services to States during the transition to this new award period and at the end of this award period, as appropriate.

Fourth and Fifth Years of the Project

In deciding whether to continue funding the project for the fourth and fifth years, the Secretary will consider the requirements of 34 CFR 75.253(a), as well as—

(a) The recommendation of a 3+2 review team consisting of experts selected by the Secretary. This review will be conducted during a one-day intensive meeting that will be held during the last half of the second year of the project period;

(b) The timeliness with which, and how well, the requirements of the negotiated cooperative agreement have been or are being met by the project; and

(c) The quality, relevance, and usefulness of the project's products and services and the extent to which the project's products and services are aligned with the project's objectives and likely to result in the project achieving its intended outcomes.

References

- Bradshaw, C.P., Waasdorp, T.E., & Leaf, P.J. (2015). Examining variation in the impact of school-wide positive behavioral interventions and supports: Findings from a randomized controlled effectiveness trial. *Journal of Educational Psychology*, 107(2), 546–557.
- Bradshaw, C.P., Koth, C.W., Thornton, L.A., & Leaf, P.J. (2009). Altering school climate through school-wide positive behavioral interventions and supports: Findings from a group-randomized effectiveness trial. *Prevention Science*. Retrieved from *https://doi.org/10.1007/ s11121-008-0114-9*.
- McIntosh, K., Filter, K.J., Bennett, J., Ryan, C., & Sugai, G. (2010). Principles of sustainable prevention: Designing scaleup of school-wide positive behavior support to promote durable systems. *Psychology in the Schools, 47*, 5–21.
- Waasdorp, T.E., Bradshaw, C.P., & Leaf, P.J. (2012). The impact of schoolwide positive behavioral interventions and supports on bullying and peer rejection: A randomized controlled effectiveness

trial. Archives of Pediatrics and Adolescent Medicine, 166(2), 149–56. doi: 10.1001/archpediatrics.2011.755.

Definitions

The following definition of "evidence-based" is from section 8101(21) of the ESEA, as amended, 20 U.S.C. 7801(21). The remaining definitions are from 34 CFR 77.1:

Evidence-based, when used with respect to a State, LEA, or school activity, means an activity, strategy, or intervention that—

(i) Demonstrates a statistically significant effect on improving student outcomes or other relevant outcomes based on—

(I) Strong evidence from at least one well-designed and well-implemented experimental study;

(II) Moderate evidence from at least one well-designed and wellimplemented quasi-experimental study; or

(III) Promising evidence from at least one well-designed and wellimplemented correlational study with statistical controls for selection bias; or

(ii)(I) Demonstrates a rationale based on high-quality research findings or positive evaluation that such activity, strategy, or intervention is likely to improve student outcomes or other relevant outcomes; and

(II) Includes ongoing efforts to examine the effects of such activity, strategy, or intervention.

Logic model (also referred to as a theory of action) means a framework that identifies key project components of the proposed project (*i.e.*, the active "ingredients" that are hypothesized to be critical to achieving the relevant outcomes) and describes the theoretical and operational relationships among the key project components and relevant outcomes.

Project component means an activity, strategy, intervention, process, product, practice, or policy included in a project. Evidence may pertain to an individual project component or to a combination of project components (*e.g.*, training teachers on instructional practices for English learners and follow-on coaching for these teachers).

Relevant outcome means the student outcome(s) or other outcome(s) the key project component is designed to improve, consistent with the specific goals of the program.

Waiver of Proposed Rulemaking: Under the Administrative Procedure Act (APA) (5 U.S.C. 553) the Department generally offers interested parties the opportunity to comment on proposed priorities and requirements. Section 681(d) of IDEA, however, makes the

public comment requirements of the APA inapplicable to Absolute Priority 1 in this notice. In addition, section 437(d)(1) of GEPA allows the Secretary to exempt from rulemaking requirements regulations governing the first grant competition under a new or substantially revised program authority. This is the first grant competition for both the School Safety National Activities Program under section 4631(a)(1)(B) of the ESEA and the National Activities for the SSAE Grants Program under section 4103(a)(3), and therefore qualifies for this exemption. In order to ensure timely grant awards, the Secretary has decided to forgo public comment on Absolute Priorities 2 and 3 and the requirements under section 437(d)(1) of GEPA. Absolute Priorities 2 and 3 and the requirements will apply to the FY 2018 grant competition and any subsequent year in which we make awards from the list of unfunded applications from this competition.

Program Authority: 20 U.S.C. 1463, 1481, 7113(a)(3), 7101, and 7281(a)(1)(B).

Applicable Regulations: (a) The **Education Department General** Administrative Regulations in 34 CFR parts 75, 77, 79, 81, 82, 84, 86, 97, 98, and 99. (b) The Office of Management and Budget Guidelines to Agencies on Governmentwide Debarment and Suspension (Nonprocurement) in 2 CFR part 180, as adopted and amended as regulations of the Department in 2 CFR part 3485. (c) The Uniform Administrative Requirements, Cost Principles, and Audit Requirements for Federal Awards in 2 CFR part 200, as adopted and amended as regulations of the Department in 2 CFR part 3474. (d) The regulations in 34 CFR part 299.

Note: The regulations in 34 CFR part 79 apply to all applicants except federally recognized Indian Tribes.

Note: The regulations in 34 CFR part 86 apply to institutions of higher education (IHEs) only.

II. Award Information

Type of Award: Cooperative agreement.

Estimated Available Funds: For Absolute Priority 1: \$1,850,000.

For Absolute Priority 2: \$3,750,000 from the School Safety National Activities Program.

For Absolute Priority 3: \$750,000 from the SSAE Grants Program.

Note: We will make one award comprised of separate funding under each of the three absolute priorities. Therefore, applicants must submit a separate Form 524b budget and budget narrative for each absolute priority. The Secretary may reject any application that does not separately address the requirements specified in Absolute Priority 1, Absolute Priority 2, and Absolute Priority 3 and include separate budgets and budget narratives for each of those priorities.

Contingent upon the availability of funds and the quality of applications, we may make additional awards in FY 2019 from the list of unfunded applications from this competition.

Maximum Award: We will not make an award exceeding \$1,850,000 for Absolute Priority 1 for a single budget period of 12 months. We will not make an award exceeding \$3,750,000 for Absolute Priority 2 for a single budget period of 12 months. We will not make an award exceeding \$750,000 for Absolute Priority 3 for a single budget period of 12 months.

Estimated Number of Awards: 1.

Note: The Department is not bound by any estimates in this notice.

Project Period: Up to 60 months.

III. Eligibility Information

1. *Eligible Applicants:* SEAs; LEAs, including charter schools that operate as LEAs under State law; IHEs; other public agencies; private nonprofit organizations; freely associated States and outlying areas; Indian Tribes or Tribal organizations; and for-profit organizations.

2. *Cost Sharing or Matching:* This program does not require cost sharing or matching.

3. Subgrantees: Under 34 CFR 75.708(b) and (c) a grantee under this competition may award subgrants—to directly carry out project activities described in its application—to the following types of entities: IHEs and private nonprofit organizations suitable to carry out the activities proposed in the application. The grantee may award subgrants to entities it has identified in an approved application.

4. Other General Requirements: (a) Recipients of funding under this competition must make positive efforts to employ and advance in employment qualified individuals with disabilities (see section 606 of IDEA).

(b) Applicants for, and recipients of, funding must, with respect to the aspects of their proposed project relating to Absolute Priority 1, involve individuals with disabilities, or parents of individuals with disabilities ages birth through 26, in planning, implementing, and evaluating the project (see section 682(a)(1)(A) of IDEA).

IV. Application and Submission Information

1. Application Submission Instructions: For information on how to submit an application please refer to our Common Instructions for Applicants to Department of Education Discretionary Grant Programs, published in the **Federal Register** on February 12, 2018 (83 FR 6003) and available at www.gpo.gov/fdsys/pkg/FR-2018-02-12/ pdf/2018-02558.pdf.

2. Intergovernmental Review: This competition is subject to Executive Order 12372 and the regulations in 34 CFR part 79. However, under 34 CFR 79.8(a), we waive intergovernmental review in order to make an award by the end of FY 2018.

3. Funding Restrictions: We reference regulations outlining funding restrictions in the Applicable Regulations section of this notice.

4. Recommended Page Limit: The application narrative (Part III of the application) is where you, the applicant, address the selection criteria that reviewers use to evaluate your application. We recommend that you (1) limit the application narrative to no more than 100 pages, and (2) use the following standards:

• A "page" is 8.5″ x 11″, on one side only, with 1″ margins at the top, bottom, and both sides.

• Double-space (no more than three lines per vertical inch) all text in the application narrative, including titles, headings, footnotes, quotations, reference citations, and captions, as well as all text in charts, tables, figures, graphs, and screen shots.

• Use a font that is 12 point or larger.

• Use one of the following fonts: Times New Roman, Courier, Courier New, or Arial.

The recommended page limit does not apply to Part I, the cover sheet; Part II, the budget section, including the narrative budget justification; Part IV, the assurances and certifications; or the abstract (follow the guidance provided in the application package for completing the abstract), the table of contents, the list of priority requirements, the resumes, the reference list, the letters of support, or the appendices. However, the recommended page limit does apply to all of the application narrative, including all text in charts, tables, figures, graphs, and screen shots.

V. Application Review Information

1. *Selection Criteria:* The selection criteria for this competition are from 34 CFR 75.210 and are as follows:

(a) Significance (10 points).

(1) The Secretary considers the

significance of the proposed project. (2) In determining the significance of

the proposed project, the Secretary considers the following factors: (i) The extent to which specific gaps or weaknesses in services, infrastructure, or opportunities have been identified and will be addressed by the proposed project, including the nature and magnitude of those gaps or weaknesses.

(ii) The importance or magnitude of the results or outcomes likely to be attained by the proposed project.

attained by the proposed project. (b) *Quality of project services (35 points).*

(1) The Secretary considers the quality of the services to be provided by the proposed project.

(2) In determining the quality of the services to be provided by the proposed project, the Secretary considers the quality and sufficiency of strategies for ensuring equal access and treatment for eligible project participants who are members of groups that have traditionally been underrepresented based on race, color, national origin, gender, age, or disability.

(3) In addition, the Secretary considers the following factors:

(i) The extent to which the goals, objectives, and outcomes to be achieved by the proposed project are clearly specified and measurable.

(ii) The extent to which there is a conceptual framework underlying the proposed research or demonstration activities and the quality of that framework.

(iii) The extent to which the services to be provided by the proposed project reflect up-to-date knowledge from research and effective practice.

(iv) The extent to which the training or professional development services to be provided by the proposed project are of sufficient quality, intensity, and duration to lead to improvements in practice among the recipients of those services.

(v) The extent to which the TA services to be provided by the proposed project involve the use of efficient strategies, including the use of technology, as appropriate, and the leveraging of non-project resources.

(c) Quality of the project evaluation (20 points).

(1) The Secretary considers the quality of the evaluation to be conducted of the proposed project.

(2) In determining the quality of the evaluation, the Secretary considers the following factors:

(i) The extent to which the methods of evaluation are thorough, feasible, and appropriate to the goals, objectives, and outcomes of the proposed project.

(ii) The extent to which the methods of evaluation provide for examining the effectiveness of project implementation strategies. (iii) The extent to which the methods of evaluation will provide performance feedback and permit periodic assessment of progress toward achieving intended outcomes.

(iv) The extent to which the methods of evaluation include the use of objective performance measures that are clearly related to the intended outcomes of the project and will produce quantitative and qualitative data to the extent possible.

(d) Adequacy of resources and quality of project personnel (15 points).

(1) The Secretary considers the adequacy of resources for the proposed project and the quality of the personnel who will carry out the proposed project.

(2) In determining the quality of project personnel, the Secretary considers the extent to which the applicant encourages applications for employment from persons who are members of groups that have traditionally been underrepresented based on race, color, national origin, gender, age, or disability.

(3) In addition, the Secretary considers the following factors:

(i) The qualifications, including relevant training and experience, of the project director or principal investigator.

(ii) The qualifications, including relevant training and experience, of key project personnel.

(iii) The qualifications, including relevant training and experience, of project consultants or subcontractors.

(iv) The qualifications, including relevant training, experience, and independence, of the evaluator.

(v) The adequacy of support, including facilities, equipment, supplies, and other resources, from the applicant organization or the lead applicant organization.

(vi) The relevance and demonstrated commitment of each partner in the proposed project to the implementation and success of the project.

(vii) The extent to which the budget is adequate to support the proposed project.

(viii) The extent to which the costs are reasonable in relation to the objectives, design, and potential significance of the proposed project.

(e) Quality of the management plan (20 points).

(1) The Secretary considers the quality of the management plan for the proposed project.

(2) In determining the quality of the management plan for the proposed project, the Secretary considers the following factors:

(i) The adequacy of the management plan to achieve the objectives of the proposed project on time and within budget, including clearly defined responsibilities, timelines, and milestones for accomplishing project tasks.

(ii) The extent to which the time commitments of the project director and principal investigator and other key project personnel are appropriate and adequate to meet the objectives of the proposed project.

(iii) The adequacy of mechanisms for ensuring high-quality products and services from the proposed project.

(iv) How the applicant will ensure that a diversity of perspectives are brought to bear in the operation of the proposed project, including those of parents, teachers, the business community, a variety of disciplinary and professional fields, recipients or beneficiaries of services, or others, as appropriate.

2. *Review and Selection Process:* We remind potential applicants that in reviewing applications in any discretionary grant competition, the Secretary may consider, under 34 CFR 75.217(d)(3), the past performance of the applicant in carrying out a previous award, such as the applicant's use of funds, achievement of project objectives, and compliance with grant conditions. The Secretary may also consider whether the applicant failed to submit a timely performance report or submitted a report of unacceptable quality.

In addition, in making a competitive grant award, the Secretary requires various assurances, including those applicable to Federal civil rights laws that prohibit discrimination in programs or activities receiving Federal financial assistance from the Department (34 CFR 100.4, 104.5, 106.4, 108.8, and 110.23).

3. Additional Review and Selection Process Factors: In the past, the Department has had difficulty finding peer reviewers for certain competitions because so many individuals who are eligible to serve as peer reviewers have conflicts of interest. The standing panel requirements under section 682(b) of IDEA also have placed additional constraints on the availability of reviewers. Therefore, the Department has determined that for some discretionary grant competitions, applications may be separated into two or more groups and ranked and selected for funding within specific groups. This procedure will make it easier for the Department to find peer reviewers by ensuring that greater numbers of individuals who are eligible to serve as reviewers for any particular group of applicants will not have conflicts of interest. It also will increase the quality, independence, and fairness of the review process, while permitting panel members to review applications under discretionary grant competitions for which they also have submitted applications.

4. Risk Assessment and Specific Conditions: Consistent with 2 CFR 200.205, before awarding grants under this competition the Department conducts a review of the risks posed by applicants. Under 2 CFR 3474.10, the Secretary may impose specific conditions and, in appropriate circumstances, high-risk conditions on a grant if the applicant or grantee is not financially stable; has a history of unsatisfactory performance; has a financial or other management system that does not meet the standards in 2 CFR part 200, subpart D; has not fulfilled the conditions of a prior grant; or is otherwise not responsible.

5. Integrity and Performance System: If you are selected under this competition to receive an award that over the course of the project period may exceed the simplified acquisition threshold (currently \$150,000), under 2 CFR 200.205(a)(2) we must make a judgment about your integrity, business ethics, and record of performance under Federal awards—that is, the risk posed by you as an applicant—before we make an award. In doing so, we must consider any information about you that is in the integrity and performance system (currently referred to as the Federal Awardee Performance and Integrity Information System (FAPIIS)), accessible through the System for Award Management. You may review and comment on any information about yourself that a Federal agency previously entered and that is currently in FAPIIS.

Please note that, if the total value of your currently active grants, cooperative agreements, and procurement contracts from the Federal Government exceeds \$10,000,000, the reporting requirements in 2 CFR part 200, Appendix XII, require you to report certain integrity information to FAPIIS semiannually. Please review the requirements in 2 CFR part 200, Appendix XII, if this grant plus all the other Federal funds you receive exceed \$10,000,000.

VI. Award Administration Information

1. *Award Notices:* If your application is successful, we notify your U.S. Representative and U.S. Senators and send you a Grant Award Notification (GAN); or we may send you an email containing a link to access an electronic version of your GAN. We may notify you informally, also. If your application is not evaluated or not selected for funding, we notify you. 2. Administrative and National Policy

2. Administrative and National Policy Requirements: We identify administrative and national policy requirements in the application package and reference these and other requirements in the Applicable Begulations section of this notice.

Regulations section of this notice. We reference the regulations outlining the terms and conditions of an award in the Applicable Regulations section of this notice and include these and other specific conditions in the GAN. The GAN also incorporates your approved application as part of your binding commitments under the grant.

3. Open Licensing Requirements: Unless an exception applies, if you are awarded a grant under this competition, you will be required to openly license to the public grant deliverables created in whole, or in part, with Department grant funds. When the deliverable consists of modifications to pre-existing works, the license extends only to those modifications that can be separately identified and only to the extent that open licensing is permitted under the terms of any licenses or other legal restrictions on the use of pre-existing works. Additionally, a grantee or subgrantee that is awarded competitive grant funds must have a plan to disseminate these public grant deliverables. This dissemination plan can be developed and submitted after your application has been reviewed and selected for funding. For additional information on the open licensing requirements please refer to 2 CFR 3474.20.

4. *Reporting:* (a) If you apply for a grant under this competition, you must ensure that you have in place the necessary processes and systems to comply with the reporting requirements in 2 CFR part 170 should you receive funding under the competition. This does not apply if you have an exception under 2 CFR 170.110(b).

(b) At the end of your project period, you must submit a final performance report, including financial information, as directed by the Secretary. If you receive a multiyear award, you must submit an annual performance report that provides the most current performance and financial expenditure information as directed by the Secretary under 34 CFR 75.118. The Secretary may also require more frequent performance reports under 34 CFR 75.720(c). For specific requirements on reporting, please go to www.ed.gov/ fund/grant/apply/appforms/ appforms.html.

5. *Performance Measures:* Under the Government Performance and Results

Act of 1993, the Department has established a set of performance measures, including long-term measures, that are designed to yield information on various aspects of the effectiveness and quality of the Technical Assistance and Dissemination to Improve Services and Results for Children With Disabilities program. These measures are:

• Program Performance Measure #1: The percentage of Technical Assistance and Dissemination products and services deemed to be of high quality by an independent review panel of experts qualified to review the substantive content of the products and services.

• Program Performance Measure #2: The percentage of Special Education Technical Assistance and Dissemination products and services deemed by an independent review panel of qualified experts to be of high relevance to educational and early intervention policy or practice.

• Program Performance Measure #3: The percentage of all Special Education Technical Assistance and Dissemination products and services deemed by an independent review panel of qualified experts to be useful to improve educational or early intervention policy or practice.

• Program Performance Measure #4: The cost efficiency of the Technical Assistance and Dissemination Program includes the percentage of milestones achieved in the current annual performance report period and the percentage of funds spent during the current fiscal year.

• Long-term Program Performance Measure: The percentage of States receiving Special Education Technical Assistance and Dissemination services regarding scientifically or evidencebased practices for infants, toddlers, children, and youth with disabilities that successfully promote the implementation of those practices in school districts and service agencies.

The measures apply to projects funded under this competition, and grantees are required to submit data on these measures as directed by OSEP.

Grantees will be required to report information on their project's performance in annual and final performance reports to the Department (34 CFR 75.590).

6. Continuation Awards: In making a continuation award under 34 CFR 75.253, the Secretary considers, among other things: whether a grantee has made substantial progress in achieving the goals and objectives of the project; whether the grantee has expended funds in a manner that is consistent with its approved application and budget; and,

if the Secretary has established performance measurement requirements, the performance targets in the grantee's approved application.

In making a continuation award, the Secretary also considers whether the grantee is operating in compliance with the assurances in its approved application, including those applicable to Federal civil rights laws that prohibit discrimination in programs or activities receiving Federal financial assistance from the Department (34 CFR 100.4, 104.5, 106.4, 108.8, and 110.23).

VII. Other Information

Accessible Format: Individuals with disabilities can obtain this document and a copy of the application package in an accessible format (*e.g.*, braille, large print, audiotape, or compact disc) by contacting the Management Support Services Team, U.S. Department of Education, 400 Maryland Avenue SW, Room 5113, Potomac Center Plaza, Washington, DC 20202–2500. Telephone: (202) 245–7363. If you use a TDD or a TTY, call the FRS, toll free, at 1–800–877–8339.

Electronic Access to This Document: The official version of this document is the document published in the **Federal Register**. You may access the official edition of the **Federal Register** and the Code of Federal Regulations via the Federal Digital System at: *www.gpo.gov/ fdsys.* At this site you can view this document, as well as all other documents of this Department published in the **Federal Register**, in text or Portable Document Format (PDF). To use PDF you must have Adobe Acrobat Reader, which is available free at the site.

You may also access documents of the Department published in the **Federal Register** by using the article search feature at: *www.federalregister.gov.* Specifically, through the advanced search feature at this site, you can limit your search to documents published by the Department.

Dated: July 20, 2018.

Johnny W. Collett,

Assistant Secretary, Special Education and Rehabilitative Services.

Frank T. Brogan,

Assistant Secretary, Elementary and Secondary Education.

[FR Doc. 2018–15928 Filed 7–24–18; 8:45 am] BILLING CODE 4000–01–P

DEPARTMENT OF EDUCATION

National Assessment Governing Board

AGENCY: National Assessment Governing Board, U.S. Department of Education.

ACTION: Announcement of open and closed meetings.

SUMMARY: This notice sets forth the agenda for the August 2-4, 2018 Quarterly Board Meeting of the National Assessment Governing Board (hereafter referred to as Governing Board). This notice provides information to members of the public who may be interested in attending the meeting or providing written comments related to the work of the Governing Board. Notice of this meeting is required under § 10(a)(2) of the Federal Advisory Committee Act (FACA). This meeting notice is published late due to the fact that approval of the August Board meeting agenda required a quorum of the Board's Executive Committee which could not be established in time to provide timely notice in the Federal Register.

DATES: The Quarterly Board Meeting will be held on the following dates:

• August 2, 2018 from 9:00 a.m. to 6:00 p.m.

• August 3, 2018 from 8:30 a.m. to 5:00 p.m.

• August 4, 2018 from 7:30 a.m. to 12:00 p.m.

ADDRESSES: Park Hyatt Washington, 1201 24th Street NW, Washington, DC 20037.

FOR FURTHER INFORMATION CONTACT: Munira Mwalimu, Executive Officer/ Designated Federal Official for the Governing Board, 800 North Capitol Street NW, Suite 825, Washington, DC 20002, telephone: (202) 357–6938, fax: (202) 357–6945, email: *Munira.Mwalimu@ed.gov.*

SUPPLEMENTARY INFORMATION:

Statutory Authority and Function: The Governing Board is established under the National Assessment of Educational Progress Authorization Act, Title III of Public Law 107–279. Written comments may be submitted electronically or in hard copy to the attention of the Executive Officer/ Designated Federal Official (see contact information noted above). Information on the Governing Board and its work can be found at www.nagb.gov.

The Governing Board is established to formulate policy for the National Assessment of Educational Progress (NAEP). The Governing Board's responsibilities include the following: Selecting subject areas to be assessed, developing assessment frameworks and specifications, developing appropriate student achievement levels for each grade and subject tested, developing standards and procedures for interstate and national comparisons, improving the form and use of NAEP, developing guidelines for reporting and disseminating results, and releasing initial NAEP results to the public.

August 2-4, 2018: Committee Meetings

The Governing Board's standing committees will meet to conduct regularly scheduled work based on agenda items planned for this Quarterly Board Meeting and follow-up items as reported in the Governing Board's committee meeting minutes available at *https://www.nagb.gov/governing-board/ quarterly-board-meetings.html.*

Detailed Meeting Agenda: August 2–4, 2018

August 2: Committee Meetings

Assessment Development Committee: Open Session: 9:00 a.m. to 9:15 a.m.; Closed Session: 9:15 a.m. to 12:05 p.m.; Open Session: 12:05 p.m. to 12:30 p.m.

Ad Hoc Committee on Measures of Postsecondary Preparedness: Open Session: 1:30 p.m. to 4:00 p.m.

Poster Gallery Session: Spotlight on NAEP Secondary Research (SV #1); Graduate Fellows: Open Session: 4:00 p.m. to 5:00 p.m.

Executive Committee: Open Session: 5:00 p.m. to 5:15 p.m.; Closed Session: 5:15 p.m. to 6:00 p.m.

August 3: Full Governing Board and Committee Meetings

Full Governing Board: Open Session: 8:30 a.m. to 9:15 a.m.; Closed Session: 12:15 p.m. to 1:30 p.m.; Open Session: 1:30 p.m. to 5:00 p.m.

Committee Meetings: 9:30 a.m. to 12:00 p.m.

Assessment Development Committee (ADC): Closed Session: 9:30 a.m. to 11:20 p.m. Open Session: 11:20 p.m. to 12:00 p.m.

Reporting and Dissemination (R&D): Open Session 9:30 a.m. to 12:00 p.m.

Committee on Standards, Design and Methodology (COSDAM): Open Session: 9:30 a.m. to 11:10 a.m.; Closed Session: 11:10 a.m. to 12:00 p.m.;

August 4: Full Governing Board and Committee Meetings

Nominations Committee: Closed Session: 7:30 a.m. to 8:15 a.m.

Full Governing Board: Closed Session: 8:30 a.m. to 8:45 a.m.; Open Session: 8:30 a.m. to 12:00 p.m.

On Thursday, August 2, 2018, the ADC will meet in open session from 9:00 a.m. to 9:15 a.m. for opening

remarks and a review of the committee agenda, followed by a closed session meeting from 9:15 a.m. to 12:05 p.m. During the closed session, ADC will receive a briefing on the secure item pool for the NAEP Mathematics Assessment and review secure cognitive and contextual items for the NAEP Assessments in Reading, Writing, Mathematics, and Science. This meeting must be conducted in closed session because the test items and data are secure and have not been released to the public. Public disclosure of the secure test items would significantly impede implementation of the NAEP assessment program if conducted in open session. Such matters are protected by exemption 9(B) of § 552b(c) of Title 5 of the United States Code.

On Thursday, August 3, 2018, the Ad Hoc Committee on Measures of Postsecondary Preparedness will meet in open session from 1:30 p.m. to 4:00 p.m. Thereafter, from 4:00 p.m. to 5:00 p.m. a Poster Gallery session will provide a spotlight on NAEP Secondary Research.

The Executive Committee will then convene in open session from 5:00 p.m. to 5:15 p.m. followed by a closed session from 5:15 p.m. to 6:00 p.m. During the closed session, the Executive Committee will receive and discuss cost estimates and implications for implementing NAEP's Assessment Schedule for 2014–2024. The first session of this closed meeting must be conducted in closed session because public disclosure of this information would likely have an adverse financial effect on the NAEP program by providing confidential cost details and proprietary contract costs of current contractors to the public. Discussion of this information would be likely to significantly impede implementation of a proposed agency action if conducted in open session. Such matters are protected by exemption 9(B) of section 552b of Title 5 U.S.C. Following this closed session, the second session of the closed meeting is being held to receive a briefing from Terry Mazany, Chair of the Search Committee for the Executive Director on the status of the search process.

On Friday, August 3, 2018, the Governing Board will meet in open session from 8:30 a.m. to 10:15 a.m. The Governing Board will review and approve the August 2–4, 2018 Governing Board meeting agenda and meeting minutes from the May 2018 Quarterly Board Meeting from 8:30 a.m. to 8:40 a.m. Thereafter, from 8:40 a.m. to 9:00 a.m. the Governing Board's Executive Director, Bill Bushaw will provide an annual report on progress made in implementing the Governing Board's Strategic Vision. From 9:00 a.m. to 9:15 a.m., the standing committee chairs will provide a preview of the agenda items for the committee meetings. At 9:15 a.m., the Governing Board will recess for a 15 minute break. Thereafter, committee meetings will take place from 9:30 a.m. to 12:00 p.m.

On Friday, August 3, 2018, the **Reporting and Dissemination Committee** will meet in open session from 9:30 a.m. to 12:00 p.m. ADC will meet in closed session from 9:30 a.m. to 11:20 a.m. to address two agenda items. For the first agenda item, ADC will complete the review of secure cognitive and contextual items for the NAEP Assessments in Reading, Writing, Mathematics, and Science. For the second agenda item, ADC will receive a briefing on secure test items and data for NAEP Assessments in Civics, Geography, and U.S. History. This meeting must be conducted in closed session because the test items and data are secure and have not been released to the public. Public disclosure of the secure test items would significantly impede implementation of the NAEP assessment program if conducted in open session. Such matters are protected by exemption 9(B) of § 552b(c) of Title 5 of the United States Code. Following the closed sessions, ADC will meet in open session from 11:20 a.m. to 12:00 p.m.

On Friday, August 3, 2018, COSDAM will meet in open session from 9:30 a.m. to 11:10 a.m. followed by a closed session from 11:10 a.m. to 12:00 p.m. During the closed session, COSDAM will discuss information regarding analyses of secure 2017 NAEP writing assessment data. This part of the meeting must be conducted in closed session because the secure writing data has not been released to the public. Public disclosure of the data would significantly impede implementation of the NAEP assessment program if conducted in open session. Such matters are protected by exemption 9(B) of § 552b(c) of Title 5 of the United States Code.

The Governing Board will meet in closed session from 12:15 p.m. to 1:30 p.m. during a working lunch to discuss the NAEP budget implications of implementing the Board's priorities for extending the NAEP Assessment Schedule beyond the year 2024. This meeting must be conducted in closed session because public disclosure of this information would likely have an adverse financial effect on the NAEP program by providing confidential cost details and proprietary contract costs of current contractors to the public. Discussion of this information would be likely to significantly impede implementation of a proposed agency action if conducted in open session. Such matters are protected by exemption 9(B) of section 552b of Title 5 U.S.C.

On Friday, August 3, 2018 from 1:30 p.m. to 2:30 p.m. the Board will meet in open session to receive an update on the NAEP Mathematics Framework followed by a full Board member discussion. From 2:30 p.m. to 3:00 p.m. Mr. Terry Mazany, Chair of the Ad Hoc Committee on Measures of Postsecondary Preparedness will provide an overview of the Ad Hoc Committee's draft recommendations. Following this session, the Board will take a 15 minute break and reconvene in open session from 3:15 p.m. to 4:15 p.m. in small groups to discuss draft the Ad Hoc Committee's recommendations. Thereafter, the Board will recess for a 15 minute break and convene at 4:30 p.m. to discuss takeaways from the small group discussions on the Ad Hoc Committee recommendations. The breakout sessions will conclude at 5:00 p.m.

The August 3, 2018 session of the Governing Board meeting will adjourn at 5:00 p.m.

On Saturday, August 4, 2018, the Nominations Committee will meet in closed session from 7:30 a.m. to 8:15 a.m. The Committee will provide updates on nominees for Governing Board vacancies for terms beginning October 1, 2018 and provide updates on plans to open the nominations cycle for Board vacancies for terms beginning October 1, 2019. The Nominations Committee's discussions pertain solely to internal personnel rules and practices of an agency and information of a personal nature where disclosure would constitute a clearly unwarranted invasion of personal privacy. As such, the discussions are protected by exemptions 2 and 6 of § 552b(c) of Title 5 of the United States Code.

On August 4, 2018, the Governing Board will convene in closed session from 8:30 a.m. to 8:45 a.m. to receive a briefing from Terry Mazany, Chair of the Search Committee for the Executive Director on the status of the search process and make decisions on the next steps for the hiring process. These discussions pertain solely to internal personnel rules and practices of an agency and information of a personal nature where disclosure would constitute a clearly unwarranted invasion of personal privacy. As such, the discussions are protected by exemptions 2 and 6 of § 552b(c) of Title 5 of the United States Code.

Following the closed session, the Governing Board will meet in open session from 8:30 a.m. to 9:30 a.m. to receive a briefing on the NAEP Assessment Schedule with a focus on Social Studies. This briefing will be led by Sharyn Rosenberg, Governing Board staff and Eunice Greer, NCES staff.

From 9:30 a.m. to 10:00 a.m. the Ad Hoc Committee Chair, Terry Mazany will provide additional reflections on the Ad Hoc Committee's recommendations on Post-Secondary Preparedness. The Governing Board will then receive reports from its standing committees from 10:00 a.m. to 10:30 a.m. Following a 15 minute break, the Board will receive a briefing and engage in discussion on the NAEP Achievement Levels Setting Policy led by Andrew Ho, COSDAM Chair. From 11:30 a.m. to 12:00 p.m. retiring Governing Board's Executive Director Bill Bushaw will provide remarks.

The August 4, 2018 session of the board meeting will adjourn at 12:00 p.m.

Access to Records of the Meeting: Pursuant to FACA requirements, the public may also inspect the meeting materials at *www.nagb.gov* beginning on Thursday, August 2, 2018, by 10:00 a.m. EST. The official verbatim transcripts of the public meeting sessions will be available for public inspection no later than 30 calendar days following the meeting.

Reasonable Accommodations: The meeting site is accessible to individuals with disabilities. If you will need an auxiliary aid or service to participate in the meeting (*e.g.*, interpreting service, assistive listening device, or materials in an alternate format), notify the contact person listed in this notice no later than 21 days prior to the meeting.

Electronic Access to this Document: The official version of this document is the document published in the Federal **Register**. Internet access to the official edition of the Federal Register and the Code of Federal Regulations is available via the Federal Digital System at: www.gpo.gov/fdsys. At this site you can view this document, as well as all other documents of this Department published in the Federal Register, in text or Adobe Portable Document Format (PDF). To use PDF, you must have Adobe Acrobat Reader, which is available free at the Adobe website. 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.

Authority: Pub. L. 107–279, Title III— National Assessment of Educational Progress § 301.

Dated: July 20, 2018.

William Bushaw,

Executive Director, National Assessment Governing Board (NAGB), U.S. Department of Education.

[FR Doc. 2018–15887 Filed 7–24–18; 8:45 am] BILLING CODE P

DEPARTMENT OF ENERGY

Federal Energy Regulatory Commission

[Docket No. CP18-522-000]

El Paso Natural Gas Company, L.L.C.; Notice of Request Under Blanket Authorization

Take notice that on July 12, 2018, El Paso Natural Gas Company, L.L.C. (EPNG), P.O. Box 1087, Colorado Springs, Colorado 80944, filed a prior notice request pursuant to sections 157.205, 157.208, and 157.210 of the Commission's regulations under the Natural Gas Act (NGA) requesting authorization to install or upgrade appurtenant facilities at various locations in Winkler and Yoakum Counties, Texas and in Eddy and Lea Counties, New Mexico. Additionally, EPNG proposes to increase the maximum allowable operating pressure for approximately 2,800 feet of its 20inch-diameter Line No. 1115 in Ector County, Texas (collectively, Permian North Project). EPNG states that the Permian North Project will provide 182,000 dekatherms per day of firm transportation service for six shippers. Specifically, EPNG proposes to install valves, actuators, station yard piping, and other auxiliary equipment at the Keystone, Pecos River Eunice B/C, and Plains Compressor Stations and the Ramsey North Meter Station. EPNG estimates the cost of the Permian North Project to be approximately \$12 million, all as more fully set forth in the application which is on file with the Commission and open to public inspection. The filing may also be viewed on the web at http:// www.ferc.gov using the "eLibrary" link. Enter the docket number excluding the last three digits in the docket number field to access the document. For assistance, please contact FERC Online Support at FERCOnlineSupport@ ferc.gov or toll free at (866) 208–3676, or TTY, contact (202) 502-8659.

Any questions concerning this application may be directed to Francisco Tarin, Director, Regulatory, El Paso Natural Gas Company, L.L.C., P.O. Box 1087, Colorado Springs, Colorado 80944, by telephone at (719) 667–7517, or by fax at (719) 520–4697.

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, will receive copies of the environmental documents, and will be notified of meetings associated with the Commission's environmental review process. Environmental commenter's will not be required to serve copies of filed documents on all other parties. However, the non-party commentary, will not receive copies of all documents filed by other parties or issued by the Commission (except for the mailing of environmental documents issued by the Commission) and will not have the right to seek court review of the Commission's final order.

The Commission strongly encourages electronic filings of comments, protests, and interventions in lieu of paper using the "eFiling" link at *http:// www.ferc.gov.* Persons unable to file electronically should submit an original and 7 copies of the protest or intervention to the Federal Energy Regulatory Commission, 888 First Street NE, Washington, DC 20426.

Dated: July 18, 2018. **Kimberly D. Bose,** *Secretary.* [FR Doc. 2018–15836 Filed 7–24–18; 8:45 am] **BILLING CODE 6717–01–P**

DEPARTMENT OF ENERGY

Federal Energy Regulatory Commission

[Docket No. IC18-11-000]

Commission Information Collection Activities (FERC–585); Comment Request; Extension

AGENCY: Federal Energy Regulatory Commission, DOE.

ACTION: Notice of information collection and request for comments.

SUMMARY: In compliance with the requirements of the Paperwork Reduction Act of 1995, the Federal **Energy Regulatory Commission** (Commission or FERC) is submitting its information collection, FERC-585 (Reporting of Electric Energy Shortages and Contingency Plans Under PURPA Section 206) to the Office of Management and Budget (OMB) for review of the information collection requirements. Any interested person may file comments directly with OMB and should address a copy of those comments to the Commission as explained below. The Commission previously issued a Notice in the Federal Register on April 12, 2018, requesting public comments. The Commission received no comments on the FERC-585 and is making this notation in its submittal to OMB.

DATES: Comments on the collection of information are due August 24, 2018. ADDRESSES: Comments filed with OMB, identified by the OMB Control No. 1902–0138, should be sent via email to the Office of Information and Regulatory Affairs: *oira_submission@omb.gov.* Attention: Federal Energy Regulatory Commission Desk Officer. The Desk Officer may also be reached via telephone at 202–395–8528. A copy of the comments should also be sent to the Commission, in Docket No. IC18–11–000, by either of the following methods:

• eFiling at Commission's Website: http://www.ferc.gov/docs-filing/ efiling.asp.

• *Mail/Hand Delivery/Courier:* Federal Energy Regulatory Commission, Secretary of the Commission, 888 First Street NE, Washington, DC 20426.

Instructions: All submissions must be formatted and filed in accordance with submission guidelines at: http:// www.ferc.gov/help/submissionguide.asp. For user assistance contact FERC Online Support by email at ferconlinesupport@ferc.gov, or by phone at: (866) 208–3676 (toll-free), or (202) 502–8659 for TTY.

Docket: Users interested in receiving automatic notification of activity in this docket or in viewing/downloading comments and issuances in this docket may do so at http://www.ferc.gov/docsfiling/docs-filing.asp.

FOR FURTHER INFORMATION CONTACT:

Ellen Brown may be reached by email at *DataClearance@FERC.gov*, telephone at (202) 502–8663, and fax at (202) 273–0873.

SUPPLEMENTARY INFORMATION:

Title: FERC–585 (Reporting of Electric Energy Shortages and Contingency Plans Under PURPA ¹ Section 206).

OMB Control No.: 1902–0138.

Type of Request: Three-year extension of the FERC–585 information collection requirements with no changes to the current reporting requirements.

Abstract: The Commission uses the information collected under the requirements of FERC–585 to implement the statutory provisions of Section 206 of PURPA. Section 206 of PURPA amended the Federal Power Act (FPA) by adding a new subsection (g) to section 202, under which the Commission, by rule, was to require each public utility to report to the Commission and any appropriate state regulatory authority:

• Any anticipated shortages of electric energy or capacity which would affect the utility's capability to serve its wholesale customers; and

• a contingency plan that would outline what circumstances might give rise to such occurrences.

• In Order No. 575,² the Commission modified the reporting requirements in 18 CFR 294.101(b) to provide that, if a public utility includes in its rates

¹ PURPA = Public Utility Regulatory Policies Act of 1979 (Pub. L. 95–617, 92 Stat. 3117), enacted 11/ 9/1978.

² Final Rule in Docket RM92–12–000, issued on 1/13/1995.

schedule, provisions that during electric energy and capacity shortages:

• It will treat firm power wholesale customers without undue discrimination or preference; and

• it will report any modifications to its contingency plan for accommodating shortages within 15 days to the appropriate state regulatory agency and to the affected wholesale customers, then the utility need not file with the Commission an additional statement of contingency plan for accommodating such shortages.

This revision merely changed the reporting mechanism; the public utility's contingency plan would be located in its filed rate rather than in a separate document.

In Order No. 659,³ the Commission modified the reporting requirements in 18 CFR 294.101(e) to provide that public utilities must comply with the requirements to report shortages and anticipated shortages by submitting this information electronically using the Office of Electric Reliability's pager system at *emergency@ferc.gov* in lieu of submitting an original and two copies to the Secretary of the Commission. The Commission uses the information to evaluate and formulate an appropriate option for action in the event an unanticipated shortage is reported and/ or materializes. Without this

information, the Commission and State agencies would be unable to:

• Examine and approve or modify utility actions;

• prepare a response to anticipated disruptions in electric energy; and/or

• ensure equitable treatment of all public utility customers under the shortage situation.

The Commission implements these filing requirements in the Code of Federal Regulations (CFR) under 18 CFR part 294.101.

Type of Respondents: Public Utilities. *Estimate of Annual Burden:*⁴ The Commission estimates the annual public reporting burden for the information collection as:

FERC-585 (REPORTING OF ELECTRIC SHORTAGES AND CONTINGENCY PLANS UNDER PURPA SECTION 206)⁵

	Number of respondents	Annual number of responses per respondent	Total number of responses	Average burden and cost per Response ⁶	Total annual burden hours and total annual cost	Cost per respondent
	(1)	(2)	(1) * (2) = (3)	(4)	(3) * (4) = (5)	(\$) 5) ÷ (1)
Contingency Plan Capacity Shortage	1	1	1		73 hrs.; \$5,767 0.25 hrs.; \$19.75	\$5,767 \$19.75
Total					73.25 hrs.; \$5,786.75	

Comments: Comments are invited on: (1) Whether the collection of information is necessary for the proper performance of the functions of the Commission, including whether the information will have practical utility; (2) the accuracy of the agency's estimate of the burden and cost of the collection of information, including the validity of the methodology and assumptions used; (3) ways to enhance the quality, utility and clarity of the information collection; and (4) ways to minimize the burden of the collection of information on those who are to respond, including the use of automated collection techniques or other forms of information technology.

Dated: July 18, 2018.

Kimberly D. Bose,

Secretary.

[FR Doc. 2018–15835 Filed 7–24–18; 8:45 am] BILLING CODE 6717–01–P

 3 Final Rule in Docket RM05–19–000, issued on 5/27/2005.

ENVIRONMENTAL PROTECTION AGENCY

[EPA-HQ-OPPT-2017-0645; FRL-9978-03]

Agency Information Collection Activities; Proposed Renewal of an Existing Collection (EPA ICR No. 0574.18); Comment Request

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

SUMMARY: In compliance with the Paperwork Reduction Act (PRA), this document announces that EPA is planning to submit an Information Collection Request (ICR) to the Office of Management and Budget (OMB). The ICR, entitled: "Premanufacture Review Reporting and Exemption Requirements for New Chemical Substances and Significant New Use Reporting Requirements for Chemical Substances" and identified by EPA ICR No. 0574.18 and OMB Control No. 2070–0012, represents the renewal of an existing ICR that is scheduled to expire on November 30, 2018. Before submitting the ICR to OMB for review and approval, EPA is soliciting comments on specific aspects of the proposed information collection that is summarized in this document. The ICR and accompanying material are available in the docket for public review and comment.

DATES: Comments must be received on or before September 24, 2018.

ADDRESSES: Submit your comments, identified by docket identification (ID) number EPA-HQ-OPPT-2017-0645, by one of the following methods:

• Federal eRulemaking Portal: http:// www.regulations.gov. Follow the online instructions for submitting comments. Do not submit electronically any information you consider to be Confidential Business Information (CBI) or other information whose disclosure is restricted by statute.

• *Mail:* Document Control Office (7407M), Office of Pollution Prevention and Toxics (OPPT), Environmental

⁴ "Burden" is defined as the total time, effort, or financial resources expended by persons to generate, maintain, retain, or disclose or provide information to or for a Federal agency. For further explanation of what is included in the information collection burden, refer to 5 Code of Federal Regulations 1320.3.

⁵ The estimates in this table are slightly different from the estimates in the 60-day notice. In the 60day notice we used wage figures from 2017. In May 2018, we began using the 2018 cost estimates. There are no other changes from the 60-day notice other than the change to wage figures. The difference in the burden cost is minimal. The burden hours remain unchanged.

⁶ The estimates for cost per response are derived using the following formula: Average Burden Hours per Response * 79.00 per Hour = Average Cost per Response. This is Based upon FERC's 2018 FTE average salary plus benefits. Commission staff believes that any industry effort applied to FERC– 585 would be compensated similarly to FERC's average salary.

Protection Agency, 1200 Pennsylvania Ave. NW, Washington, DC 20460–0001.

• *Hand Delivery*: To make special arrangements for hand delivery or delivery of boxed information, please follow the instructions at *http://www.epa.gov/dockets/contacts.html*.

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

FOR FURTHER INFORMATION CONTACT:

For technical information contact: Adam Ross, Chemical Control Division (7101M), Office of Pollution Prevention and Toxics, Environmental Protection Agency, 1200 Pennsylvania Ave. NW, Washington, DC 20460–0001; telephone number: (202) 564–1625; email address: ross.adam@epa.gov.

For general information contact: The TSCA-Hotline, ABVI-Goodwill, 422 South Clinton Ave., Rochester, NY 14620; telephone number: (202) 554– 1404; email address: *TSCA-Hotline*@ *epa.gov.*

SUPPLEMENTARY INFORMATION:

I. What information is EPA particularly interested in?

Pursuant to PRA section 3506(c)(2)(A) (44 U.S.C. 3506(c)(2)(A)), EPA specifically solicits comments and information to enable it to:

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 estimates 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.

4. Minimize the burden of the collection of information on those who are to respond, including through the use of appropriate automated electronic, mechanical, or other technological collection techniques or other forms of information technology, *e.g.*, permitting electronic submission of responses. In particular, EPA is requesting comments from very small businesses (those that employ less than 25) on examples of specific additional efforts that EPA could make to reduce the paperwork burden for very small businesses affected by this collection.

II. What information collection activity or ICR does this action apply to?

Title: Premanufacture Review Reporting and Exemption Requirements for New Chemical Substances and Significant New Use Reporting Requirements for Chemical Substances.

ICR number: EPA ICR No. 0574.18. *OMB control number:* OMB Control No. 2070–0012.

ICR status: This ICR is currently scheduled to expire on November 30, 2018. An Agency may not conduct or sponsor, and a person is not required to respond to, a collection of information, unless it displays a currently valid OMB control number. The OMB control numbers for EPA's regulations in title 40 of the Code of Federal Regulations (CFR), after appearing in the Federal Register when approved, are listed in 40 CFR part 9, are displayed either by publication in the Federal Register or by other appropriate means, such as on the related collection instrument or form, if applicable. The display of OMB control numbers for certain EPA regulations is consolidated in 40 CFR part 9.

Abstract: Section 5 of the Toxic Substances Control Act (TSCA), as amended by the Frank R. Lautenberg Chemical Safety for the 21st Century Act requires that any person who proposes to manufacture (which includes import) a "new chemical" (i.e., a chemical not listed on the TSCA section 8(b) Inventory) must provide a notice to EPA at least 90 days prior to commencing manufacture of that chemical. EPA must review a section 5 notice, make an affirmative determination on the safety of the new chemical substance, and, if appropriate, regulate the chemical to address any unreasonable risks identified before it can proceed to the marketplace.

EPA is authorized to determine that a use of a chemical substance is a significant new use and promulgate a significant new use rule (SNUR). In certain instances, persons may opt to pursue that use, in which case they must submit a notice and undergo a review. For such circumstances, TSCA section 5 requires a significant new use notice (SNUN) from any person who proposes to manufacture or process a chemical for a use that is determined by EPA to be a "significant new use."

Furthermore, TSCA section 5 requires EPA to make determinations regarding the manufacture, processing, distribution in commerce, use and/or disposal of new chemical substances or significant new uses. To assist in the evaluation, EPA encourages notice submitters to contact an EPA specialist through a pre-submission consultation to ensure that the submitter understands EPA's review process and information needed to make a determination regarding the chemical. On June 20,

2018, EPA issued guidance entitled "Points to Consider When Preparing TSCA New Chemical Notifications" to inform and assist submitters planning to prepare notices, and exemption applications for Agency review (see https://www.epa.gov/reviewing-newchemicals-under-toxic-substancescontrol-act-tsca/points-consider-whenpreparing-tsca). Using the notice submitted to the Agency, EPA evaluates the health and environmental effects of new chemical substances. On the basis of its review, EPA must make one of five possible regulatory determinations with respect to the new chemical substance or significant new use and take action, as appropriate, to ensure adequate protection of human health and the environment. If EPA takes no action within the 90-day review period for PMNs (or 30 or 45 days for PMN exemption applications), the Lautenberg amendments state that the PMN submitter is entitled to receive a refund of fees. EPA requires that the submitter of a PMN or MCAN inform EPA when non-exempt commercial manufacture of the substance in question actually begins by submitting a Notice of Commencement.

This information collection addresses the reporting and recordkeeping requirements associated with TSCA section 5.

Responses to the collection of information are mandatory (see 40 CFR parts 700, 720, 721, 723 and 725). Respondents may claim all or part of a document confidential. EPA will disclose information that is covered by a claim of confidentiality only to the extent permitted by, and in accordance with, the procedures in TSCA section 14 and 40 CFR part 2.

Burden statement: The annual public reporting and recordkeeping burden for this collection of information is estimated to range between approximately 17 and 524 hours per response. Burden is defined in 5 CFR 1320.3(b).

The ICR, which is available in the docket along with other related materials, provides a detailed explanation of the collection activities and the burden estimate that is only briefly summarized here:

Respondents/affected entities: Entities potentially affected by this ICR are companies that manufacture, process or import chemical substances.

Êstimated total number of potential respondents: 234.

Frequency of response: Annual. Estimated total average number of responses for each respondent: 1,795.

Éstimatéd total annual respondent burden hours: 148,312 hours.

Estimated total annual respondent costs: \$46,765,6135. This includes an estimated burden cost of \$138,093 and an estimated cost of \$0.00 for capital investment or maintenance and operational costs.

III. Are there changes in the estimates from the last approval?

There is an increase of 146,312 hours in the total estimated respondent burden compared with that identified in the ICR currently approved by OMB. This increase reflects a change in the mix of EPA's estimated number of each type of notice. Similarly, the estimated number of annual CDX registrants also increased. Lastly, there was an increase in burden associated with new CBI substantiation requirements resulting from the 2016 amendment to TSCA. The change in burden is explained more fully in the ICR Supporting Statement. This change is an adjustment and a program change.

IV. What is the next step in the process for this ICR?

EPA will consider the comments received and amend the ICR as appropriate. The final ICR package will then be submitted to OMB for review and approval pursuant to 5 CFR 1320.12. EPA will issue another **Federal Register** document pursuant to 5 CFR 1320.5(a)(1)(iv) to announce the submission of the ICR to OMB and the opportunity to submit additional comments to OMB. If you have any questions about this ICR or the approval process, please contact the technical person listed under **FOR FURTHER INFORMATION CONTACT.**

Authority: 44 U.S.C. 3501 et seq.

Dated: July 13, 2018.

Charlotte Bertrand,

Acting Principal Deputy Assistant Administrator, Office of Chemical Safety and Pollution Prevention.

[FR Doc. 2018–15920 Filed 7–24–18; 8:45 am] BILLING CODE 6560–50–P

ENVIRONMENTAL PROTECTION AGENCY

[EPA-HQ-OPPT-2017-0646; FRL-9980-27]

Agency Information Collection Activities; Proposed Renewal of an Existing Collection (EPA ICR No. 0575.16); Comment Request

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

SUMMARY: In compliance with the Paperwork Reduction Act (PRA), this

document announces that EPA is planning to submit an Information Collection Request (ICR) to the Office of Management and Budget (OMB). The ICR, entitled: "Health and Safety Data Reporting, Submission of Lists and Copies of Health and Safety Studies" and identified by EPA ICR No. 0575.16 and OMB Control No. 2070–0004, represents the renewal of an existing ICR that is scheduled to expire on November 30, 2018. Before submitting the ICR to OMB for review and approval, EPA is soliciting comments on specific aspects of the proposed information collection that is summarized in this document. The ICR and accompanying material are available in the docket for public review and comment.

DATES: Comments must be received on or before September 24, 2018.

ADDRESSES: Submit your comments, identified by docket identification (ID) number EPA-HQ-OPPT-2017-0646, by one of the following methods:

• Federal eRulemaking Portal: http:// www.regulations.gov. Follow the online instructions for submitting comments. Do not submit electronically any information you consider to be Confidential Business Information (CBI) or other information whose disclosure is restricted by statute.

• *Mail:* Document Control Office (7407M), Office of Pollution Prevention and Toxics (OPPT), Environmental Protection Agency, 1200 Pennsylvania Ave. NW, Washington, DC 20460–0001.

• *Hand Delivery:* To make special arrangements for hand delivery or delivery of boxed information, please follow the instructions at *http://www.epa.gov/dockets/contacts.html.*

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

FOR FURTHER INFORMATION CONTACT:

For technical information contact: Andrea Mojica, Chemical Control Division (7405M), Office of Pollution Prevention and Toxics, Environmental Protection Agency, 1200 Pennsylvania Ave. NW, Washington, DC 20460–0001; telephone number: (202) 564–0599; email address: *mojica.andrea@epa.gov*.

For general information contact: The TSCA-Hotline, ABVI-Goodwill, 422 South Clinton Ave., Rochester, NY 14620; telephone number: (202) 554– 1404; email address: *TSCA-Hotline*@ *epa.gov.*

SUPPLEMENTARY INFORMATION:

I. What information is EPA particularly interested in?

Pursuant to PRA section 3506(c)(2)(A) (44 U.S.C. 3506(c)(2)(A)), EPA specifically solicits comments and information to enable it to:

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 estimates 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.

4. Minimize the burden of the collection of information on those who are to respond, including through the use of appropriate automated electronic, mechanical, or other technological collection techniques or other forms of information technology, *e.g.*, permitting electronic submission of responses. In particular, EPA is requesting comments from very small businesses (those that employ less than 25) on examples of specific additional efforts that EPA could make to reduce the paperwork burden for very small businesses affected by this collection.

II. What information collection activity or ICR does this action apply to?

Title: Health and Safety Data Reporting, Submission of Lists and Copies of Health and Safety Studies.

ICR number: EPA ICR No. 0575.16. *OMB control number:* OMB Control No. 2070–0004.

ICR status: This ICR is currently scheduled to expire on November 30, 2018. An Agency may not conduct or sponsor, and a person is not required to respond to, a collection of information, unless it displays a currently valid OMB control number. The OMB control numbers for EPA's regulations in title 40 of the Code of Federal Regulations (CFR), after appearing in the **Federal Register** when approved, are listed in 40 CFR part 9, are displayed either by publication in the Federal Register or by other appropriate means, such as on the related collection instrument or form, if applicable. The display of OMB control numbers for certain EPA regulations is consolidated in 40 CFR part 9.

Abstract: Section 8(d) of the Toxic Substances Control Act (TSCA) and 40 CFR part 716 require manufacturers and processors of chemicals to submit lists and copies of health and safety studies relating to the health and/or environmental effects of certain chemical substances and mixtures. In order to comply with the reporting requirements of TSCA section 8(d), respondents must search their records to identify any health and safety studies in their possession, copy and process relevant studies, list studies that are currently in progress, and submit this information to EPA.

EPA uses this information to construct a complete picture of the known effects of the chemicals in question, leading to determinations by ÉPA of whether additional testing of the chemicals is required. The information enables EPA to base its testing decisions on the most complete information available and to avoid demands for testing that may be duplicative. EPA will use information obtained via this collection to support its investigation of the risks posed by chemicals and, in particular, to support its decisions on whether to require industry to test chemicals under section 4 of TSCA. This information collection request addresses the reporting requirements found in TSCA section 8(d).

Responses to the collection of information are mandatory (see 40 CFR part 716). Respondents may claim all or part of a response confidential. EPA will disclose information that is covered by a claim of confidentiality only to the extent permitted by, and in accordance with, the procedures in TSCA section 14 and 40 CFR part 2.

Burden statement: The annual public reporting and recordkeeping burden for this collection of information is estimated to average 11.0 hours per response. Burden is defined in 5 CFR 1320.3(b).

The ICR, which is available in the docket along with other related materials, provides a detailed explanation of the collection activities and the burden estimate that is only briefly summarized here:

Respondents/Affected Entities: Entities potentially affected by this ICR are persons who manufacture, process, or distribute in commerce chemical substances or mixtures, or who propose to do so.

Estimated total number of potential respondents: 21.

Frequency of response: On occasion. Estimated total average number of responses for each respondent: 1.2.

Estimated total annual burden hours: 302 hours.

Estimated total annual costs: \$24,435. This includes an estimated burden cost of \$24,435 and an estimated cost of \$0 for capital investment or maintenance and operational costs.

III. Are there changes in the estimates from the last approval?

There is a decrease of 1,303 hours in the total estimated respondent burden compared with that identified in the ICR currently approved by OMB. This decrease reflects the realization that the methodology used in the previous ICR overestimated the burden resulting from the addition of chemicals to the TSCA section 8(d) rule. The ICR supporting statement provides a detailed analysis of the change in burden estimate. This change is an adjustment.

IV. What is the next step in the process for this ICR?

EPA will consider the comments received and amend the ICR as appropriate. The final ICR package will then be submitted to OMB for review and approval pursuant to 5 CFR 1320.12. EPA will issue another **Federal Register** document pursuant to 5 CFR 1320.5(a)(1)(iv) to announce the submission of the ICR to OMB and the opportunity to submit additional comments to OMB. If you have any questions about this ICR or the approval process, please contact the technical person listed under **FOR FURTHER INFORMATION CONTACT.**

Authority: 44 U.S.C. 3501 et seq.

Dated: July 16, 2018.

Charlotte Bertrand,

Acting Principal Deputy Assistant Administrator, Office of Chemical Safety and Pollution Prevention.

[FR Doc. 2018–15921 Filed 7–24–18; 8:45 am] BILLING CODE 6560–50–P

ENVIRONMENTAL PROTECTION AGENCY

[EPA-HQ-OPPT-2017-0317; FRL-9978-00]

Agency Information Collection Activities; Proposed Reinstatement of an Expired Collection (EPA ICR No. 1198.11); Comment Request

AGENCY: Environmental Protection Agency (EPA).

ACTION: Notice.

SUMMARY: In compliance with the Paperwork Reduction Act (PRA), this document announces that EPA is planning to submit an Information Collection Request (ICR) to the Office of Management and Budget (OMB). The ICR, entitled: "Chemical-Specific Rules, TSCA Section 8(a)" and identified by EPA ICR No. 1198.11 and OMB Control No. 2070–0067, represents the reinstatement of an ICR that expired on June 30, 2018. Before submitting the ICR to OMB for review and approval, EPA is soliciting comments on specific aspects of the proposed information collection that is summarized in this document. The ICR and accompanying material are available in the docket for public review and comment.

DATES: Comments must be received on or before September 24, 2018.

ADDRESSES: Submit your comments, identified by docket identification (ID) number EPA-HQ-OPPT-2017-0317, by one of the following methods:

• Federal eRulemaking Portal: http:// www.regulations.gov. Follow the online instructions for submitting comments. Do not submit electronically any information you consider to be Confidential Business Information (CBI) or other information whose disclosure is restricted by statute.

• *Mail:* Document Control Office (7407M), Office of Pollution Prevention and Toxics (OPPT), Environmental Protection Agency, 1200 Pennsylvania Ave. NW, Washington, DC 20460–0001.

• *Hand Delivery:* To make special arrangements for hand delivery or delivery of boxed information, please follow the instructions at *http://www.epa.gov/dockets/contacts.html*.

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

FOR FURTHER INFORMATION CONTACT:

For technical information contact: Harlan Weir, Chemical Control Division (7405M), Office of Pollution Prevention and Toxics, Environmental Protection Agency, 1200 Pennsylvania Ave. NW, Washington, DC 20460–0001; telephone number: (202) 564–9885; email address: weir.harlan@epa.gov.

For general information contact: The TSCA-Hotline, ABVI-Goodwill, 422 South Clinton Ave., Rochester, NY 14620; telephone number: (202) 554– 1404; email address: *TSCA-Hotline*@ epa.gov.

SUPPLEMENTARY INFORMATION:

I. What information is EPA particularly interested in?

Pursuant to PRA section 3506(c)(2)(A) (44 U.S.C. 3506(c)(2)(A)), EPA specifically solicits comments and information to enable it to:

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 estimates 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.

4. Minimize the burden of the collection of information on those who are to respond, including through the use of appropriate automated electronic, mechanical, or other technological collection techniques or other forms of information technology, *e.g.*, permitting electronic submission of responses. In particular, EPA is requesting comments from very small businesses (those that employ less than 25) on examples of specific additional efforts that EPA could make to reduce the paperwork burden for very small businesses affected by this collection.

II. What information collection activity or ICR does this action apply to?

Title: Chemical-Specific Rules, TSCA Section 8(a).

ICR number: EPA ICR No. 1198.11. OMB control number: OMB Control No. 2070–0067.

ICR status: This ICR expired on June 30, 2018. An Agency may not conduct or sponsor, and a person is not required to respond to, a collection of information, unless it displays a currently valid OMB control number. The OMB control numbers for EPA's regulations in title 40 of the Code of Federal Regulations (CFR), after appearing in the Federal Register when approved, are listed in 40 CFR part 9, are displayed either by publication in the Federal Register or by other appropriate means, such as on the related collection instrument or form, if applicable. The display of OMB control numbers for certain EPA regulations is consolidated in 40 CFR part 9.

Abstract: Section 8(a) of the Toxic Substances Control Act (TSCA) authorizes the Administrator of EPA to promulgate rules that require persons who manufacture, import or process chemical substances and mixtures, or who propose to manufacture, import, or process chemical substances and mixtures, to maintain such records and submit such reports to EPA as may be reasonably required. Any chemical covered by TSCA for which EPA or another Federal agency has a reasonable need for information and which cannot be satisfied via other sources is a proper potential subject for a chemical-specific TSCA section 8(a) rulemaking. Information that may be collected under TSCA section 8(a) includes, but is not limited to, chemical names; categories of use; production or processing volume, byproducts of chemical production, processing, use or disposal;

existing data concerning environmental and health effects; exposure data; and disposal information. Generally, EPA uses chemical-specific information under TSCA section 8(a) to evaluate the potential for adverse human health and environmental effects caused by the manufacture (including import), processing, use or disposal of identified chemical substances and mixtures. Additionally, EPA may use TSCA section 8(a) information to assess the need or set priorities for testing and/or further regulatory action. To the extent that reported information is not considered confidential, environmental groups, environmental justice advocates, state and local government entities and other members of the public will also have access to this information for their use.

Responses to the collection of information are mandatory (see 40 CFR part 704). Respondents may claim all or part of a response confidential. EPA will disclose information that is covered by a claim of confidentiality only to the extent permitted by, and in accordance with, the procedures in TSCA section 14 and 40 CFR part 2.

Burden statement: The annual public reporting and recordkeeping burden for this collection of information is estimated to range between 60.75 and 70.75 hours per response, depending upon whether the response is by electronic means or paper-based, respectively. Burden is defined in 5 CFR 1320.3(b).

The ICR, which is available in the docket along with other related materials, provides a detailed explanation of the collection activities and the burden estimate that is only briefly summarized here:

Respondents/affected entities: Entities potentially affected by this ICR are primarily those businesses that enter the marketplace to manufacture (import) or process a chemical substance listed in 40 CFR part 704. These entities fall under NAICS codes 325, Chemical Manufacturers and Processors, and 324110, Petroleum Refineries.

Estimated total number of potential respondents: 4.

Frequency of response: On occasion. Estimated total average number of

responses for each respondent: 1.0.

Estimated total annual burden hours: 281 hours.

Estimated total annual costs: \$20,480. This includes an estimated burden cost of \$20,480 and an estimated cost of \$0 for capital investment or maintenance and operational costs.

III. Are there changes in the estimates from the last approval?

There is an increase of 6 hours in the total estimated respondent burden compared with that identified in the ICR currently approved by OMB. This increase reflects new reporting requirements in the Frank R. Lautenberg Chemical Safety for the 21st Century Act to substantiate CBI claims. This change is the result of a program change.

IV. What is the next step in the process for this ICR?

EPA will consider the comments received and amend the ICR as appropriate. The final ICR package will then be submitted to OMB for review and approval pursuant to 5 CFR 1320.12. EPA will issue another **Federal Register** document pursuant to 5 CFR 1320.5(a)(1)(iv) to announce the submission of the ICR to OMB and the opportunity to submit additional comments to OMB. If you have any questions about this ICR or the approval process, please contact the technical person listed under **FOR FURTHER INFORMATION CONTACT.**

Authority: 44 U.S.C. 3501 et seq.

Dated: July 13, 2018.

Charlotte Bertrand,

Acting Principal Deputy Assistant Administrator, Office of Chemical Safety and Pollution Prevention.

[FR Doc. 2018–15918 Filed 7–24–18; 8:45 am] BILLING CODE 6560–50–P

ENVIRONMENTAL PROTECTION AGENCY

[EPA-HQ-OPP-2018-0266; FRL-9979-93]

Agency Information Collection Activities; Proposed Renewal of an Existing Collection (EPA ICR No. 0161.14); Comment Request

AGENCY: Environmental Protection Agency (EPA).

ACTION: Notice.

SUMMARY: In compliance with the Paperwork Reduction Act (PRA), this document announces that EPA is planning to submit an Information Collection Request (ICR) to the Office of Management and Budget (OMB). The ICR, entitled: "Foreign Purchaser Acknowledgement Statement of Unregistered Pesticides" and identified by EPA ICR No. 0161.14 and OMB Control No. 2070–0027, represents the renewal of an existing ICR that is scheduled to expire on March 31, 2019. Before submitting the ICR to OMB for review and approval, EPA is soliciting comments on specific aspects of the proposed information collection that is summarized in this document. The ICR and accompanying material are available in the docket for public review and comment.

DATES: Comments must be received on or before September 24, 2018.

ADDRESSES: Submit your comments, identified by docket identification (ID) number EPA-HQ-OPP-2018-0266, by one of the following methods:

• Federal eRulemaking Portal: http:// www.regulations.gov. Follow the online instructions for submitting comments. Do not submit electronically any information you consider to be Confidential Business Information (CBI) or other information whose disclosure is restricted by statute.

• *Mail:* OPP Docket, Environmental Protection Agency Docket Center (EPA/ DC), (28221T), 1200 Pennsylvania Ave. NW, Washington, DC 20460–0001.

• *Hand Delivery:* To make special arrangements for hand delivery or delivery of boxed information, please follow the instructions at *http://www.epa.gov/dockets/contacts.html.*

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

FOR FURTHER INFORMATION CONTACT: Carolyn Siu, Field and External Affairs Division (7506P), Office of Pesticide Programs, Environmental Protection Agency, 1200 Pennsylvania Ave. NW, Washington, DC 20460–0001; telephone number: (703) 347–0159; email address: *siu.carolyn@epa.gov.*

SUPPLEMENTARY INFORMATION:

I. What information is EPA particularly interested in?

Pursuant to PRA section 3506(c)(2)(A) (44 U.S.C. 3506(c)(2)(A)), EPA specifically solicits comments and information to enable it to:

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 estimates 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.

4. Minimize the burden of the collection of information on those who are to respond, including through the use of appropriate automated electronic,

mechanical, or other technological collection techniques or other forms of information technology, *e.g.*, permitting electronic submission of responses. In particular, EPA is requesting comments from very small businesses (those that employ less than 25) on examples of specific additional efforts that EPA could make to reduce the paperwork burden for very small businesses affected by this collection.

II. What information collection activity or ICR does this action apply to?

Title: "Foreign Purchaser Acknowledgement Statement of Unregistered Pesticides".

ICR number: EPA ICR No. 0161.14. OMB control number: OMB Control No. 2070–0027.

ICR status: This ICR is currently scheduled to expire on March 31, 2019. An Agency may not conduct or sponsor, and a person is not required to respond to, a collection of information, unless it displays a currently valid OMB control number. The OMB control numbers for EPA's regulations in title 40 of the Code of Federal Regulations (CFR), after appearing in the Federal Register when approved, are listed in 40 CFR part 9, are displayed either by publication in the Federal Register or by other appropriate means, such as on the related collection instrument or form, if applicable. The display of OMB control numbers for certain EPA regulations is consolidated in 40 CFR part 9.

Abstract: This information collection enables the EPA to provide notice to foreign purchasers of unregistered pesticides exported from the United States that the pesticide product cannot be sold in the United States. Section 17(a)(2) of the Federal Insecticide, Fungicide, and Rodenticide Act (FIFRA) requires an exporter of any pesticide not registered under FIFRA section 3 or sold under FIFRA section 6(a)(1) to obtain a signed statement from the foreign purchaser acknowledging that the purchaser is aware that the pesticide is not registered for use in, and cannot be sold in, the United States. A copy of this statement; which is known as the Foreign Purchaser Acknowledgement Statement (FPAS), must be transmitted to the Designated National Authority or appropriate official of the government in the importing country. This information is submitted in the form of annual or per-shipment statements to the EPA, which maintains original records and transmits copies, along with an explanatory letter to appropriate government officials of the countries which are importing the pesticide.

In addition to the export notification for unregistered pesticides, FIFRA

requires that all exported pesticides include appropriate labeling. There are different requirements for registered and unregistered products. Export labeling requirements meet the definition of third-party notification. In the interests of consolidating various related information collection requests, this ICR includes the burden estimates for the FPAS requirement for unregistered pesticides, as well as the labeling requirement for all exported pesticides, both registered and unregistered. These burdens have been consolidated in this information collection since the implementation of the 1993 pesticide export policy governing the export of pesticides, devices, and active ingredients used in producing pesticides.

Burden statement: The annual public reporting and recordkeeping burden for this collection of information is estimated to be 1 to 8 hours per response, depending on the activity. Burden is defined in 5 CFR 1320.3(b).

The ICR, which is available in the docket along with other related materials, provides a detailed explanation of the collection activities and the burden estimate that is only briefly summarized here:

Respondents/Affected Entities: Entities potentially affected by this ICR are individuals or entities engaged that either manufacture and export pesticides or that reformulate or repackage and export pesticides. The North American Industrial Classification System (NAICS) code assigned to the parties responding to this information is 3250A1.

Estimated total number of potential respondents: 2,240 annually.

Frequency of response: On occasion. *Estimated total average number of*

responses for each respondent: 2. Estimated total annual burden hours: 16,660 hours.

Estimated total annual costs: \$1,087,102. This includes an estimated burden cost of \$1,087,102 and an estimated cost of \$0 or capital investment or maintenance and operational costs.

III. Are there changes in the estimates from the last approval?

There is a decrease of 1,333 hours in the total estimated respondent burden compared with that identified in the ICR currently approved by OMB. This decrease reflects EPA's decrease in the annual number of foreign purchaser acknowledgment statements submitted (from 3,024 to 2,774) which resulted in a change to the annual burden hours for respondents from 3,205 in the previous renewal to 2,940 in the current renewal. The respondent burden associated with labeling requirements for unregistered exported pesticides decreased from 4,888 in the previous renewal to 4,480 in the current renewal. The respondent burden associated with labeling requirements for registered exported pesticides decreased from 9,900 in the previous renewal to 9,240 in the current renewal. The decrease in burden is due to a decrease in the estimated number of respondents per calendar year of 2015–2017. Total labor costs for respondents decreased due to a decrease in the estimated number of respondents per calendar year from 2015-2017 and changes in the wage rates made to reflect current wage rates. The new wage estimates incorporated higher estimates for benefits than was used in the previous renewal. These changes are an adjustment.

IV. What is the next step in the process for this ICR?

EPA will consider the comments received and amend the ICR as appropriate. The final ICR package will then be submitted to OMB for review and approval pursuant to 5 CFR 1320.12. EPA will issue another **Federal Register** document pursuant to 5 CFR 1320.5(a)(1)(iv) to announce the submission of the ICR to OMB and the opportunity to submit additional comments to OMB. If you have any questions about this ICR or the approval process, please contact the person listed under **FOR FURTHER INFORMATION CONTACT.**

Authority: 44 U.S.C. 3501 et seq.

Dated: July 16, 2018.

Charlotte Bertrand,

Acting Principal Deputy Assistant Administrator, Office of Chemical Safety and Pollution Prevention.

[FR Doc. 2018–15923 Filed 7–24–18; 8:45 am]

BILLING CODE 6560-50-P

FEDERAL COMMUNICATIONS COMMISSION

[OMB 3060-0009, OMB 3060-0594, OMB 3060-0601 and OMB 3060-0609]

Information Collections Being Reviewed by the Federal Communications Commission Under Delegated Authority

Correction

In notice document 2018–14858, appearing on pages 32288 through

32289, in the issue of Thursday, July 12, 2018, make the following correction:

On page 32288, in the second column, in the **DATES** paragraph, on the second line, "August 13, 2018" should read "September 10, 2018".

[FR Doc. C1–2018–14858 Filed 7–24–18; 8:45 am] BILLING CODE 1301–00–D

FEDERAL MARITIME COMMISSION

Performance Review Board Memberships

AGENCY: Federal Maritime Commission. **ACTION:** Notice.

SUMMARY: Notice is hereby given of the names of the members of the Performance Review Board.

FOR FURTHER INFORMATION CONTACT: William "Todd" Cole, Director Office of Human Resources, Federal Maritime Commission, 800 North Capitol Street NW, Washington, DC 20573.

SUPPLEMENTARY INFORMATION: Sec. 4314(c) (1) through (5) of title 5, U.S.C., requires each agency to establish, in accordance with regulations prescribed by the Office of Personnel Management, one or more performance review boards. The board shall review and evaluate the initial appraisal of a senior executive's performance by the supervisor, along with any recommendations to the appointing authority relative to the performance of the senior executive.

Rachel Dickon,

Secretary.

The Members of the Performance Review Board Are

- 1. Rebecca F. Dye, Commissioner
- 2. Florence A. Carr, Director, Bureau of Trade Analysis
- 3. Rebecca A. Fenneman, Director, Office of Consumer Affairs & Dispute Resolution Services
- 4. Karen V. Gregory, Managing Director
- 5. Clay G. Guthridge, Chief Administrative Law Judge
- 6. Mary T. Hoang, Chief of Staff
- 7. Peter J. King, Deputy Managing Director
- 8. Sandra L. Kusumoto, Director, Bureau of Certification and Licensing
- 9. Erin M. Wirth, Administrative Law Judge
- 10. Tyler J. Wood, General Counsel

[FR Doc. 2018–15875 Filed 7–24–18; 8:45 am]

BILLING CODE 6731-AA-P

DEPARTMENT OF HEALTH AND HUMAN SERVICES

Administration for Children and Families

Submission for OMB Review; Comment Request

Title: Childhood & Family Experiences Study.

OMB No.: New Collection.

Description: The Administration for Children and Families (ACF), U.S. Department of Health and Human Services (HHS) is proposing data collection activities as part of a project to understand how public programs can better serve low-income families. The Childhood & Family Experiences study. will examine the perspectives and lived experiences of children and families living in poverty. This qualitative study intends to use this information to increase understanding of the lives of children in poverty and their families in order to improve how human services programs can help families achieve selfsufficiency.

This Federal Register Notice provides the opportunity to comment on proposed new information collection activities for this study: (1) Adult interviews will collect information about household income and finances, conversations parents have with their children about finances, and their experiences, if applicable, receiving public benefits. (2) Adolescent interviews will collect information about adolescents' understanding of their family's economic circumstances, how they communicate with their parents about them, and how they feel about these circumstances, including public benefits, if applicable. (3) Child interviews will collect information about children's understanding of their family's economic circumstances, how they communicate with their parents about them, and how they feel about these circumstances, including public benefits, if applicable. (4) A phone screener will be used with prospective families to assess their eligibility for the study and, for those who are eligible, provide them with additional materials about the study, including any risks, to assess their interest in participating.

Respondents: Children and their parents who are living in poverty.

ANNUAL BURDEN ESTIMATES

Instrument	Total number of respondents	Annual number of respondents	Number of responses per respondent	Average burden hours per response	Annual burden hours
Adult Interview Guide	45	15	1	1.5	23
Adolescent Interview Guide	20	7	1	.875	6
Child Interview Guide	30	10	1	.50	5
Phone Screener for Prospective Families	120	40	1	.50	20

Estimated Total Annual Burden Hours: 54.

Additional Information: Copies of the proposed collection may be obtained by writing to the Administration for Children and Families, Office of Planning, Research and Evaluation, 330 C Street SW, Washington, DC 20201, Attn: OPRE Reports Clearance Officer. All requests should be identified by the title of the information collection. Email address: OPREinfocollection@ acf.hhs.gov.

OMB Comment: OMB is required to make a decision concerning the collection of information between 30 and 60 days after publication of this document in the Federal Register. Therefore, a comment is best assured of having its full effect if OMB receives it within 30 days of publication. Written comments and recommendations for the proposed information collection should be sent directly to the following: Office of Management and Budget, Paperwork Reduction Project, Email: OIRA SUBMISSION@OMB.EOP.GOV, Attn: Desk Officer for the Administration for Children and Families.

Mary B. Jones,

ACF/OPRE Certifying Officer. [FR Doc. 2018–15830 Filed 7–24–18; 8:45 am] BILLING CODE 4184–09–P

DEPARTMENT OF HEALTH AND HUMAN SERVICES

Administration for Community Living; Notice of Federal Review of the Puerto Rico State Council on Developmental Disabilities (SCDD) and the Protection and Advocacy System (P&A)

AGENCY: Administration for Community Living, HHS.

ACTION: Notice.

SUMMARY: Representatives of the Administration on Intellectual and Developmental Disabilities (AIDD), Administration for Community Living (ACL), will be conducting a federal review of the Puerto Rico State Council on Developmental Disabilities (SCDD) and the Protection and Advocacy System (P&A) on September 17–21, 2018.

AIDD is soliciting comments from interested parties on your experiences with the work, program, and strategies employed by P&A and SDCC in meeting the needs of individuals with developmental disabilities and their families in Puerto Rico. You are encouraged to share your experiences by way of any of the following methods:

Émail: Člare.huerta@acl.hhs.gov. Telephone: 202–795–7301.

Mail Comments To: Clare Huerta, Program Specialist, Administration on Intellectual and Developmental Disabilities, Administration for Community Living, 330 C Street SW, 1st Floor, Washington, DC 20201.

Comments should be received by September 10, 2018 in order to be included in the final report.

FOR FURTHER INFORMATION CONTACT: Clare Barnett Huerta, Administration for Community Living, Administration on Intellectual and Developmental Disabilities, Office of Program Support, 330 C Street SW, 1st Floor, Washington, DC 20201, 202–795–7301.

Dated: July 12, 2018.

Mary Lazare,

Principal Deputy Administrator. [FR Doc. 2018–15905 Filed 7–24–18; 8:45 am] BILLING CODE 4154–01–P

DEPARTMENT OF HEALTH AND HUMAN SERVICES

Administration for Community Living

Agency Information Collection Activities; Submission for OMB Review; Public Comment Request; New Data Collection; National Center on Law and Elder Rights (NCLER)

AGENCY: Administration for Community Living (ACL), HHS. **ACTION:** Notice.

SUMMARY: The Administration for Community Living is announcing that the proposed collection of information listed above has been submitted to the Office of Management and Budget (OMB) for review and clearance as required under section 506(c)(2)(A) of the Paperwork Reduction Act of 1995. This 30-Day notice collects comments on the information collection requirements related to ACL's National Center on Law and Elder Rights.

DATES: Submit written comments on the collection of information by August 24, 2018.

ADDRESSES: Submit written comments on the collection of information by:

(a) Email to: *OIRA_submission@ omb.eop.gov*, Attn: OMB Desk Officer for ACL;

(b) fax to 202.395.5806, Attn: OMB Desk Officer for ACL; or

(c) by mail to the Office of Information and Regulatory Affairs, OMB, New Executive Office Bldg., 725 17th St. NW, Rm. 10235, Washington, DC 20503, Attn: OMB Desk Officer for ACL.

FOR FURTHER INFORMATION CONTACT: Omar Valverde at *omar.valverde*@

acl.hhs.gov or 202–795–7460.

SUPPLEMENTARY INFORMATION: Under the PRA (44 U.S.C. 3501–3520), Federal agencies must obtain approval from the Office of Management and Budget (OMB) for each collection of information they conduct or sponsor. The proposed collection of information represents new information requested from aging/disability networks to fulfill requirements regarding the provision of services and overall performance of ACL legal assistance programs.

ACL contracts with a national legal assistance resource center, the National Center on Law and Elder Rights, to provide the required services. Through the contract, ACL provides aging, disability, and related legal professionals with training, case consultations and technical assistance for demonstration projects regarding contractually identified priority legal topics.

The purpose of the information requested is for ACL to ensure that the resource center creates and prioritizes the training, case consultations and technical assistance resources it was contracted to provide and to ensure that the center targets the contractually designated aging network practitioners about priority subject matters. This approach enables ACL to make datainformed decisions about the deployment of its resource center assets. These data are necessary for ACL to evaluate contractual compliance with established performance indicators. These metrics include quantifiable increases in uptake by stakeholders of training, case consultation and technical assistance, and measures of satisfaction with and perceived benefit from these services. For example, the metrics measure successful problem resolution as a result of the services provided and quantifiable data on fulfillment of requests for training, technical assistance, and consultation related to the contractually designated legal and systems development topic areas.

The information requested by ACL from legal and aging/disability professionals falls into the following areas: (1) Requests for training, case consultation, and technical assistance through an online, secure Uniform Resource Support Request Tool; (2) general requests for Legal Training (including the volume of Webinar registrations); (3) Case Consultation and Technical Assistance; and (4) information about satisfaction and use of the services and support received in order to enable ACL to measure performance outcomes.

Comments in Response to the 60-Day Federal Register Notice

As required by 5 CFR 1320.8(d), a 60day notice was published in the **Federal** **Register** on December 5, 2017 (Volume 82, Number 232, pp. 57458–57460). One email was received expressing support for the data collection as proposed. No modifications were made to the proposed data collection elements and associated data collection instruments.

Estimated Annualized Burden Hours

The total estimated burden is 460.78 hours per year for individuals requesting and/or receiving resource support through NCLER. This figure is based on ACL field testing of 8 providers working within aging/ disability/legal networks who measured the time required to fully submit information by answering the required questions using standardized forms:

Respondent/data collection activity	Number of respondents	Minutes per response	Annual burden hours
Resource Support Requests Legal Training, Case Consultation, Technical Assistance Requests Outcome Measurement		1 min 54 sec 1 min 42 sec 1 min 3 sec	2.53 397 61.25
Total	17,580	4 min 39 sec	460.78

Dated: July 12, 2018. **Mary Lazare,** *Principal Deputy Administrator.* [FR Doc. 2018–15906 Filed 7–24–18; 8:45 am] **BILLING CODE 4154–01–P**

DEPARTMENT OF HEALTH AND HUMAN SERVICES

Food and Drug Administration

[Docket No. FDA-2018-N-2544]

Use of Liquids and/or Soft Foods as Vehicles for Drug Administration: General Considerations for Selection and In Vitro Methods for Product Quality Assessments; Draft Guidance for Industry; Availability

AGENCY: Food and Drug Administration, HHS.

ACTION: Notice of availability.

SUMMARY: The Food and Drug Administration (FDA or Agency) is announcing the availability of a draft guidance for industry entitled "Use of Liquids and/or Soft Foods as Vehicles for Drug Administration: General Considerations for Selection and In Vitro Methods for Product Quality Assessments." This draft guidance applies to orally administered drug products and provides recommendations to sponsors who will use or recommend use of liquids and/ or soft foods as vehicles for drug administration in investigational new drug applications (INDs), new drug applications (NDAs), Biologics License Applications (BLAs), as applicable, and in supplements to these applications.

DATES: Submit either electronic or written comments on the draft guidance by September 24, 2018 to ensure that the Agency considers your comment on this draft guidance before it begins work on the final version of the guidance.

ADDRESSES: You may submit comments on any guidance at any time as follows:

Electronic Submissions

Submit electronic comments in the following way:

• Federal eRulemaking Portal: *https://www.regulations.gov.* Follow the instructions for submitting comments. Comments submitted electronically, including attachments, to https:// www.regulations.gov will be posted to the docket unchanged. Because your comment will be made public, you are solely responsible for ensuring that your comment does not include any confidential information that you or a third party may not wish to be posted, such as medical information, your or anyone else's Social Security number, or confidential business information, such as a manufacturing process. Please note that if you include your name, contact information, or other information that identifies you in the body of your comments, that information will be posted on https://www.regulations.gov.

• If you want to submit a comment with confidential information that you do not wish to be made available to the public, submit the comment as a written/paper submission and in the manner detailed (see "Written/Paper Submissions" and "Instructions").

Written/Paper Submissions

Submit written/paper submissions as follows:

• Mail/Hand delivery/Courier (for written/paper submissions): Dockets Management Staff (HFA–305), Food and Drug Administration, 5630 Fishers Lane, Rm. 1061, Rockville, MD 20852.

• For written/paper comments submitted to the Dockets Management Staff, FDA will post your comment, as well as any attachments, except for information submitted, marked and identified, as confidential, if submitted as detailed in "Instructions."

Instructions: All submissions received must include the Docket No. FDA– 2018–N–2544 for "Use of Liquids and/ or Soft Foods as Vehicles for Drug Administration: General Considerations for Selection and In Vitro Methods for Product Quality Assessments." Received comments will be placed in the docket and, except for those submitted as "Confidential Submissions," publicly viewable at https://www.regulations.gov or at the Dockets Management Staff between 9 a.m. and 4 p.m., Monday through Friday.

• Confidential Submissions-To submit a comment with confidential information that you do not wish to be made publicly available, submit your comments only as a written/paper submission. You should submit two copies total. One copy will include the information you claim to be confidential with a heading or cover note that states "THIS DOCUMENT CONTAINS CONFIDENTIAL INFORMATION." The Agency will review this copy, including the claimed confidential information, in its consideration of comments. The second copy, which will have the claimed confidential information redacted/blacked out, will be available for public viewing and posted on https://www.regulations.gov. Submit both copies to the Dockets Management Staff. If you do not wish your name and contact information to be made publicly available, you can provide this information on the cover sheet and not in the body of your comments and you must identify this information as "confidential." Any information marked as "confidential" will not be disclosed except in accordance with 21 CFR 10.20 and other applicable disclosure law. For more information about FDA's posting of comments to public dockets, see 80 FR 56469, September 18, 2015, or access the information at: https://www.gpo.gov/ fdsys/pkg/FR-2015-09-18/pdf/2015-23389.pdf.

Docket: For access to the docket to read background documents or the electronic and written/paper comments received, go to *https:// www.regulations.gov* and insert the docket number, found in brackets in the heading of this document, into the "Search" box and follow the prompts and/or go to the Dockets Management Staff, 5630 Fishers Lane, Rm. 1061, Rockville, MD 20852.

You may submit comments on any guidance at any time (see 21 CFR 10.115(g)(5)).

Submit written requests for single copies of the draft guidance to the Division of Drug Information, Center for Drug Evaluation and Research, Food and Drug Administration, 10001 New Hampshire Ave., Hillandale Building, 4th Floor, Silver Spring, MD 20993– 0002. Send one self-addressed adhesive label to assist that office in processing your requests. See the **SUPPLEMENTARY INFORMATION** section for electronic access to the draft guidance document.

FOR FURTHER INFORMATION CONTACT:

Mamta Gautam-Basak, Center for Drug Evaluation and Research, Food and Drug Administration, 10903 New Hampshire Ave. Bldg. 21, Rm. 2508, Silver Spring, MD 20993, 301–796–0712.

SUPPLEMENTARY INFORMATION:

I. Background

FDA is announcing the availability of a draft guidance for industry entitled "Use of Liquids and/or Soft Foods as Vehicles for Drug Administration: General Considerations for Selection and In Vitro Methods for Product Quality Assessments." In the absence of availability of a dosage form that is appropriate for the targeted patient population (e.g., pediatric, geriatric), small amounts of liquids and/or soft foods can be used as described in the FDA-approved product labeling for immediate ingestion as the suitable vehicle(s) for oral administration of the specific drug product.

Generally, drug products mixed in small amounts of liquids (5 to 15 milliliters) or soft foods are used in pediatric and other patient populations who are unable to swallow solid oral dosage forms. Liquids and/or soft foods that are shown not to alter performance of the drug product, and are deemed compatible and suitable for use in the targeted patient populations, are considered suitable for use as vehicles with the specific drug product.

This draft guidance addresses the approaches recommended for suitability determination of vehicles intended for use with specific drug products by providing the following:

• Considerations for selection of liquids and/or soft foods as vehicles.

• Standardized in vitro methodology and data recommendations for drug product quality assessments to qualify vehicle(s) for drug product administration.

• Recommendations to communicate acceptable (qualified) vehicles in drug product labeling. If certain foods are found unacceptable, they should also be included in the labeling.

This draft guidance and the methods it describes do not replace existing guidance documents that address foodeffect assessments on the drug product or dosage form, or stability testing conducted to support a shelf-life determination. For those drug products marketed with a vehicle for administration (*i.e.*, the vehicle is copackaged with the drug product), the recommendations regarding selection and methods provided in this draft guidance are applicable, but additional considerations and recommendations may also apply.

This draft guidance is being issued consistent with FDA's good guidance practices regulation (21 CFR 10.115). The draft guidance, when finalized, will represent the current thinking of FDA on "Use of Liquids and/or Soft Foods as Vehicles for Drug Administration: General Considerations for Selection and In Vitro Methods for Product Quality Assessments." It does not establish any rights for any person and is not binding on FDA or the public. You can use an alternative approach if it satisfies the requirements of the applicable statutes and regulations. This guidance is not subject to Executive Order 12866.

II. Paperwork Reduction Act of 1995

This draft guidance refers to previously approved collections of information that are subject to review by the Office of Management and Budget under the Paperwork Reduction Act of 1995 (44 U.S.C. 3501–3520). The collections of information in 21 CFR part 312 (INDs) have been approved under 0910-0014, the collections of information in 21 CFR part 314 (NDAs and ANDAs) have been approved under 0910-0001, and the collections of information in 21 CFR 201.56 and 201.57 (Prescription Drug Product Labeling) have been approved under 0910-0572.

III. Electronic Access

Persons with access to the internet may obtain the draft guidance at either https://www.fda.gov/Drugs/Guidance ComplianceRegulatoryInformation/ Guidances/default.htm or https:// www.regulations.gov.

Dated: July 19, 2018.

Leslie Kux,

Associate Commissioner for Policy. [FR Doc. 2018–15870 Filed 7–24–18; 8:45 am] BILLING CODE 4164–01–P

DEPARTMENT OF HEALTH AND HUMAN SERVICES

Scholarly and Journalistic Activities Deemed Not To Be Research: 2018 Requirements; Draft Guidance; When Continuing Review Is Not Required During the 6-Month Delay Period of July 19, 2018 Through January 20, 2019: 2018 Requirements; Draft Guidance Elimination of Institutional Review Board (IRB) Review of Research Applications and Proposals: 2018 Requirements; Draft Guidance

AGENCY: The Office for Human Research Protections, Office of the Assistant Secretary for Health, Office of the Secretary, HHS.

ACTION: Notice of availability.

SUMMARY: The Office for Human Research Protections (OHRP), Office of the Assistant Secretary for Health is announcing the availability of three draft guidance documents titled, "Scholarly and Journalistic Activities Deemed Not to be Research: 2018 Requirements," "When Continuing Review Is Not Required During the 6-Month Delay Period of July 19, 2018 through January 20, 2019: 2018 Requirements," and "Elimination of Institutional Review Board (IRB) Review of Research Applications and Proposals: 2018 Requirements," respectively.

DATES: Submit written comments by August 24, 2018.

ADDRESSES: Submit written requests for single copies of the draft guidance documents titled "Scholarly and Journalistic Activities Deemed Not to be Research: 2018 Requirements," "When Continuing Review Is Not Required During the 6-Month Delay Period of July 19, 2018 through January 20, 2019: 2018 Requirements," and "Elimination of Institutional Review Board (IRB) Review of Research Applications and Proposals: 2018 Requirements," respectively, to the Division of Policy and Assurances, Office for Human Research Protections, 1101 Wootton Parkway, Suite 200, Rockville, MD 20852. Send one selfaddressed adhesive label to assist that office in processing your request, or fax your request to 240–453–6909. See the SUPPLEMENTARY INFORMATION section for information on electronic access to the draft guidance documents.

You may submit comments identified by docket ID number HHS-OS-OPHS-2018-0012 (Scholarly and Journalistic Activities Deemed Not to be Research: 2018 Requirements), docket ID number HHS-OS-OPHS-2018-0013 (When Continuing Review Is Not Required During the 6-Month Delay Period of July 19, 2018 through January 20, 2019: 2018 Requirements), and docket ID number HHS-OS-OPHS-2018-0014 (Elimination of Institutional Review Board (IRB) Review of Research Applications and Proposals: 2018 Requirements), respectively, by one of the following methods:

• Federal eRulemaking Portal: http:// www.regulations.gov. Enter the docket ID number and click on "Search." On the next page, click the "Comment Now" action and follow the instructions.

• Mail/Hand Delivery/Courier [For Paper, Disk, or CD–ROM Submissions]: Irene Stith-Coleman, Ph.D., Office for Human Research Protections, 1101 Wootton Parkway, Suite 200, Rockville, MD 20852. Comments received, including any personal information, will be posted without change to *http://www.regulations.gov.*

FOR FURTHER INFORMATION CONTACT: Irene Stith-Coleman, Ph.D., Office for Human Research Protections, 1101 Wootton Parkway, Suite 200, Rockville, MD 20852, 240–453–6900; email *Irene.Stith-Coleman@hhs.gov*.

SUPPLEMENTARY INFORMATION:

I. Background

A. Overview

OHRP, Office of the Assistant Secretary for Health, is announcing the availability of three draft guidance documents entitled "Scholarly and Journalistic Activities Deemed Not to be Research: 2018 Requirements," "When Continuing Review Is Not Required During the 6-Month Delay Period of July 19, 2018 through January 20, 2019: 2018 Requirements," and "Elimination of Institutional Review Board (IRB) Review of Research Applications and Proposals: 2018 Requirements." The draft guidance documents, when finalized, will represent OHRP's current thinking on these topics. OHRP obtained input from HHS agencies and the Common Rule departments and agencies in developing the draft guidance documents.

The "Scholarly and Journalistic Activities Deemed Not to be Research: 2018 Requirements" draft guidance explains how certain scholarly and journalistic activities that focus directly on the specific individuals about whom the information is collected are deemed not to be research under the 2018 Requirements of the regulations for the protection of human subjects (45 CFR part 46), and consequently do not have to satisfy the requirements of those regulations. It is intended for IRB administrators, IRB chairpersons, relevant institutional officials, and investigators who may be concerned about whether scholarly or journalistic activities need to satisfy the 2018 Requirements of the regulations.

The "When Continuing Review Is Not Required During the 6-Month Delay Period of July 19, 2018 through January 20, 2019: 2018 Requirements" draft guidance provides information on the HHS regulations for the protection of human research subjects at 45 CFR part 46 related to the circumstances in which continuing review of research is not required. In particular, this guidance applies to research that transitions to comply with the 2018 Requirements during the 6-month delay period from July 19, 2018 through January 20, 2019. This guidance only applies during the 6month delay period. It is intended for

Institutional Review Boards (IRBs), investigators, HHS funding agencies, and others that may be responsible for the review, conduct, or oversight of human subjects research conducted or supported by HHS.

The ''Elimination of Institutional Review Board (IRB) Review of Research Applications and Proposals: 2018 Requirements" draft guidance provides guidance on the elimination of the requirement in the pre-2018 Requirements (45 CFR 46.103(f)) that each application or proposal for research undergo IRB review and approval as part of the certification process. It is intended for Institutions, IRBs, investigators, HHS funding agencies, and others that may be responsible for the review, conduct, or oversight of nonexempt research involving human subjects conducted or supported by HHS.

II. Electronic Access

Persons with access may obtain the draft guidance documents on OHRP's website at https://www.hhs.gov/ohrp/regulations-and-policy/requests-for-comments/index.html.

Dated: July 19, 2018.

Jerry Menikoff,

Director, Office for Human Research Protections.

[FR Doc. 2018–15908 Filed 7–24–18; 8:45 am] BILLING CODE 4150–36–P

DEPARTMENT OF HEALTH AND HUMAN SERVICES

National Institutes of Health

Government-Owned Inventions; Availability for Licensing

AGENCY: National Institutes of Health, HHS.

ACTION: Notice.

SUMMARY: The invention listed below is jointly owned by an agency of the U.S. Government with Vanderbilt University, University of Alabama and University of Pennsylvania and is available for licensing to achieve expeditious commercialization of results of federally-funded research and development. Foreign patent applications are filed on selected inventions to extend market coverage for companies and may also be available for licensing.

FOR FURTHER INFORMATION CONTACT: Licensing information and copies of the U.S. patent application listed below may be obtained by communicating with Sury Vepa, Ph.D., J.D., Senior Licensing and Patenting Manager, National Center for Advancing Translational Sciences, NIH, 9800 Medical Center Drive, Rockville, MD 20850, Phone: 301–827–7181, or email *sury.vepa@nih.gov.* A signed Confidential Disclosure Agreement will be required to receive copies of unpublished patent applications.

SUPPLEMENTARY INFORMATION:

Technology description follows.

Thiazole Based Inhibitors of Lactate Dehydrogenase (LDH) for the Treatment of Cancer

Description of Technology: Agents that target enzymes involved in cancer cell metabolism offer an attractive therapeutic route in view of the potential to preferentially target cancer tissue over normal tissue. While normal tissue typically uses glycolysis as a major cellular metabolic path only when the oxygen supply is low, cancer tissue relies heavily on aerobic glycolysis regardless of the oxygen supply level. In addition, metabolic switching to a more glycolytic phenotype is a required step with inflammatory cells and other pathologies which require activated glycolysis in their metabolism. Lactate dehydrogenase (LDH) is involved in the final step of glycolysis, in which pyruvate is converted to lactate and the conversion of NADH to NAD+. There are two different genes of LDH, LDHA and LDHB, but both proteins (subunits) have the same active site and catalyze the conversion of pyruvate to lactate or lactate to pyruvate. In cancer patients, serum total lactate dehydrogenase (levels are often increased, and the gene for LDH, is up-regulated. LDH inhibition is expected to reduce the ability of the cell to effectively metabolize glucose and reduce tumor cell proliferation and tumor growth and other pathologies which involve a glycolytic metabolic switch. Thus, compounds that inhibit LDH activity have potential for the development of anti-cancer therapeutics. Previously developed LDH inhibitors have significant drawbacks, including poor potency and/or poor bioavailability, limiting their utility as therapeutics. The present technology provides novel 1 H-PYRAZOL-1 -YL-THIAZOLE based LDH inhibitors with improved potency, selectivity, and/or bioavailability for the treatment of cancer.

This technology is available for licensing for commercial development in accordance with 35 U.S.C. 209 and 37 CFR part 404, as well as for further development and evaluation under a research collaboration.

Potential Commercial Applications:Novel therapeutics for cancer AND

Novel therapeutics for cancer ANI indications which depend on a

metabolic switch to glycolysis (*e.g.,* inflammation, autoimmune disease, etc.)

Competitive Advantages:

• Novel LDH inhibitors with improved potency, selectivity, and/or bioavailability for the treatment of cancer.

Development Stage:

• Optimized lactate dehydrogenase inhibitors are in pre-clinical development.

Inventors:

• David J. Maloney, Alex Gregory Waterson, Ganesha Rai Bantukallu, Kyle Ryan Brimacombe, Plamen Christov, Chi V. Dang, Victor M. Darley-Usmar, Matthew Hall, Xin Hu, Ajit Jadhav, Somnath Jana, Kwangho Kim, William J. Moore, Brian T. Mott, Leonard M. Neckers, Anton Simeonov, Gary Allen Sulikowski, Daniel Jason URBAN, and Shyh Ming Yang.

Publications: This manuscript reports early compounds in the series: *https:// pubs.acs.org/doi/10.1021/ acs.jmedchem.7b00941.*

Intellectual Property: 1. SMALL MOLECULE INHIBITORS OF LACTATE DEHYDROGENASE AND METHODS OF USE THERE OF, PCT/US2015/ 067895 filed on December 29, 2015 and published as WO 2016/109559 on July 7, 2016 (HHS Ref. No. E–244–2014), and

2. 1 H-PYRAZOL-1 -YL-THIAZOLES AS INHIBITORS OF LACTATE DEHYDROGENASE AND METHODS OF USE THERE OF, PCP/US2017/ 040021 filed on June 29, 2017 and published as WO 2018/005807 on January 8, 2018 9HHS Ref. No. E–190– 2016).

Related Intellectual Property: HHS Reference Number E–293–2011.

Licensing Contact: Sury Vepa, Ph.D., J.D., 301–827–7181; sury.vepa@nih.gov.

Dated: July 5, 2018.

Lili Portilla,

Technology Development Coordinator, National Center for Advancing Translational Sciences.

[FR Doc. 2018–15907 Filed 7–24–18; 8:45 am] BILLING CODE 4140–01–P

DEPARTMENT OF HEALTH AND HUMAN SERVICES

Substance Abuse and Mental Health Services Administration

Agency Information Collection Activities: Submission for OMB Review; Comment Request

Periodically, the Substance Abuse and Mental Health Services Administration (SAMHSA) will publish a summary of information collection requests under OMB review, in compliance with the Paperwork Reduction Act (44 U.S.C. chapter 35). To request a copy of these documents, call the SAMHSA Reports Clearance Officer on (240) 276–1243.

Project: Projects for Assistance in Transition From Homelessness (PATH) Program Annual Report (OMB No. 0930–0205)—Revision

The Center for Mental Health Services awards grants each fiscal year to each of the states, the District of Columbia, the Commonwealth of Puerto Rico, the Virgin Islands, Guam, American Samoa, and the Commonwealth of the Northern Mariana Islands from allotments authorized under the PATH program established by Public Law 101-645, 42 U.S.C. 290cc-21 et seq., the Stewart B. McKinney Homeless Assistance Amendments Act of 1990 (section 521 et seq. of the Public Health Service (PHS) Act) and the 21st Century Cures Act (Pub. L. 114-255). Section 522 of the PHS Act and the 21st Century Cures Act require that the grantee states and territories must expend their payments under the Act solely for making grants to political subdivisions of the state, and to nonprofit private entities (including community-based veterans' organizations and other community organizations) for the purpose of providing services specified in the Act. Available funding is allotted in accordance with the formula provision of section 524 of the PHS Act.

This submission is for a revision of the current approval of the annual grantee reporting requirements. Section 528 of the PHS Act and the 21st Century Cures Act specify that not later than January 31 of each fiscal year, a funded entity will prepare and submit a report in such form and containing such information as is determined necessary for securing a record and description of the purposes for which amounts received under section 521 were expended during the preceding fiscal year and of the recipients of such amounts and determining whether such amounts were expended in accordance with statutory provisions.

The proposed changes to the PATH Annual Report are as follows:

1. Reporting on Contacts

To ensure that all contacts made by PATH providers are reflected in the report, a new question has been added that reports out on all contacts provided during the reporting period. The previous PATH Annual Report only reported on contacts through the date of enrollment. 2. Referrals Provided

To align with the HMIS Data Standards, all PATH Referral response categories are now included in the PATH Annual Report.

3. HMIS Data Standards Updates

When needed, field response options and questions have been updated to align with the most recent version of the HMIS Data Standards. The estimated annual burden for these reporting requirements is summarized in the table below.

Respondents	Number of respondents	Responses per respondent	Burden per response (hrs.)	Total burden
States Local provider agencies	56 487	1	20 15	1,120 7,305
Total	543			8,425

Written comments and recommendations concerning the proposed information collection should be sent by August 24, 2018 to the SAMHSA Desk Officer at the Office of Information and Regulatory Affairs, Office of Management and Budget (OMB). To ensure timely receipt of comments, and to avoid potential delays in OMB's receipt and processing of mail sent through the U.S. Postal Service, commenters are encouraged to submit their comments to OMB via email to: OIRA Submission@omb.eop.gov. Although commenters are encouraged to send their comments via email, commenters may also fax their comments to: 202-395-7285. Commenters may also mail them to: Office of Management and Budget, Office of Information and Regulatory Affairs, New Executive Office Building, Room 10102, Washington, DC 20503.

Summer King,

Statistician.

[FR Doc. 2018–15825 Filed 7–24–18; 8:45 am] BILLING CODE 4162–20–P

DEPARTMENT OF HEALTH AND HUMAN SERVICES

Substance Abuse and Mental Health Services Administration

Center for Substance Abuse Treatment: Notice of Meeting

Pursuant to Public Law 92–463, notice is hereby given that the Substance Abuse and Mental Health Services Administration's (SAMHSA's) Center for Substance Abuse Treatment (CSAT) National Advisory Council will meet on September 11, 2018, 2:00 p.m.– 3:00 p.m. (EDT) in a closed teleconference meeting.

The meeting will include discussions and evaluations of grant applications reviewed by SAMHSA's Initial Review Groups, and involve an examination of confidential financial and business information as well as personal information concerning the applicants. Therefore, the meeting will be closed to the public as determined by the SAMHSA Assistant Secretary for Mental Health and Substance Use in accordance with Title 5 U.S.C 552b(c)(4) and (6) and Title 5 U.S.C. App. 2, 10(d).

Meeting information and a roster of Council members may be obtained by accessing the SAMHSA Committee website at http://www.samhsa.gov/ about-us/advisory-councils/csatnational-advisory-council or by contacting the CSAT National Advisory Council Designated Federal Officer; Tracy Goss (see contact information below).

Council Name: SAMHSA's Center for Substance Abuse Treatment National Advisory Council.

Date/Time/Type: September 11, 2018, 2:00 p.m.–3:00 p.m. EDT, CLOSED.

Place: SAMHSA, 5600 Fishers Lane, Rockville, Maryland 20857.

Contact: Tracy Goss, Designated Federal Officer, CSAT National Advisory Council, 5600 Fishers Lane, Rockville, Maryland 20857 (mail), Telephone: (240) 276–0759, Fax: (240) 276–2252, Email: *tracy.goss@ samhsa.hhs.gov.*

Carlos Castillo,

Committee Management Officer, SAMHSA. [FR Doc. 2018–15824 Filed 7–24–18; 8:45 am] BILLING CODE 4162–20–P

DEPARTMENT OF HOMELAND SECURITY

Federal Emergency Management Agency

[Internal Agency Docket No. FEMA-4368-DR; Docket ID FEMA-2018-0001]

New Jersey; Amendment No. 1 to Notice of a Major Disaster Declaration

AGENCY: Federal Emergency Management Agency, DHS.

ACTION: Notice.

SUMMARY: This notice amends the notice of a major disaster declaration for the State of New Jersey (FEMA–4368–DR), dated June 8, 2018, and related determinations.

DATES: This amendment was issued July 13, 2018.

FOR FURTHER INFORMATION CONTACT:

Dean Webster, Office of Response and Recovery, Federal Emergency Management Agency, 500 C Street SW, Washington, DC 20472, (202) 646–2833.

SUPPLEMENTARY INFORMATION: The notice of a major disaster declaration for the State of New Jersey is hereby amended to include the following area among those areas determined to have been adversely affected by the event declared a major disaster by the President in his declaration of June 8, 2018.

Burlington County for Public Assistance.

The following Catalog of Federal Domestic Assistance Numbers (CFDA) are to be used for reporting and drawing funds: 97.030, Community Disaster Loans; 97.031, Cora Brown Fund; 97.032, Crisis Counseling; 97.033, Disaster Legal Services; 97.034, Disaster Unemployment Assistance (DUA); 97.046, Fire Management Assistance Grant; 97.048, Disaster Housing Assistance to Individuals and Households In Presidentially Declared Disaster Areas; 97.049, Presidentially Declared Disaster Assistance-Disaster Housing Operations for Individuals and Households; 97.050 Presidentially Declared Disaster Assistance to Individuals and Households-Other Needs; 97.036, Disaster Grants—Public Assistance (Presidentially Declared Disasters); 97.039, Hazard Mitigation Grant.

Brock Long,

Administrator, Federal Emergency Management Agency. [FR Doc. 2018–15840 Filed 7–24–18; 8:45 am] BILLING CODE 9111–23–P

DEPARTMENT OF HOMELAND SECURITY

Federal Emergency Management Agency

[Internal Agency Docket No. FEMA-4377-DR; Docket ID FEMA-2018-0001]

Texas; Major Disaster and Related Determinations

AGENCY: Federal Emergency Management Agency, DHS. **ACTION:** Notice.

SUMMARY: This is a notice of the Presidential declaration of a major disaster for the State of Texas (FEMA– 4377–DR), dated July 6, 2018, and related determinations.

DATES: The declaration was issued July 6, 2018.

FOR FURTHER INFORMATION CONTACT:

Dean Webster, Office of Response and Recovery, Federal Emergency Management Agency, 500 C Street SW, Washington, DC 20472, (202) 646–2833.

SUPPLEMENTARY INFORMATION: Notice is hereby given that, in a letter dated July 6, 2018, the President issued a major disaster declaration under the authority of the Robert T. Stafford Disaster Relief and Emergency Assistance Act, 42 U.S.C. 5121 *et seq.* (the "Stafford Act"), as follows:

I have determined that the damage in certain areas of the State of Texas resulting from severe storms and flooding beginning on June 19, 2018, and continuing, is of sufficient severity and magnitude to warrant a major disaster declaration under the Robert T. Stafford Disaster Relief and Emergency Assistance Act, 42 U.S.C. 5121 *et seq.* (the "Stafford Act"). Therefore, I declare that such a major disaster exists in the State of Texas.

In order to provide Federal assistance, you are hereby authorized to allocate from funds available for these purposes such amounts as you find necessary for Federal disaster assistance and administrative expenses.

You are authorized to provide Individual Assistance in the designated areas and Hazard Mitigation throughout the State. Consistent with the requirement that Federal assistance be supplemental, any Federal funds provided under the Stafford Act for Hazard Mitigation and Other Needs Assistance will be limited to 75 percent of the total eligible costs.

Further, you are authorized to make changes to this declaration for the approved assistance to the extent allowable under the Stafford Act.

The time period prescribed for the implementation of section 310(a), Priority to Certain Applications for Public Facility and Public Housing Assistance, 42 U.S.C. 5153, shall be for a period not to exceed six months after the date of this declaration. The Federal Emergency Management Agency (FEMA) hereby gives notice that pursuant to the authority vested in the Administrator, under Executive Order 12148, as amended, Jerry S. Thomas, of FEMA is appointed to act as the Federal Coordinating Officer for this major disaster.

The following areas of the State of Texas have been designated as adversely affected by this major disaster:

Cameron and Hidalgo Counties for Individual Assistance.

All areas within the State of Texas are eligible for assistance under the Hazard Mitigation Grant Program.

The following Catalog of Federal Domestic Assistance Numbers (CFDA) are to be used for reporting and drawing funds: 97.030, Community Disaster Loans; 97.031, Cora Brown Fund; 97.032, Crisis Counseling; 97.033, Disaster Legal Services; 97.034, Disaster Unemployment Assistance (DUA); 97.046, Fire Management Assistance Grant; 97.048, Disaster Housing Assistance to Individuals and Households In Presidentially Declared Disaster Areas; 97.049, Presidentially Declared Disaster Assistance-Disaster Housing Operations for Individuals and Households; 97.050, Presidentially Declared Disaster Assistance to Individuals and Households-Other Needs; 97.036, Disaster Grants—Public Assistance (Presidentially Declared Disasters); 97.039, Hazard Mitigation Grant.

Brock Long,

Administrator, Federal Emergency Management Agency. [FR Doc. 2018–15841 Filed 7–24–18; 8:45 am] BILLING CODE 9111–23–P

BILLING CODE 9111-23-P

DEPARTMENT OF HOMELAND SECURITY

Federal Emergency Management Agency

Agency [Docket ID FEMA–2018–0002; Internal Agency Docket No. FEMA–B–1839]

Changes in Flood Hazard Determinations

AGENCY: Federal Emergency Management Agency, DHS. **ACTION:** Notice.

SUMMARY: This notice lists communities where the addition or modification of Base Flood Elevations (BFEs), base flood depths, Special Flood Hazard Area (SFHA) boundaries or zone designations, or the regulatory floodway (hereinafter referred to as flood hazard determinations), as shown on the Flood Insurance Rate Maps (FIRMs), and where applicable, in the supporting Flood Insurance Study (FIS) reports, prepared by the Federal Emergency Management Agency (FEMA) for each

community, is appropriate because of new scientific or technical data. The FIRM, and where applicable, portions of the FIS report, have been revised to reflect these flood hazard determinations through issuance of a Letter of Map Revision (LOMR), in accordance with Federal Regulations. The LOMR will be used by insurance agents and others to calculate appropriate flood insurance premium rates for new buildings and the contents of those buildings. For rating purposes, the currently effective community number is shown in the table below and must be used for all new policies and renewals.

DATES: These flood hazard determinations will be finalized on the dates listed in the table below and revise the FIRM panels and FIS report in effect prior to this determination for the listed communities.

From the date of the second publication of notification of these changes in a newspaper of local circulation, any person has 90 days in which to request through the community that the Deputy Associate Administrator for Insurance and Mitigation reconsider the changes. The flood hazard determination information may be changed during the 90-day period.

ADDRESSES: The affected communities are listed in the table below. Revised flood hazard information for each community is available for inspection at both the online location and the respective community map repository address listed in the table below. Additionally, the current effective FIRM and FIS report for each community are accessible online through the FEMA Map Service Center at *https:// msc.fema.gov* for comparison.

Submit comments and/or appeals to the Chief Executive Officer of the community as listed in the table below.

FOR FURTHER INFORMATION CONTACT: Rick Sacbibit, Chief, Engineering Services Branch, Federal Insurance and Mitigation Administration, FEMA, 400 C Street SW, Washington, DC 20472, (202) 646–7659, or (email) *patrick.sacbibit@fema.dhs.gov;* or visit the FEMA Map Information eXchange (FMIX) online at *https://*

www.floodmaps.fema.gov/fhm/fmx_main.html.

SUPPLEMENTARY INFORMATION: The specific flood hazard determinations are not described for each community in this notice. However, the online location and local community map repository address where the flood

hazard determination information is available for inspection is provided.

Any request for reconsideration of flood hazard determinations must be submitted to the Chief Executive Officer of the community as listed in the table below.

The modifications are made pursuant to section 201 of the Flood Disaster Protection Act of 1973, 42 U.S.C. 4105, and are in accordance with the National Flood Insurance Act of 1968, 42 U.S.C. 4001 *et seq.*, and with 44 CFR part 65. The FIRM and FIS report are the basis

The FIRM and FIS report are the basis of the floodplain management measures that the community is required either to adopt or to show evidence of having in effect in order to qualify or remain qualified for participation in the National Flood Insurance Program (NFIP).

These flood hazard determinations, together with the floodplain management criteria required by 44 CFR 60.3, are the minimum that are required. They should not be construed to mean that the community must change any existing ordinances that are more stringent in their floodplain management requirements. The community may at any time enact stricter requirements of its own or pursuant to policies established by other Federal, State, or regional entities. The flood hazard determinations are in accordance with 44 CFR 65.4.

The affected communities are listed in the following table. Flood hazard

determination information for each community is available for inspection at both the online location and the respective community map repository address listed in the table below. Additionally, the current effective FIRM and FIS report for each community are accessible online through the FEMA Map Service Center at https:// msc.fema.gov for comparison.

(Catalog of Federal Domestic Assistance No. 97.022, "Flood Insurance.")

David I. Maurstad,

Deputy Associate Administrator for Insurance and Mitigation, Department of Homeland Security, Federal Emergency Management Agency.

State and county	Location and case No.	Chief executive officer of community	Community map repository	Online location of letter of map revision	Date of modification	Community, No.
Arizona: Maricopa	Unincorporated Areas of Mari- copa County (17–09– 2756P)	The Honorable Steve Chucri, Chairman, Board of Supervisors, Maricopa County, 301 West Jefferson Street 10th Floor, Phoenix, AZ 85003	Flood Control District of Maricopa County, 2801 West Durango Street, Phoenix, AZ 85009	https://msc.fema.gov/portal/ advanceSearch.	Sep. 28, 2018	040037
California:						
Orange	City of Irvine (18–09– 0287P)	The Honorable Donald P. Wagner, Mayor, City of Irvine, 1 Civic Center Plaza, Irvine, CA 92606	City Hall, 1 Civic Center Plaza, Irvine, CA 92606	https://msc.fema.gov/portal/ advanceSearch.	Oct. 5, 2018	060222
Santa Clara	Town of Los Altos Hills (17– 09–0578P)	The Honorable John Radford, Mayor, Town of Los Altos Hills, 26379 Fremont Road, Los Altos Hills, CA 94022	Town Hall, 26379 Fre- mont Road, Los Altos, Hills, CA 94022	https://msc.fema.gov/portal/ advanceSearch.	Oct. 9, 2018	060342
Ventura	City of Simi Val- ley (18–09– 0442P)	The Honorable Bob Huber, Mayor, City of Simi Valley, 2929 Tapo Canyon Road, Simi Valley, CA 93063	City Hall, 2929 Tapo Canyon Road, Simi Valley, CA 93063	https://msc.fema.gov/portal/ advanceSearch.	Sep. 27, 2018	060421
Florida: Duval	City of Jackson-	The Honorable Lenny	City Hall, 117 West Duval	https://msc.fema.gov/portal/	Sep. 21, 2018	120077
	ville (18–04– 0586P)	Curry, Mayor, City of Jacksonville, 117 West Duval Street, Suite 400, Jacksonville, FL 32202	Street, Jacksonville, FL 32202.	advanceSearch.	Зер. 21, 2010	120077
St. Johns	Unincorporated Areas of St. Johns County (18–04– 0875P)	The Honorable Henry Dean, Chairman, St. Johns County Board of Commissioners, 500 San Sebastian View, St. Augustine, FL 32084	St. Johns County Admin- istration Building, 4020 Lewis Speedway, St. Augustine, FL 32084	https://msc.fema.gov/portal/ advanceSearch.	Oct. 4, 2018	125147
St. Johns	Unincorporated Areas of St. Johns County (18–04– 2412P)	The Honorable Henry Dean, Chairman, St. Johns County Board of Commissioners, 500 San Sebastian View, St. Augustine, FL 32084	St. Johns County Admin- istration Building, 4020 Lewis Speedway, St. Augustine, FL 32084	https://msc.fema.gov/portal/ advanceSearch.	Oct. 5, 2018	125147
Illinois:		T I II II II II II II			0 01 0010	170110
Cook	Village of Orland Park (18–05– 2733P)	The Honorable Keith Pekau, Village Presi- dent, Village of Orland Park, 14700 South Ravinia Avenue, Orland Park, IL 60462	Village Hall, 14700 South Ravinia Avenue, Orland Park, IL 60462	https://msc.fema.gov/portal/ advanceSearch.	Sep. 21, 2018	170140
Kane	Village of Gil- berts (17–05– 3110P)	The Honorable Rick Zirk, Village President, Vil- lage of Gilberts, 87 Galligan Road, Gil- berts, IL 60136	Village Hall, 87 Galligan Road, Gilberts, IL 60136	https://msc.fema.gov/portal/ advanceSearch.	Sep. 20, 2018	170326

State and county	Location and case No.	Chief executive officer of community	Community map repository	Online location of letter of map revision	Date of modification	Community, No.
Missouri: Scott	City of Scott City (18–07– 0675P)	The Honorable Ron Cummins, Mayor, City of Scott City, 215 Chester Avenue, Scott City, MO 63780	City Hall, 215 Chester Avenue, Scott City, MO 63780	https://msc.fema.gov/portal/ advanceSearch.	Oct. 3, 2018	290414
Nevada: Clark	City of Las Vegas (18– 09–1058P)	The Honorable Carolyn G. Goodman, Mayor, City of Las Vegas, City Hall, 495 South Main Street, Las Vegas, NV 89101	Public Works Depart- ment, 400 Stewart Ave- nue, 4th Floor, Las Vegas, NV 89101	https://msc.fema.gov/portal/ advanceSearch.	Oct. 5, 2018	325276
Oregon:						
Clatsop	City of Seaside (18–10– 0563P)	The Honorable Jay Bar- ber, Mayor, City of Seaside, City Hall, 989 Broadway, Seaside, OR 97138	City Hall, 989 Broadway, Seaside, OR 27138	https://msc.fema.gov/portal/ advanceSearch.	Sep. 24, 2018	410032
Clatsop	Unincorporated Areas of Clatsop Coun- ty (18–10– 0563P)	Mr. Scott Lee, Chair, Clatsop County Board of Commissioners, County Government Offices, 800 Exchange Street, Suite 410, Astoria, OR 97103	Clatsop County, County Government Offices, 800 Exchange Street, Suite 410, Astoria, OR 97103	https://msc.fema.gov/portal/ advanceSearch.	Sep. 24, 2018	410027
Washington:						
Pierce	City of Gig Har- bor (17–10– 1309P)	The Honorable Kit Kuhn, Mayor, City of Gig Har- bor, 3510 Grandview Street, Gig Harbor, WA 98335	City Clerk's Office, 3510 Grandview Street, Gig Harbor, WA 98335	https://msc.fema.gov/portal/ advanceSearch.	Sep. 28, 2018	530142
Pierce	City of Tacoma (17–10– 1309P)	The Honorable Victoria Woodards, Mayor, City of Tacoma, 747 Market Street, 12th Floor, Ta- coma, WA 98402	Municipal Building, 747 Market Street, Tacoma, WA 98402	https://msc.fema.gov/portal/ advanceSearch.	Sep. 28, 2018	530148
Pierce	Unincorporated Areas of Pierce County (17–10– 1309P)	The Honorable Douglas Richardson, Chairman, County Council, Pierce County, 930 Tacoma Avenue South, Ta- coma, WA 98402	Pierce County, Pierce County Annex, 2401 South 35th Street, Ta- coma, WA 98409	https://msc.fema.gov/portal/ advanceSearch.	Sep. 28, 2018	530138

[FR Doc. 2018–15839 Filed 7–24–18; 8:45 am] BILLING CODE 9110–12–P

DEPARTMENT OF THE INTERIOR

National Park Service

[NPS-WASO-NRNHL-DTS#-26012; PPWOCRADI0, PCU00RP14.R50000]

National Register of Historic Places; Notification of Pending Nominations and Related Actions

AGENCY: National Park Service, Interior. **ACTION:** Notice.

SUMMARY: The National Park Service is soliciting comments on the significance of properties nominated before July 7, 2018, for listing or related actions in the National Register of Historic Places. **DATES:** Comments should be submitted by August 9, 2018.

ADDRESSES: Comments may be sent via U.S. Postal Service and all other carriers to the National Register of Historic Places, National Park Service, 1849 C St. NW, MS 7228, Washington, DC 20240. **SUPPLEMENTARY INFORMATION:** The

properties listed in this notice are being

considered for listing or related actions in the National Register of Historic Places. Nominations for their consideration were received by the National Park Service before July 7, 2018. Pursuant to Section 60.13 of 36 CFR part 60, written comments are being accepted concerning the significance of the nominated properties under the National Register criteria for evaluation.

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. Nominations submitted by State Historic Preservation Officers:

MASSACHUSETTS

Hampden County

Hampden County Training School, 702 S Westfield St., Agawam, SG100002781

Plymouth County

Cardinal Cushing Center Historic District, 369 Washington St., Hanover, SG100002782

Worcester County

Pan Historic District, Main St., Annie Moore, Burnham, Hudson & Long Hill Rds., Bolton, SG100002783 A request for removal has been made for the following resource:

ALASKA

Fairbanks North Star Borough

Masonic Temple, 809 1st Ave., Fairbanks, OT80004568

Nominations submitted by Federal Preservation Officers:

The State Historic Preservation Officer reviewed the following nominations and responded to the Federal Preservation Officer within 45 days of receipt of the nominations and supports listing the properties in the National Register of Historic Places.

ALASKA

Denali Borough

Kantishna Roadhouse, (Kantishna Historic Mining Resources of Denali National Park and Preserve, MPS), Approx .1 mi. W of mi. 91 of Denali Park Rd., Denali vicinity, MP100002780

UTAH

Kane County

Paso por Aqui—Anno 1776 Inscription, Address Restricted, Big Water vicinity, SG100002785

Authority: Section 60.13 of 36 CFR part 60.

Dated: July 11, 2018.

Julie H. Ernstein,

Acting Chief, National Register of Historic Places/National Historic Landmarks Program and Deputy Keeper of the National Register of Historic Places.

[FR Doc. 2018–15869 Filed 7–24–18; 8:45 am] BILLING CODE 4312–52–P

DEPARTMENT OF THE INTERIOR

Bureau of Reclamation

[RR02471000, 18XR0680A4, RX.08804994.2000000]

Notice of Proposed New Fee Site, Lake Berryessa, Napa, California; Federal Lands Recreation Enhancement Act

AGENCY: Bureau of Reclamation, Interior.

ACTION: Notice of proposed new fee site; request for comments.

SUMMARY: The Bureau of Reclamation is proposing to charge and retain fees for day use and boat launch at Capell Cove Boat Launch, Oak Shores and Smittle Creek Day Use Areas located at Lake Berryessa. Special Recreation Event authorization fees, and shade shelter reservations are also proposed to be retained under this authority.

DATES: Submit written comments on the new fee site on or before January 31, 2019. The proposed new fees would begin May 1, 2019. Public meeting dates and location will be announced locally by press release and posted on the Lake Berryessa website at *www.usbr.gov/mp/ccao/berryessa/.*

ADDRESSES: Send written comments on the proposed new fee site to Drew Lessard, Area Manager, Central California Area Office, Bureau of Reclamation, 7794 Folsom Dam Road, Folsom, California 95630.

FOR FURTHER INFORMATION CONTACT: Margaret David Bailey, Lake Berryessa Park Manager, Bureau of Reclamation, 5520 Knoxville Road, Napa, California 94558; or call (707) 966–2111 extension 106; or send email to *mbailey@usbr.gov*.

SUPPLEMENTARY INFORMATION: The Federal Lands Recreation Enhancement Act (Title VII, Pub. L. 108–447) directed the Secretary of the Interior to publish a 6-month advance notice in the **Federal Register** whenever new recreation fee areas are established. Once public outreach is complete, the new fees proposed below will be reviewed by the Bureau of Reclamation Mid-Pacific Regional Director prior to a final decision and implementation. Visitors wanting to reserve shade shelters would need to do so through the National Reservation Service at *www.recreation.gov*, or by calling 1–877–444–6777.

The proposed fee for day use is \$5 per vehicle (\$50 annual fee); boat launch is \$10 per launch (\$100 annual fee); and \$25 per shade shelter. All interagency Senior and Access Passes will be accepted for day use and discounted boat launching (50% discount). An analysis of the nearby Federal and state recreation offerings with similar amenities shows that the proposed fees are reasonable and typical of similar sites in the area. Funds from fees will be used for the continued operation, maintenance, and improvements of the reservoir area recreation amenities and related programs.

Public Disclosure. 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.

Dated: July 19, 2018. Richard J. Woodley,

Acting Regional Director. [FR Doc. 2018–15909 Filed 7–24–18; 8:45 am] BILLING CODE 4332–90–P

DEPARTMENT OF THE INTERIOR

Bureau of Reclamation

[RR83570000, 189R5065C6, RX.59389832.1009676; OMB Control Number 1006–0002]

Agency Information Collection Activities; Recreation Use Data Report

AGENCY: Bureau of Reclamation, Interior.

ACTION: Notice of information collection; request for comment.

SUMMARY: In accordance with the Paperwork Reduction Act of 1995, we, the Bureau of Reclamation (Reclamation), are proposing to renew an information collection with revisions.

DATES: Interested persons are invited to submit comments on or before September 24, 2018.

ADDRESSES: Send your comments on this information collection request (ICR) by mail to Ronnie Baca, Bureau of Reclamation, Office of Policy and Administration, 84–57000, P.O. Box 25007, Denver, CO 80225–0007; or by email to *rbaca@usbr.gov*. Please reference OMB Control Number 1006– 0002 in the subject line of your comments.

FOR FURTHER INFORMATION CONTACT: To request additional information about this ICR, contact Ronnie Baca by email at *rbaca@usbr.gov*, or by telephone at 303–445–3257.

SUPPLEMENTARY INFORMATION: In accordance with the Paperwork Reduction Act of 1995, we provide the general public and other Federal agencies with an opportunity to comment on new, proposed, revised, and continuing collections of information. This helps us assess the impact of our information collection requirements and minimize the public's reporting burden. It also helps the public understand our information collection requirements and provide the requested data in the desired format.

We are soliciting comments on the proposed ICR that is described below. We are especially interested in public comment addressing the following issues: (1) Is the collection necessary to the proper functions of Reclamation; (2) will this information be processed and used in a timely manner; (3) is the estimate of burden accurate; (4) how might Reclamation enhance the quality, utility, and clarity of the information to be collected; and (5) how might Reclamation minimize the burden of this collection on the respondents, including through the use of information technology.

Comments that you submit in response to this notice are a matter of public record. We will include or summarize each comment in our request to OMB to approve this ICR. Before including your address, phone number, email address, or other personal identifying information in your comment, you should be aware that your entire comment-including your personal identifying information-may be made publicly available at any time. While you can ask us in your comment to withhold your personal identifying information from public review, we cannot guarantee that we will be able to do so.

Abstract: Reclamation collects agency-wide recreation and concession information to fulfill congressional

reporting requirements pursuant to current public laws, including the Land and Water Conservation Fund Act (Pub. L. 88-578), the Federal Water Project Recreation Act (Pub. L. 89-72), and the Federal Lands Recreation Enhancement Act (Pub. L. 108–477). In addition, collected information will permit relevant program assessments of resources managed by Reclamation, its recreation managing partners, and/or concessionaires for the purpose of contributing to the implementation of Reclamation's mission. More specifically, the collected information enables Reclamation to (1) evaluate the effectiveness of program management based on existing recreation and

concessionaire resources and facilities, and (2) validate the efficiency of resources for public use within partner managed recreation resources, located on Reclamation project lands in the 17 Western States.

Title of Collection: Recreation Use Data Report.

OMB Control Number: 1006–0002. Form Number: Form 7–2534—

Managing Partners and Direct Managed Recreation Areas.

Type of Review: Revision of a currently approved collection.

Respondents/Affected Public: State, local, or tribal governments; agencies who manage Reclamation's recreation resources and facilities; and commercial concessions, sub-concessionaires, and nonprofit organizations located on Reclamation lands with associated recreation services.

Total Estimated Number of Annual Respondents: 212.

Total Estimated Number of Annual Responses: 212.

Estimated Completion Time per Response: See table.

Total Estimated Number of Annual Burden Hours: 120 hours.

Respondent's Obligation: Required to obtain or retain a benefit.

Frequency of Collection: Annually. Total Estimated Annual Nonhour Burden Cost: 0.

Section of form	Burden estimate per form (in minutes)	Annual number of respondents	Annual burden on respondents (in hours)	
Form 7–2534, Section 1 only: Managing Partners Form 7–2534 (Section 1, Managing Partners & Section 2, Concessionaires)	30 45	156 56	78 42	
Total Burden Hours			120	

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*).

Dated: June 12, 2018.

Ruth Welch,

Director, Policy and Administration. [FR Doc. 2018–15911 Filed 7–24–18; 8:45 am] BILLING CODE 4332–90–P

INTERNATIONAL TRADE COMMISSION

[Investigation No. 337-TA-1095]

Certain Load Supporting Systems, Including Composite Mat Systems, and Components Thereof; Commission Determination Not To Review an Initial Determination Granting a Joint Motion To Terminate the Investigation Based on Consent Orders and a Settlement Agreement; Issuance of Consent Orders; Termination of the Investigation

AGENCY: U.S. International Trade Commission.

ACTION: Notice.

SUMMARY: Notice is hereby given that the U.S. International Trade Commission has determined not to review an initial determination (Order No. 10) granting a joint motion to terminate the investigation based on consent orders and a settlement agreement. The Commission has issued the consent orders. The investigation is terminated.

FOR FURTHER INFORMATION CONTACT:

Lucy Grace D. Novola, Office of the General Counsel, U.S. International Trade Commission, 500 E Street SW, Washington, DC 20436, telephone 202-205-3438. Copies of non-confidential documents filed in connection with this investigation are or will be available for inspection during official business hours (8:45 a.m. to 5:15 p.m.) in the Office of the Secretary, U.S. International Trade Commission, 500 E Street SW, Washington, DC 20436, telephone 202-205-2000. General information concerning the Commission may also be obtained by accessing its internet server (*https://www.usitc.gov*). The public record for this investigation may be viewed on the Commission's electronic docket (EDIS) at https:// edis.usitc.gov. 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 January 22, 2018, based on a complaint filed by Newpark Mats & Integrated Services LLC of The Woodlands, Texas ("Newpark"). 83 FR 3022 (Jan. 22, 2018). The complaint, as amended, 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, and the sale within the United States after importation of certain load supporting systems, including composite mat systems, and components thereof by reason of infringement of certain claims of U.S. Patent Nos. 6,511,257 and 6,695,527. The notice of investigation, as amended, names as respondents Checkers Industrial Products, LLC of Broomfield, Colorado; Checkers Safety Group UK LTD of Cheshire, United Kingdom; Zigma Ground Solutions LTD of Essex, United Kingdom; and Isokon d.o.o. of Slovenske Konjice, Slovenia ("Isokon"). The Office of Unfair Import Investigations was not named as a party to the investigation.

On June 28, 2018, the Commission determined not to review an initial determination ("ID") terminating the investigation in part as to Isokon. Notice (June 28, 2018) (determining not to review Order No. 8 (May 29, 2018)).

On June 13, 2018, Newpark and the remaining respondents filed a joint motion to terminate the investigation in its entirety based on consent orders and a settlement agreement.

On June 26, 2018, the administrative law judge ("ALJ") issued the subject ID (Order No. 10) granting the motion. The ALJ found that the motion, consent order stipulation, and proposed consent orders satisfy the requirements of 19 CFR 210.21(b) and (c). The ALJ also found that termination of the investigation would not be contrary to the public interest. No petitions for review of the subject ID were filed.

The Commission has determined not to review the subject ID and has issued the consent orders. 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: July 20, 2018.

Lisa Barton,

Secretary to the Commission. [FR Doc. 2018–15930 Filed 7–24–18; 8:45 am] BILLING CODE 7020–02–P

DEPARTMENT OF LABOR

Employment and Training Administration

Notice of a Change in Status of an Extended Benefit (EB) Period for the United States Virgin Islands

AGENCY: Employment and Training Administration, Labor. **ACTION:** Notice.

SUMMARY: This notice announces a change in benefit period eligibility under the EB program for the Virgin Islands.

The following change has occurred since the publication of the last notice regarding the Virgin Islands' EB status:

• The Virgin Islands' 13-week insured unemployment rate for the week ending June 2, 2018, was below the 5.00 percent threshold. Therefore, the EB period for the Virgin Islands will end on June 23, 2018. The State will remain in an "off" period for a minimum of 13 weeks.

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 ending an EB period, the State Workforce Agency will furnish a written notice to each individual who is currently filing claims for EB of the forthcoming termination of the EB period and its effect on the individual's right to EB (20 CFR 615.13 (c)).

FOR FURTHER INFORMATION CONTACT: U.S. Department of Labor, Employment and Training Administration, Office of

Unemployment Insurance, Room S-4524, Attn: Anatoli Sznoluch, 200 Constitution Avenue NW, Washington, DC 20210, telephone number (202) 693– 3176 (this is not a toll-free number) or by email: *Sznoluch.Anatoli@dol.gov*.

Rosemary Lahasky,

Deputy Assistant Secretary, Employment and Training, Labor.

[FR Doc. 2018–15910 Filed 7–24–18; 8:45 am] BILLING CODE 4510–FT–P

NUCLEAR REGULATORY COMMISSION

Advisory Committee on the Medical Uses of Isotopes: Meeting Notice

AGENCY: U.S. Nuclear Regulatory Commission.

ACTION: Notice of meeting.

SUMMARY: The U.S. Nuclear Regulatory Commission (NRC) will convene a meeting of the Advisory Committee on the Medical Uses of Isotopes (ACMUI) on September 20-21, 2018. Tentative agenda items to be discussed during the public session include: (1) Medicalrelated events; (2) an update on nursing mother guidelines; (3) licensing of thorium-227 chloride; (4) an update on the yttrium-90 microspheres licensing guidance revision; and (5) status of the NRC's training and experience (T&E) evaluation and stakeholder outreach plans for T&E. The agenda is subject to change. The current agenda and any updates will be available at http:// www.nrc.gov/reading-rm/doccollections/acmui/meetings/2018.html or may be requested by emailing Ms. Lisa Dimmick at the contact information helow

Purpose: Discuss issues related to 10 CFR part 35, Medical Use of Byproduct Material.

Date and Time for Open Sessions: September 20, 2018, from 8:30 a.m. to 3:00 p.m. and September 21, 2018, from 8:30 a.m. to 3:30 p.m. Eastern Standard Time.

Date and Time for Closed Sessions: September 20, 2018, from 8:00 a.m. to 8:30 a.m. and 3:30 p.m. to 5:00 .pm.

Address for Public Meeting: U.S. Nuclear Regulatory Commission, One White Flint North Building, Commission Hearing Room, 11545 Rockville Pike, Rockville, Maryland 20852.

Public Participation: Any member of the public who wishes to participate in the meeting in person or via phone should contact Ms. Dimmick using the information below. The meeting will also be webcast live at https:// video.nrc.gov/. *Contact Information:* Lisa Dimmick, email: *lisa.dimmick@nrc.gov*, telephone: (301) 415–0694.

Conduct of the Meeting

Christopher J. Palestro, M.D. will chair the meeting. Dr. Palestro will conduct the meeting in a manner that will facilitate the orderly conduct of business. The following procedures apply to public participation in the meeting:

1. Persons who wish to provide a written statement should submit an electronic copy to Ms. Dimmick using the contact information listed above. All submittals must be received by September 17, 2018, three business days before the meeting, and must pertain to the topics on the agenda for the meeting.

2. Questions and comments from members of the public will be permitted during the meeting, at the discretion of the Chairman.

3. The draft transcript and meeting summary will be available on ACMUI's website http://www.nrc.gov/reading-rm/ doc-collections/acmui/meetings/ 2018.html on or about November 2, 2018.

4. Persons who require special services, such as those for the hearing impaired, should notify Ms. Dimmick of their planned attendance.

This meeting will be held in accordance with the Atomic Energy Act of 1954, as amended (primarily Section 161a); the Federal Advisory Committee Act (5 U.S.C. App); and the Commission's regulations in title 10 of the *Code of Federal Regulations*, part 7.

Dated at Rockville, Maryland, this 20th day of July 2018.

For the Nuclear Regulatory Commission. **Russell E. Chazell**,

Federal Advisory Committee Management Officer.

[FR Doc. 2018–15884 Filed 7–24–18; 8:45 am] BILLING CODE 7590–01–P

POSTAL REGULATORY COMMISSION

[Docket Nos. CP2017–203; MC2018–193 and CP2018–271; MC2018–194 and CP2018–272; MC2018–195 and CP2018–273]

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: July 27, 2018.

ADDRESSES: Submit comments electronically via the Commission's Filing Online system at *http:// www.prc.gov.* Those who cannot submit comments electronically should contact the person identified in the FOR FURTHER INFORMATION CONTACT section by telephone for advice on filing alternatives.

FOR FURTHER INFORMATION CONTACT:

David A. Trissell, General Counsel, at 202–789–6820.

SUPPLEMENTARY INFORMATION:

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I. Introduction

II. Docketed Proceeding(s)

I. Introduction

The Commission gives notice that the Postal Service filed request(s) for the Commission to consider matters related to negotiated service agreement(s). The request(s) may propose the addition or removal of a negotiated service agreement from the market dominant or the competitive product list, or the modification of an existing product currently appearing on the market dominant or the competitive product list.

Section II identifies the docket number(s) associated with each Postal Service request, the title of each Postal Service request, the request's acceptance date, and the authority cited by the Postal Service for each request. For each request, the Commission appoints an officer of the Commission to represent the interests of the general public in the proceeding, pursuant to 39 U.S.C. 505 (Public Representative). Section II also establishes comment deadline(s) pertaining to each request.

The public portions of the Postal Service's request(s) can be accessed via the Commission's website (*http:// www.prc.gov*). Non-public portions of the Postal Service's request(s), if any, can be accessed through compliance with the requirements of 39 CFR 3007.40.

The Commission invites comments on whether the Postal Service's request(s) in the captioned docket(s) are consistent with the policies of title 39. For request(s) that the Postal Service states concern market dominant product(s), applicable statutory and regulatory requirements include 39 U.S.C. 3622, 39 U.S.C. 3642, 39 CFR part 3010, and 39 CFR part 3020, subpart B. For request(s) that the Postal Service states concern competitive product(s), applicable statutory and regulatory requirements include 39 U.S.C. 3632, 39 U.S.C. 3633, 39 U.S.C. 3642, 39 CFR part 3015, and 39 CFR part 3020, subpart B. Comment deadline(s) for each request appear in section II.

II. Docketed Proceeding(s)

1. Docket No(s).: CP2017–203; Filing Title: USPS Notice of Amendment to Priority Mail & First-Class Package Service Contract 43, Filed Under Seal; Filing Acceptance Date: July 19, 2018; Filing Authority: 39 CFR 3015.5; Public Representative: Kenneth R. Moeller; Comments Due: July 27, 2018.

2. Docket No(s).: MC2018–193 and CP2018–271; Filing Title: USPS Request to Add Priority Mail Express, Priority Mail & First-Class Package Service Contract 42 to Competitive Product List and Notice of Filing Materials Under Seal; Filing Acceptance Date: July 19, 2018; Filing Authority: 39 U.S.C. 3642, 39 CFR 3020.30 et seq., and 39 CFR 3015.5; Public Representative: Christopher C. Mohr; Comments Due: July 27, 2018.

3. Docket No(s).: MC2018–194 and CP2018–272; Filing Title: USPS Request to Add Priority Mail & First-Class Package Service Contract 84 to Competitive Product List and Notice of Filing Materials Under Seal; Filing Acceptance Date: July 19, 2018; Filing Authority: 39 U.S.C. 3642, 39 CFR 3020.30 et seq., and 39 CFR 3015.5; Public Representative: Kenneth R. Moeller; Comments Due: July 27, 2018.

4. Docket No(s).: MC2018–195 and CP2018–273; Filing Title: USPS Request to Add Priority Mail Contract 454 to Competitive Product List and Notice of Filing Materials Under Seal; Filing Acceptance Date: July 19, 2018; Filing Authority: 39 U.S.C. 3642, 39 CFR 3020.30 et seq., and 39 CFR 3015.5; Public Representative: Christopher C. Mohr; Comments Due: July 27, 2018. This notice will be published in the

Federal Register.

Stacy L. Ruble,

Secretary.

[FR Doc. 2018–15892 Filed 7–24–18; 8:45 am] BILLING CODE 7710–FW–P

POSTAL SERVICE

Product Change—Priority Mail and First-Class Package Service Negotiated Service Agreement

AGENCY: Postal ServiceTM. ACTION: Notice.

SUMMARY: The Postal Service gives notice of filing a request with the Postal Regulatory Commission to add a domestic shipping services contract to the list of Negotiated Service Agreements in the Mail Classification Schedule's Competitive Products List. **DATES:** Date of required notice: July 25, 2018.

FOR FURTHER INFORMATION CONTACT: Elizabeth Reed, 202–268–3179.

SUPPLEMENTARY INFORMATION: The United States Postal Service® hereby gives notice that, pursuant to 39 U.S.C. 3642 and 3632(b)(3), on July 19, 2018, it filed with the Postal Regulatory Commission a USPS Request to Add Priority Mail & First-Class Package Service Contract 84 to Competitive Product List. Documents are available at www.prc.gov, Docket Nos. MC2018–194, CP2018–272.

Elizabeth Reed,

Attorney, Corporate and Postal Business Law. [FR Doc. 2018–15842 Filed 7–24–18; 8:45 am] BILLING CODE 7710–12–P

POSTAL SERVICE

Product Change—Priority Mail Negotiated Service Agreement

AGENCY: Postal ServiceTM. ACTION: Notice.

SUMMARY: The Postal Service gives notice of filing a request with the Postal Regulatory Commission to add a domestic shipping services contract to the list of Negotiated Service Agreements in the Mail Classification Schedule's Competitive Products List. **DATES:** Date of required notice: July 25, 2018.

FOR FURTHER INFORMATION CONTACT: Elizabeth Reed, 202–268–3179.

SUPPLEMENTARY INFORMATION: The United States Postal Service® hereby gives notice that, pursuant to 39 U.S.C. 3642 and 3632(b)(3), on July 19, 2018, it filed with the Postal Regulatory Commission a USPS Request to Add Priority Mail Contract 454 to Competitive Product List. Documents are available at www.prc.gov, Docket Nos. MC2018–195, CP2018–273.

Elizabeth Reed,

Attorney, Corporate and Postal Business Law. [FR Doc. 2018–15844 Filed 7–24–18; 8:45 am] BILLING CODE 7710–12–P

POSTAL SERVICE

Product Change—Priority Mail Express, Priority Mail, & First-Class Package Service Negotiated Service Agreement

AGENCY: Postal ServiceTM.

ACTION: Notice.

SUMMARY: The Postal Service gives notice of filing a request with the Postal Regulatory Commission to add a domestic shipping services contract to the list of Negotiated Service Agreements in the Mail Classification Schedule's Competitive Products List. **DATES:** Date of required notice: July 25, 2018.

FOR FURTHER INFORMATION CONTACT: Elizabeth Reed, 202–268–3179.

SUPPLEMENTARY INFORMATION: The United States Postal Service® hereby gives notice that, pursuant to 39 U.S.C. 3642 and 3632(b)(3), on July 19, 2018, it filed with the Postal Regulatory Commission a USPS Request to Add Priority Mail Express, Priority Mail, & First-Class Package Service Contract 42 to Competitive Product List. Documents are available at www.prc.gov, Docket Nos. MC2018–193, CP2018–271.

Elizabeth Reed,

Attorney, Corporate and Postal Business Law. [FR Doc. 2018–15843 Filed 7–24–18; 8:45 am] BILLING CODE 7710–12–P

POSTAL SERVICE

Unused Label Refunds

AGENCY: Postal Service[™]. **ACTION:** Notice.

SUMMARY: The Postal Service will implement two new options for mailers to submit refund requests for unused labels using an automated online process. A hyperlink will be located on the Electronic Verification System (eVS®) Monthly Account and Sampling Summary page where users can access a portal to submit unused label refunds. DATES: These options shall be implemented August 1, 2018.

FOR FURTHER INFORMATION CONTACT:

Direct questions to Jimmy A. Palma by email at *jimmy.a.palma@usps.gov* or by phone at (202) 268–8798.

SUPPLEMENTARY INFORMATION:

Background

Currently the Postal Service allows eVS mailers to submit a refund request for unused labels using a Type "4" Corrections Shipping Services File. Additionally, eVS mailers can submit refund requests for unused labels through the Dispute Queue accessible from the Business Customer Gateway. In this Notice, the Postal Service is announcing its plan to replace these methods with two new options for eVS mailers to submit refund requests for unused labels, using an automated online process. A hyperlink titled "Submit Refund Request for Unused Labels" will be added to the eVS Monthly Account and Sampling Summary page. This hyperlink provides access to the portal to use the two new options. The two options are as follows:

Option 1—PIC/EFN Submission (Text File Option)

A mailer can upload a text (.txt) file with multiple Package Identification Codes/Electronic File Numbers (PIC/ EFNs). There is no limit to the number of PIC/EFNs submitted if using the text (.txt) upload option. Refer to appendix N in Postal Service Publication 205, Electronic Verification System (eVS®) Business and Technical Guide (https:// postalpro.usps.com/node/3724) for guidance on using the online interface for uploading text files or using the entry box when requesting refunds for unused labels. All refund requests made through the online interface must be submitted within 60 days of the date of mailing. The system will validate if PIC/ EFNs are formatted appropriately, and will create a dispute queue case number accessible through both the eVS landing page and the dispute queue. If PIC/EFNs fail format validation, an error message will be displayed for any of the following reasons: Invalid PIC length, duplicate EFN, commas in EFN, invalid EFN prefix, EFN submitted as a PIC, and/or invalid EFN length. If PIC/EFNs pass format validation, the system will reconcile the uploaded file to manifest data to verify payment activity, physical scan activity, timely submission, and uniqueness. As a result of the system evaluation, PIC/EFNs are approved or denied. Mailers can view the status and the results by accessing the Unused Label Refund Report in the Dispute Queue in *PostalOne*!®. A refund will be issued within 20 days to the shipper's CAPS account for the approved PIC/ EFNs. As is the current practice, the refund will be 90 percent of the labels' postage value unless a different percentage is authorized.

Option 2—PIC/EFN Submission (Entry Option)

A mailer can enter up to 200 PIC/ EFNs in the online entry form in *PostalOne!*. Refer to appendix N in Postal Service Publication 205 (*https:// postalpro.usps.com/node/3724*) for guidance on using the online interface for uploading text files or using the entry box when requesting refunds for unused labels. All refund requests made through the online interface must be submitted within 60 days of the date of mailing. The system will validate if PIC/ EFNs are formatted appropriately, and

will create a dispute queue case number, accessible through both the eVS landing page and the dispute queue. If PIC/EFNs fail format validation, an error message will be displayed for any of the following reasons: invalid PIC length, duplicate EFN, commas in EFN, invalid EFN prefix, EFN submitted as a PIC, and/or invalid EFN length. If PIC/EFNs pass format validation, the system will reconcile uploaded file to manifest data to verify payment activity, physical scan activity, timely submission, and uniqueness. As a result of the system evaluation, PIC/EFNs are approved or denied. Mailers can view the status and the results by accessing the Unused Label Refund Report in the Dispute Queue in *PostalOne!*. A refund will be issued within 20 days to the shipper's CAPS account for the approved PIC/ EFNs. As is the current practice, the refund will be 90 percent of the labels' postage value unless a different percentage is authorized.

The addition of the above two automated options will provide a benefit to mailers by reducing the processing time of refund requests for unused labels while providing mailers better visibility into the status of refund cases. Once deployed, the two automated options will be the only method to submit unused label refund requests.

Maria W. Votsch,

Attorney, Corporate and Postal Business Law. [FR Doc. 2018–15826 Filed 7–24–18; 8:45 am] BILLING CODE 7710–12–P

SECURITIES AND EXCHANGE COMMISSION

[Investment Company Act Release No. 33163; 812–14889]

IndexIQ ETF Trust, et al.

July 19, 2018. AGENCY: Securities and Exchange Commission ("Commission"). ACTION: Notice.

Notice of an application for an order under section 6(c) of the Investment Company Act of 1940 (the "Act") for an exemption from sections 2(a)(32), 5(a)(1), 22(d), and 22(e) of the Act and rule 22c-1 under the Act, under sections 6(c) and 17(b) of the Act for an exemption from sections 17(a)(1) and 17(a)(2) of the Act, and under section 12(d)(1)(J) for an exemption from sections 12(d)(1)(A) and 12(d)(1)(B) of the Act. The requested order would permit (a) index-based series of certain open-end management investment companies ("Funds") to issue shares redeemable in large aggregations ("Creation Units"); (b) secondary market transactions in Fund shares to occur at negotiated market prices rather than at net asset value ("NAV"); (c) certain Funds to pay redemption proceeds, under certain circumstances, more than seven days after the tender of shares for redemption; (d) certain affiliated persons of a Fund to deposit securities into, and receive securities from, the Fund in connection with the purchase and redemption of Creation Units; (e) certain registered management investment companies and unit investment trusts outside of the same group of investment companies as the Funds ("Funds of Funds") to acquire shares of the Funds; (f) certain Funds ("Feeder Funds") to create and redeem Creation Units in-kind in a masterfeeder structure; and (g) certain Funds to issue Shares in less than Creation Unit size to investors participating in a distribution reinvestment program. The requested order would supersede the applicant's prior orders.¹

APPLICANTS: IndexIQ ETF Trust (the "Trust"), a Delware statutory trust registered under the Act as an open-end management investment company with multiple series, IndexIQ Advisors LLC (the "Adviser"), a Delaware limited liability company registered as an investment adviser under the Investment Advisers Act of 1940, and ALPS Distributors, Inc. (the "Distributor"), a Colorado corporation and broker-dealer registered under the Securities Exchange Act of 1934 ("Exchange Act").

FILING DATES: The application was filed on March 16, 2018 and amended on May 25, 2018, July 2, 2018, and July 12, 2018.

HEARING OR NOTIFICATION OF HEARING: An order granting the requested relief will be issued unless the Commission orders a hearing. Interested persons may request a hearing by writing to the Commission's Secretary and serving applicants with a copy of the request, personally or by mail. Hearing requests should be received by the Commission by 5:30 p.m. on August 13, 2018, and should be accompanied by proof of service on applicants, in the form of an affidavit, or for lawyers, a certificate of service. Pursuant to rule 0–5 under the Act, hearing requests should state the nature of the writer's interest, any facts

bearing upon the desirability of a hearing on the matter, the reason for the request, and the issues contested. Persons who wish to be notified of a hearing may request notification by writing to the Commission's Secretary.

ADDRESSES: Secretary, Securities and Exchange Commission, 100 F Street NE, Washington, DC 20549–1090; Applicants: The Trust and the Adviser, 51 Madison Avenue 4th Floor, New York, NY 10010, and the Distributor, 1290 Broadway, Suite 1100, Denver, CO 80203.

FOR FURTHER INFORMATION CONTACT: Hae-Sung Lee, Attorney-Adviser, at (202) 551–7345, or Andrea Ottomanelli Magovern, Branch Chief, at (202) 551– 6825 (Division of Investment Management, Chief Counsel's Office).

SUPPLEMENTARY INFORMATION: The following is a summary of the application. The complete application may be obtained via the Commission's website by searching for the file number, or for an applicant using the Company name box, at *http://www.sec.gov/search/search.htm* or by calling (202) 551–8090.

Summary of the Application

1. Applicants request an order that would allow Funds to operate as index exchange traded funds ("ETFs").² Fund shares will be purchased and redeemed at their NAV in Creation Units (other than pursuant to a distribution reinvestment program, as described in the application). All orders to purchase Creation Units and all redemption requests will be placed by or through an "Authorized Participant," which will have signed a participant agreement with the Distributor. Shares will be listed and traded individually on a national securities exchange, where share prices will be based on the current bid/offer market. Certain Funds may operate as Feeder Funds in a masterfeeder structure. Any order granting the requested relief would be subject to the terms and conditions stated in the application.

2. Each Fund will hold investment positions selected to correspond closely to the performance of an Underlying Index. In the case of Self-Indexing Funds, an affiliated person, as defined in section 2(a)(3) of the Act ("Affiliated Person"), or an affiliated person of an Affiliated Person ("Second-Tier Affiliate"), of the Trust or a Fund, of the Adviser, of any sub-adviser to or promoter of a Fund, or of the Distributor will compile, create, sponsor or maintain the Underlying Index.³

3. Shares will be purchased and redeemed in Creation Units and generally on an in-kind basis, or issued in less than Creation Unit size to investors participating in a distribution reinvestment program. Except where the purchase or redemption will include cash under the limited circumstances specified in the application, purchasers will be required to purchase Creation Units by depositing specified instruments ("Deposit Instruments"), and shareholders redeeming their shares will receive specified instruments ("Redemption Instruments"). The Deposit Instruments and the **Redemption Instruments will each** correspond pro rata to the positions in the Fund's portfolio (including cash positions) except as specified in the application.

4. Because shares will not be individually redeemable, applicants request an exemption from section 5(a)(1) and section 2(a)(32) of the Act that would permit the Funds to register as open-end management investment companies and issue shares that are redeemable in Creation Units.

5. Applicants also request an exemption from section 22(d) of the Act and rule 22c-1 under the Act as secondary market trading in shares will take place at negotiated prices, not at a current offering price described in a Fund's prospectus, and not at a price based on NAV. Applicants state that (a) secondary market trading in shares does not involve a Fund as a party and will not result in dilution of an investment in shares, and (b) to the extent different prices exist during a given trading day, or from day to day, such variances occur as a result of third-party market forces,

¹ IndexIQ ETF Trust, et. al., Investment Company Act Release Nos. 28638 (Feb. 27, 2009) (notice) and 28653 (Mar. 20, 2009) (order) and IndexIQ ETF Trust, et. al., Investment Company Release Nos. 30843 (Dec. 23, 2013) (notice) and 30888 (Jan. 22, 2014) (order).

² Applicants request that the order apply to the current series of the Trust identified and described in Appendix A to the application ("Current Funds") and any additional series of the Trust, and any other existing or future open-end management investment company or existing or future series thereof (together with the Current Funds, "Funds"), each of which will operate as an ETF, and their respective existing or future Master Funds, and will track a specified index comprised of domestic and/ or foreign equity securities and/or domestic and/or foreign fixed income securities (each, an "Underlying Index"). Any Fund will (a) be advised by the Adviser or an entity controlling, controlled by, or under common control with the Adviser (each such entity and any successor thereto, an "Adviser") and (b) comply with the terms and conditions of the application. For purposes of the requested order, a "successor" is limited to an entity or entities that result from a reorganization into another jurisdiction or a change in the type of business organization.

³Each Self-Indexing Fund will post on its website the identities and quantities of the investment positions that will form the basis for the Fund's calculation of its NAV at the end of the day. Applicants believe that requiring Self-Indexing Funds to maintain full portfolio transparency will help address, together with other protections, conflicts of interest with respect to such Funds.

such as supply and demand. Therefore, applicants assert that secondary market transactions in shares will not lead to discrimination or preferential treatment among purchasers. Finally, applicants represent that share market prices will be disciplined by arbitrage opportunities, which should prevent shares from trading at a material discount or premium from NAV.

6. With respect to Funds that effect creations and redemptions of Creation Units in kind and that are based on certain Underlying Indexes that include foreign securities, applicants request relief from the requirement imposed by section 22(e) in order to allow such Funds to pay redemption proceeds within fifteen calendar days following the tender of Creation Units for redemption. Applicants assert that the requested relief would not be inconsistent with the spirit and intent of section 22(e) to prevent unreasonable, undisclosed or unforeseen delays in the actual payment of redemption proceeds.

7. Applicants request an exemption to permit Funds of Funds to acquire Fund shares beyond the limits of section 12(d)(1)(A) of the Act; and the Funds, and any principal underwriter for the Funds, and/or any broker or dealer registered under the Exchange Act, to sell shares to Funds of Funds beyond the limits of section 12(d)(1)(B) of the Act. The application's terms and conditions are designed to, among other things, help prevent any potential (i) undue influence over a Fund through control or voting power, or in connection with certain services, transactions, and underwritings, (ii) excessive layering of fees, and (iii) overly complex fund structures, which are the concerns underlying the limits in sections 12(d)(1)(A) and (B) of the Act.

8. Applicants request an exemption from sections 17(a)(1) and 17(a)(2) of the Act to permit persons that are Affiliated Persons, or Second Tier Affiliates, of the Funds, solely by virtue of certain ownership interests, to effectuate purchases and redemptions in-kind. The deposit procedures for in-kind purchases of Creation Units and the redemption procedures for in-kind redemptions of Creation Units will be the same for all purchases and redemptions, and Deposit Instruments and Redemption Instruments will be valued in the same manner as those investment positions currently held by the Funds. Applicants also seek relief from the prohibitions on affiliated transactions in section 17(a) to permit a Fund to sell its shares to and redeem its shares from a Fund of Funds, and to engage in the accompanying in-kind

transactions with the Fund of Funds.⁴ The purchase of Creation Units by a Fund of Funds directly from a Fund will be accomplished in accordance with the policies of the Fund of Funds and will be based on the NAVs of the Funds.

9. Applicants also request relief to permit a Feeder Fund to acquire shares of another registered investment company managed by the Adviser having substantially the same investment objectives as the Feeder Fund ("Master Fund") beyond the limitations in section 12(d)(1)(A) and permit the Master Fund, and any principal underwriter for the Master Fund, to sell shares of the Master Fund to the Feeder Fund beyond the limitations in section 12(d)(1)(B).

10. Section 6(c) of the Act permits the Commission to exempt any persons or transactions from any provision of the Act if such exemption is necessary or appropriate in the public interest and consistent with the protection of investors and the purposes fairly intended by the policy and provisions of the Act. Section 12(d)(1)(J) of the Act provides that the Commission may exempt any person, security, or transaction, or any class or classes of persons, securities, or transactions, from any provision of section 12(d)(1) if the exemption is consistent with the public interest and the protection of investors. Section 17(b) of the Act authorizes the Commission to grant an order permitting a transaction otherwise prohibited by section 17(a) if it finds that (a) the terms of the proposed transaction are fair and reasonable and do not involve overreaching on the part of any person concerned; (b) the proposed transaction is consistent with the policies of each registered investment company involved; and (c) the proposed transaction is consistent with the general purposes of the Act.

For the Commission, by the Division of Investment Management, under delegated authority.

Eduardo A. Aleman,

Assistant Secretary. [FR Doc. 2018–15861 Filed 7–24–18; 8:45 am] BILLING CODE 8011–01–P

SECURITIES AND EXCHANGE COMMISSION

[Release No. 34–83673; File No. SR– CboeBZX–2018–051]

Self-Regulatory Organizations; Cboe BZX Exchange, Inc.; Notice of Filing and Immediate Effectiveness of a Proposed Rule Change to Exchange Rule 11.13, Order Execution and Routing, To Amend the Operation of the Super Aggressive Order Instruction

July 19, 2018.

Pursuant to Section 19(b)(1) of the Securities Exchange Act of 1934 ("Act"),¹ and Rule 19b-4 thereunder,² notice is hereby given that on July 11, 2018, Cboe BZX Exchange, Inc. (the "Exchange" or "BZX") filed with the Securities and Exchange Commission ("Commission") the proposed rule change as described in Items I and II below, which Items have been prepared by the Exchange. The Exchange has designated this proposal as a "noncontroversial" proposed rule change pursuant to Section 19(b)(3)(A) of the Act³ and Rule 19b-4(f)(6) thereunder,⁴ which renders it effective upon filing with the Commission. The Commission is publishing this notice to solicit comments on the proposed rule change from interested persons.

I. Self-Regulatory Organization's Statement of the Terms of Substance of the Proposed Rule Change

The Exchange filed a proposal to amend the operation of the Super Aggressive order instruction under paragraph (b)(4)(C) of Exchange Rule 11.13.

The text of the proposed rule change is available at the Exchange's website at *www.markets.cboe.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 Exchange included statements concerning the purpose of and basis for the proposed rule change and discussed any comments it received on the proposed rule change. The text of these statements may be examined at the places specified in Item IV below. The Exchange has prepared summaries, set forth in Sections A, B, and C below, of

⁴ The requested relief would apply to direct sales of shares in Creation Units by a Fund to a Fund of Funds and redemptions of those shares. Applicants, moreover, are not seeking relief from section 17(a) for, and the requested relief will not apply to, transactions where a Fund could be deemed an Affiliated Person, or a Second-Tier Affiliate, of a Fund of Funds because an Adviser or an entity controlling, controlled by or under common control with an Adviser provides investment advisory services to that Fund of Funds.

^{1 15} U.S.C. 78s(b)(1).

² 17 CFR 240.19b–4.

^{3 15} U.S.C. 78s(b)(3)(A).

⁴¹⁷ CFR 240.19b-4(f)(6).

the most significant parts of such statements.

A. Self-Regulatory Organization's Statement of the Purpose of, and Statutory Basis for, the Proposed Rule Change

1. Purpose

The Exchange proposes to amend the description of the Super Aggressive Re-Route instruction ("Super Aggressive instruction'') under paragraph (b)(4)(C) of Exchange Rule 11.13, Order Execution and Routing to: (i) Specify that an incoming BZX Post Only Order or Partial Post Only at Limit Order that locks a resting order with a Super Aggressive instruction must be designated as eligible for display on the Exchange (a "displayed order") for the order with a Super Aggressive instruction to engage in a liquidity swap and execute against that incoming order; and (ii) modify language from the description of the Super Aggressive instruction that states if an order that does not contain a Super Aggressive instruction maintains higher priority than one or more Super Aggressive eligible orders, the Super Aggressive eligible order(s) with lower priority will not be converted and an incoming BZX Post Only Order or Partial Post Only at Limit Order will be posted or cancelled in accordance with Exchange Rule 11.9(c)(6) or 11.9(c)(7).

Super Aggressive is an optional order instruction that directs the System ⁵ to route an order when an away Trading Center locks or crosses the limit price of the order resting on the BZX Book.⁶ When an order with a Super Aggressive instruction is locked by an incoming BZX Post Only Order or Partial Post Only at Limit Order (hereafter collectively referred to as a "Post Only Order") that does not remove liquidity pursuant to Rule 11.9(c)(6) or 11.9(c)(7), respectively,⁷ the order with a Super Aggressive instruction is converted to an executable order and will remove liquidity against such incoming order.

First, the Exchange proposes to modify the behavior of the Super Aggressive instruction to require that the incoming Post Only Order that locks a resting order with a Super Aggressive instruction must be designated as a displayed order for an execution to occur. The Super Aggressive instruction is generally utilized for best execution purposes because it enables the order to immediately attempt to access displayed liquidity on another Trading Center that is either priced equal to or better than the order with a Super Aggressive instruction's limit price. The Super Aggressive instruction also enables the order to execute against an equally priced incoming Post Only Order that would otherwise not execute by being willing to act as the liquidity remover in such a scenario. Today, the incoming Post Only Order may either be a displayed order or a non-displayed order for it to engage in a liquidity swap with an order with a Super Aggressive instruction resting on the BZX Book.

Consistent with the Super Aggressive instruction to access liquidity displayed on other Trading Centers, the Exchange proposes to amend the Super Aggressive instruction such that an order with such instruction will execute against an equally priced incoming Post Only Order only when such order is to be displayed on the BZX Book. The order with a Super Aggressive instruction would continue to act as a liquidity remover in such a scenario. Should such an equally priced incoming Post Only Order not be designated as a displayed order, the resting order with a Super Aggressive instruction would remain on the BZX Book and await an execution where it may act as a liquidity provider. The incoming Post Only Order that is also designated as a non-displayed order would be posted to the BZX Book at its limit price, creating an internally locked non-displayed book. As is the case today, an execution would continue to occur where an incoming Post Only Order is priced more aggressively than the order with a Super Aggressive instruction resting on the BZX Book, regardless of whether the incoming Post Only Order was designated as a displayed order or a non-displayed order.8

The Exchange notes that Users seeking to act as a liquidity remover once resting on the BZX Book in all cases (*i.e.*, seeking to execute against incoming Post Only orders regardless of the display instruction) may attach the Non-Displayed Swap ("NDS")

instruction to their order.9 The NDS instruction is similar to the Super Aggressive instruction, in that it also is an optional order instruction that a User may include on an order that directs the Exchange to have such order, when resting on the BZX Book, execute against an incoming Post Only Order rather than have it be locked by the incoming order. Today, because orders with either instruction (i.e., Super Aggressive and NDS) will execute against incoming Post Only Orders regardless of whether the order is to be displayed, the instructions are currently identical with two exceptions. First, an order with a Super Aggressive instruction will not convert into a liquidity removing order and execute against a Post Only Order if there is an order on the order book with priority over such order that does not also contain a Super Aggressive instruction. As further described below, the Exchange is proposing to modify this feature of the Super Aggressive instruction. The second current distinction between the two instructions, which would remain, is that an order with a Super Aggressive instruction can be displayed on the Exchange whereas an order with the NDS instruction must be non-displayed. As amended, the additional distinction between the two instructions would be whether an order would become a liquidity removing order against any Post Only Order that would lock it (i.e., NDS) or only when the Post Only Order that would lock it also is a displayed order (*i.e.*, Super Aggressive).

The below examples illustrate the proposed behavior. Assume the National Best Bid and Offer ("NBBO") is \$10.00 by \$10.10. An order to buy is displayed on the BZX Book at \$10.00 with a Super Aggressive instruction. There are no other orders resting on the BZX Book. An order to sell at \$10.00 with a Post Only that is designated as a displayed order is entered. The incoming order to sell would execute against the resting order to buy at \$10.00, the locking price, because the incoming order was designated as a displayed order. The order to buy would act as the liquidity remover and the order to sell would act as the liquidity adder. However, no execution would occur if the incoming order to sell was designated as a non-displayed order. Instead, the incoming order to sell would be posted non-displayed to the BZX Book at \$10.00, its limit price, causing the BZX Book to be internally locked.

⁵ The term "System" is defined as "the electronic communications and trading facility designated by the Board through which securities orders of Users are consolidated for ranking, execution and, when applicable, routing away." *See* Exchange Rule 1.5(aa).

⁶ See Exchange Rule 1.5(e).

⁷ A BZX Post Only Order will remove contra-side liquidity from the BZX Book if the order is an order to buy or sell a security priced below \$1.00 or if the value of such execution when removing liquidity equals or exceeds the value of such execution if the order instead posted to the BZX Book and subsequently provided liquidity, including the applicable fees charged or rebates provided. See Exchange Rule 11.9(c)(6). A Partial Post Only at Limit Order will remove liquidity from the BZX Book up to the full size of the order if, at the time of receipt, it can be executed at prices better than its limit price. See Exchange Rule 11.9(c)(7).

⁸ See id.

⁹ See Exchange Rule 11.9(c)(12).

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Second, the Exchange proposes to enable a Post Only Order that is designated as a displayed order to execute against an equally priced nondisplayed order with a Super Aggressive instruction where a non-displayed order without a Super Aggressive instruction maintains time priority over the Super Aggressive eligible order at that price. In such case, the non-displayed, non-Super Aggressive order seeks to remain a liquidity provider and would cede time priority to the order with a Super Aggressive instruction, which is willing to act as a liquidity remover to facilitate the execution. The Exchange proposes to effect this change by modifying language in the description of the Super Aggressive instruction to state that if an order displayed on the BZX Book does not contain a Super Aggressive instruction and maintains higher priority than one or more Super Aggressive eligible orders, the Super Aggressive eligible order(s) with lower priority will not be converted and the incoming Post Only Order will be posted or cancelled in accordance with Exchange Rule 11.9(c)(6) or Rule 11.9(c)(7). Thus, an order with a Super Aggressive instruction, whether displayed on the Exchange or nondisplayed, will never execute ahead of a displayed order that maintains time priority.

The Super Aggressive instruction is designed to facilitate executions that would otherwise not occur due to Post Only Order requirement to not remove liquidity. Users entering orders with the Super Aggressive instruction tend to be fee agnostic because an order with a Super Aggressive instruction is willing to route to an away Trading Center displaying an equally or better priced order (*i.e.*, pay a fee at such Trading Center). Meanwhile, an order without the Super Aggressive instruction elects to remain on the BZX Book as the liquidity provider until it may execute against an incoming order that would act as the liquidity remover. Therefore, enabling the Super Aggressive order to execute against an incoming order, regardless of whether a non-displayed order without a Super Aggressive instruction maintains priority, is consistent with the User's intent for both orders-one choses to remain the liquidity provider and forgo the execution while the other is willing to execute irrespective of whether it is the liquidity provider or remover. The Exchange notes that similar behavior occurs for orders utilizing the NDS instruction,¹⁰ which also seeks to

engage in a liquidity swap against incoming Post Only Orders. The Exchange, however, has proposed to retain the existing limitation with respect to orders displayed on the BZX Book.

The following example illustrates the operation of an order with a Super Aggressive instruction under the proposed rule change. Assume the NBBO is \$10.00 by \$10.04. There is a non-displayed Limit Order to buy resting on the BZX Book at \$10.03 ("Order A"). A second non-displayed Limit Order to buy at \$10.03 is then entered with a Super Aggressive instruction and has time priority behind the first Limit Order ("Order B"). A Post Only Order to sell priced at \$10.03 is entered. Under current behavior, the incoming sell Post Only Order would not execute against Order A and would post to the BZX Book ¹¹ because the value of such execution against the resting buy order when removing liquidity does not equal or exceed the value of such execution if the order instead posted to the BZX Book and subsequently provided liquidity, including the applicable fees charged or rebates provided. Further, the incoming sell Post Only Order could not execute against Order B because Order A is on the BZX Book and maintains time priority over Order B. Under the proposed change, the incoming sell order, if it was designated as a displayed order, would execute against Order B and Order B would become the remover of liquidity while the incoming sell Post Only Order would become the liquidity provider. In such case, Order A cedes priority to Order B because Order A did not also include a Super Aggressive instruction ¹² and thus the User that submitted the order did not indicate the preference to be treated as the remover of liquidity in favor of an execution; instead, by not using Super Aggressive, a User indicates the preference to remain posted on the BZX Book as a liquidity provider. However, if the incoming sell order was priced at \$10.02, it would receive sufficient price improvement to execute upon entry against all resting buy Limit Orders in time priority at \$10.03.13 Also, if Order

A was displayed on the BZX Book, no execution would occur, as the proposed change would only apply to nondisplayed liquidity.

2. Statutory Basis

The Exchange believes that its proposal is consistent with Section 6(b) of the Act ¹⁴ in general, and furthers the objectives of Section 6(b)(5) of the Act ¹⁵ in particular, in that it is designed 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.

The proposed changes to the Super Aggressive order instruction are designed 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. The Super Aggressive instruction is an optional feature that is intended to reflect the order management practices of various market participants. The proposal to limit the execution of an order with a Super Aggressive instruction to execute against incoming Post Only Orders that also are designated as displayed orders promotes just and equitable principles of trade because it enables Users to elect an order instruction consistent with their intent to execute only against displayed orders, in part, for best execution purposes. The amended Super Aggressive instruction would ensure executions at the best available price displayed on another Trading Center or against an incoming order that would have been displayed on the BZX Book. Users seeking to act as a liquidity remover once resting on the BZX Book and execute against an incoming Post Only Order that is also designated as a non-displayed order may attach the NDS instruction to their order.¹⁶

The proposed change to the Super Aggressive instruction also removes impediments to and perfects the mechanism of a free and open market and a national market system because it

- 14 15 U.S.C. 78f(b).
- 15 15 U.S.C. 78f(b)(5).
- ¹⁶ See Exchange Rule 11.9(c)(12).

¹⁰ See Exchange Rule 11.9(c)(12). See also Securities Exchange Act Release No. 83537 (June

^{28, 2018), (}SR–CboeBZX–2018–042) (including an example where an order cedes execution priority to an order with an NDS instruction).

 $^{^{11}}$ Such order would be posted to the BZX Book in accordance with the Exchange's re-pricing instructions to comply with Rule 610(d) of Regulation NMS. See Exchange Rules 11.9(g)(1) and (g)(2). See also 242 CFR 242.610(d).

¹² This behavior is consistent with the operation of the Exchange's NDS instruction. *See supra* note 10.

¹³ The execution occurs here because the value of the execution against the buy order when removing

liquidity exceeds the value of such execution if the order instead posted to the BZX Book and subsequently provided liquidity, including the applicable fees charged or rebates provided. *See supra* note 7.

is designed to facilitate executions that would otherwise not occur due to the Post Only Order requirement to not remove liquidity. The proposal enables non-displayed Super Aggressive orders to execute against an incoming order, regardless of whether another nondisplayed order without a Super Aggressive instruction maintains priority consistent with the User's intent for both orders-one chooses to remain the liquidity provider and forgo the execution while the other is willing to execute irrespective of whether it is the liquidity provider or remover. The non-Super Aggressive order seeks to remain a liquidity provider and cede its time priority to the order with a Super Aggressive instruction, which is willing to act as a liquidity remover to facilitate the execution. It also enables an order without the Super Aggressive instruction to remain on the BZX Book as a liquidity provider, consistent with the expected operation of their resting order. The Exchange notes that similar behavior occurs for orders utilizing the NDS 17 instruction, which also seeks to engage in a liquidity swap against incoming Post Only Orders. Finally, by limiting the proposed change to nondisplayed orders, the proposal remains consistent with NDS and also retains existing functionality with respect to the handling of displayed orders.

For the reasons set forth above, the Exchange believes the proposal removes impediments to and perfects the mechanism of a free and open market and a national market system, and, in general, protects investors and the public interest.

B. Self-Regulatory Organization's Statement on Burden on Competition

The Exchange does not believe that the proposed rule change will result in any burden on competition that is not necessary or appropriate in furtherance of the purposes of the Act. as amended. On the contrary, the proposed changes to the Super Aggressive order instruction are intended to improve the usefulness of the instruction and to align its operation with the intention of the User, resulting in enhanced competition through increased usage and execution quality on the Exchange. Thus, to the extent the change is intended to improve functionality on the Exchange to encourage Users to direct their orders to the Exchange, the change is competitive, but the Exchange does not believe the proposed change will result in any burden on intermarket competition as it is a minor change to available functionality. The proposed

changes to the Super Aggressive order instruction also promote intramarket competition because they will facilitate the execution of orders that would otherwise remain unexecuted consistent with the intent of the User entering the order, thereby increasing the efficient functioning of the Exchange. Further, the Super Aggressive order instruction will remain available to all Users in the same way it is today. Thus, Users can continue to choose between various optional order instructions, including Super Aggressive, NDS, and others, depending on the order handling they prefer the Exchange to utilize. Therefore, the Exchange does not believe the proposed rule change will result in any burden on intramarket competition that is not necessary or appropriate in furtherance of the purposes of the Act.

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 written comments on the proposed rule change.

III. Date of Effectiveness of the Proposed Rule Change and Timing for Commission Action

Because the foregoing 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 for 30 days from the date on which it was filed, or such shorter time as the Commission may designate, it has become effective pursuant to Section 19(b)(3)(A)(iii) of the Act ¹⁸ and subparagraph (f)(6) of Rule 19b–4 thereunder.¹⁹

A proposed rule change filed under Rule 19b–4(f)(6) normally does not become operative for 30 days after the date of the filing. However, Rule 19b– $4(f)(6)(iii)^{20}$ permits the Commission to designate a shorter time if such action is consistent with the protection of investors and the public interest. In its filing, BZX requested that the Commission waive the 30-day operative delay so that the Exchange can implement the proposed rule change promptly after filing. The Exchange stated that the proposal to allow an

order with a Super Aggressive instruction to execute against an incoming Post Only order only if the Post Only order is displayable is consistent with the use of the Super Aggressive instruction to access liquidity displayed on other Trading Centers. Further, according to the Exchange, users seeking to execute against incoming non-displayable Post Only orders will continue to be able to attach the NDS order instruction, as well as other order instructions that may permit such executions. In addition, the Exchange stated that the proposed priority change where non-displayed orders without a Super Aggressive instruction would cede priority to nondisplayed orders with a Super Aggressive instruction is similar to, and consistent with, the Exchange's priority ceding functionality for orders with an NDS instruction and would facilitate executions that would otherwise not occur due to an incoming Post Only order's requirement not to remove liquidity. The Commission believes that waiver of the 30-day operative delay is consistent with the protection of investors and the public interest, as the proposed rule change relates to optional functionality that is consistent with existing functionality and, if selected by Exchange users, may enable them to better manage their orders and may increase order interaction on the Exchange. Accordingly, the Commission hereby waives the 30-day operative delay and designates the proposed rule change operative upon filing.²¹

At any time within 60 days of the filing of the proposed rule change, the Commission summarily may temporarily suspend such rule change if it appears to the Commission that such action is: (i) Necessary or appropriate in the public interest; (ii) for the protection of investors; or (iii) otherwise in furtherance of the purposes of the Act. If the Commission takes such action, the Commission shall institute proceedings to determine whether the proposed rule should be approved or disapproved.

IV. Solicitation of Comments

Interested persons are invited to submit written data, views, and arguments concerning the foregoing, including whether the proposed rule change is consistent with the Act. Comments may be submitted by any of the following methods:

¹⁸15 U.S.C. 78s(b)(3)(A)(iii).

 $^{^{19}}$ 17 CFR 240.19b–4(f)(6). In addition, Rule 19b– 4(f)(6) 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 Exchange has satisfied this requirement.

²⁰ 17 CFR 240.19b-4(f)(6)(iii).

²¹For purposes only of waiving the 30-day operative delay, the Commission has also considered the proposed rule's impact on efficiency, competition, and capital formation. *See* 15 U.S.C. 78c(f).

¹⁷ See supra note 10.

Electronic Comments

• Use the Commission's internet comment form (*http://www.sec.gov/rules/sro.shtml*); or

• Send an email to *rule-comments*@ *sec.gov.* Please include File Number SR– CboeBZX–2018–051 on the subject line.

Paper Comments

• Send paper comments in triplicate to Secretary, Securities and Exchange Commission, 100 F Street NE, Washington, DC 20549–1090.

All submissions should refer to File Number SR–CboeBZX–2018–051. This file number should be included on the subject line if email is used. To help the Commission process and review your comments more efficiently, please use only one method. The Commission will post all comments on the Commission's internet website (http://www.sec.gov/ rules/sro.shtml). Copies of the submission, all subsequent amendments, all written statements with respect to the proposed rule change that are filed with the Commission, and all written communications relating to the proposed rule change between the Commission and any person, other than those that may be withheld from the public in accordance with the provisions of 5 U.S.C. 552, will be available for website viewing and printing in the Commission's Public Reference Room, 100 F Street NE, Washington, DC 20549, on official business days between the hours of 10:00 a.m. and 3:00 p.m. Copies of the filing also will be available for inspection and copying at the principal office of the Exchange. All comments received will be posted without change. Persons submitting comments are cautioned that we do not redact or edit personal identifying information from comment submissions. You should submit only information that you wish to make available publicly. All submissions should refer to File Number SR-CboeBZX-2018-051, and should be submitted on or before August 15, 2018.

For the Commission, by the Division of Trading and Markets, pursuant to delegated authority.²²

Eduardo A. Aleman,

Assistant Secretary. [FR Doc. 2018–15848 Filed 7–24–18; 8:45 am]

BILLING CODE 8011-01-P

SECURITIES AND EXCHANGE COMMISSION

Proposed Collection; Comment Request

Upon Written Request, Copies Available From: Securities and Exchange Commission, Office of FOIA Services, 100 F Street NE, Washington, DC 20549–2736

Extension:

Form N–8B–2, SEC File No. 270–186, OMB Control No. 3235–0186

Notice is hereby given that, pursuant to the Paperwork Reduction Act of 1995 (44 U.S.C. 3501 *et seq.*), the Securities and Exchange Commission (the "Commission") is soliciting comments on the collection of information summarized below. The Commission plans to submit this existing collection of information to the Office of Management and Budget for extension and approval.

Form N-8B-2 (17 CFR 274.12) is the form used by unit investment trusts ("UITs") other than separate accounts that are currently issuing securities, including UITs that are issuers of periodic payment plan certificates and UITs of which a management investment company is the sponsor or depositor, to comply with the filing and disclosure requirements imposed by section 8(b) of the Investment Company Act of 1940 (15 U.S.C. 80a-8(b)). Form N-8B-2 requires disclosure about the organization of a UIT, its securities, the personnel and affiliated persons of the depositor, the distribution and redemption of securities, the trustee or custodian, and financial statements. The Commission uses the information provided in the collection of information to determine compliance with section 8(b) of the Investment Company Act.

Each registrant subject to the Form N– 8B–2 filing requirement files Form N– 8B–2 for its initial filing and does not file post-effective amendments on Form N–8B–2.¹ The Commission staff estimates that approximately one respondent files one Form N–8B–2 filing annually with the Commission.² Staff estimates that the burden for compliance with Form N–8B–2 is approximately 10 hours per filing. The total hour burden for the Form N–8B– 2 filing requirement therefore is 10 hours in the aggregate (1 respondent \times one filing per respondent \times 10 hours per filing).

Estimates of the burden hours are made solely for the purposes of the PRA and are not derived from a comprehensive or even a representative survey or study of the costs of SEC rules and forms. The information provided on Form N–8B–2 is mandatory. The information provided on Form N–8B–2 will not be kept confidential. 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.

Written comments are invited on: (a) Whether the proposed collection of information is necessary for the proper performance of the functions of the agency, including whether the information will have practical utility; (b) the accuracy of the agency's estimate of the burden of the collection of information; (c) ways to enhance the quality, utility, and clarity of the information collected; and (d) ways to minimize the burden of the collection of information on respondents, including through the use of automated collection techniques or other forms of information technology. Consideration will be given to comments and suggestions submitted in writing within 60 days of this publication.

Please direct your written comments to Pamela Dyson, Director/Chief Information Officer, Securities and Exchange Commission, c/o Candace Kenner, 100 F Street NE, Washington, DC 20549; or send an email to: *PRA_Mailbox@sec.gov.*

Dated: July 19, 2018.

Eduardo A. Aleman,

Assistant Secretary.

[FR Doc. 2018–15857 Filed 7–24–18; 8:45 am] BILLING CODE 8011–01–P

SECURITIES AND EXCHANGE COMMISSION

Submission for OMB Review; Comment Request

Upon Written Request, Copies Available From: Securities and Exchange Commission, Office of FOIA Services, 100 F Street NE, Washington, DC 20549–2736

Extension:

Rule 24b–1; SEC File No. 270–205; OMB Control No. 3235–0194

Notice is hereby given that pursuant to the Paperwork Reduction Act of 1995 (44 U.S.C. 3501 *et seq.*), the Securities

²² 17 CFR 200.30–3(a)(12) and (59).

 $^{^1}$ Post-effective amendments are filed with the Commission on the UIT's Form S–6. Hence, respondents only file Form N–8B–2 for their initial registration statement and not for post-effective amendments.

² In 2015 the Commission received 3 filings, while in 2016 and 2017, the Commission received 0 filings, respectively. The cumulative 3-year average is, therefore, 1 filing per year.

and Exchange Commission ("Commission") has submitted to the Office of Management and Budget ("OMB") a request for approval of extension of the existing collection of information provided for in the following rule: Rule 24b–1 (17 CFR 240.24b–1).

Rule 24b–1 under the Securities Exchange Act of 1934 (15 U.S.C. 78a *et seq.*) requires a national securities exchange to keep and make available for public inspection a copy of its registration statement and exhibits filed with the Commission, along with any amendments thereto.

There are 21 national securities exchanges that spend approximately one half hour each complying with this rule, for an aggregate total compliance burden of 10.5 hours per year. The staff estimates that the average cost per respondent is \$65.18 per year, calculated as the costs of copying (\$13.97) plus storage (\$51.21), resulting in a total cost of compliance for the respondents of \$1,368.78

An agency may not conduct or sponsor, and a person is not required to respond to, a collection of information under the PRA unless it displays a currently valid OMB control number.

The public may view background documentation for this information collection at the following website: www.reginfo.gov. Comments should be directed to: (i) Desk Officer for the Securities and Exchange Commission, Office of Information and Regulatory Affairs, Office of Management and Budget, Room 10102, New Executive Office Building, Washington, DC 20503, or by sending an email to: Shagufta Ahmed@omb.eop.gov; and (ii) Pamela Dyson, Director/Chief Information Officer, Securities and Exchange Commission, c/o Candace Kenner, 100 F Street NE, Washington, DC 20549, or by sending an email to: PRA Mailbox@ sec.gov. Comments must be submitted to OMB within 30 days of this notice.

Dated: July 19, 2018.

Eduardo A. Aleman,

Assistant Secretary.

[FR Doc. 2018–15852 Filed 7–24–18; 8:45 am] BILLING CODE 8011–01–P

SECURITIES AND EXCHANGE COMMISSION

Proposed Collection; Comment Request

Upon Written Request, Copies Available From: Securities and Exchange Commission, Office of FOIA Services, 100 F Street NE, Washington, DC 20549–2736 Extension:

Rule 17f–1(b), SEC File No. 270–028, OMB Control No. 3235–0032

Notice is hereby given that pursuant to the Paperwork Reduction Act of 1995 ("PRA") (44 U.S.C. 3501 *et seq.*), the Securities and Exchange Commission ("Commission") is soliciting comments on the existing collection of information provided for in Rule 17f–1(b) (17 CFR 240.17f–1(b)), under the Securities Exchange Act of 1934 (15 U.S.C. 78a *et seq.*). The Commission plans to submit this existing collection of information to the Office of Management and Budget ("OMB") for extension and approval.

Under Rule 17f–1(b) under the Exchange Act, approximately 10,000 entities in the securities industry are registered in the Lost and Stolen Securities Program ("Program"). Registration fulfills a statutory requirement that entities report and inquire about missing, lost, counterfeit, or stolen securities. Registration also allows entities in the securities industry to gain access to a confidential database that stores information for the Program.

The Commission staff estimates that 10 new entities will register in the Program each year. The staff estimates that the average number of hours necessary to comply with Rule 17f-1(b) is one-half hour. Accordingly, the staff estimates that total annual burden for all participants is 5 hours $(10 \times \text{one-half})$ hour). The Commission staff estimates that compliance staff work at subject entities results in an internal cost of compliance, at an estimated hourly wage of \$283, of \$141.50 per year per entity (.5 hours \times \$283 per hour = \$141.50 per year). Therefore, the aggregate annual internal cost of compliance is approximately \$1,415 $(\$141.50 \times 10 = \$1,415).$

Written comments are invited on: (a) 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; (b) the accuracy of the Commission's estimates of the burden of the proposed collection of information; (c) ways to enhance the quality, utility, and clarity of the information collected; and (d) ways to minimize the burden of the collection of information on respondents, including through the use of automated collection techniques or other forms of information technology. Consideration will be given to comments and suggestions submitted in writing within 60 days of this publication.

An agency may not conduct or sponsor, and a person is not required to respond to, a collection of information under the PRA unless it displays a currently valid OMB control number.

Please direct your written comments to: Pamela Dyson, Director/Chief Information Officer, Securities and Exchange Commission, c/o Candace Kenner, 100 F Street NE, Washington, DC 20549, or send an email to: *PRA_Mailbox@sec.gov.*

Dated: July 19, 2018.

Eduardo A. Aleman,

Assistant Secretary.

[FR Doc. 2018–15854 Filed 7–24–18; 8:45 am] BILLING CODE 8011–01–P

SECURITIES AND EXCHANGE COMMISSION

[Release No. 34–83674; File No. SR– CboeEDGX–2018–025]

Self-Regulatory Organizations; Cboe EDGX Exchange, Inc.; Notice of Filing and Immediate Effectiveness of a Proposed Rule Change to Exchange Rule 11.6, Definitions, To Amend the Operation of the Super Aggressive Order Instruction

July 19, 2018.

Pursuant to Section 19(b)(1) of the Securities Exchange Act of 1934 ("Act"),¹ and Rule 19b-4 thereunder,² notice is hereby given that on July 11, 2018, Cboe EDGX Exchange, Inc. (the "Exchange" or "EDGX") filed with the Securities and Exchange Commission ("Commission") the proposed rule change as described in Items I and II below, which Items have been prepared by the Exchange. The Exchange has designated this proposal as a "noncontroversial" proposed rule change pursuant to Section 19(b)(3)(A) of the Act³ and Rule 19b-4(f)(6) thereunder,⁴ which renders it effective upon filing with the Commission. The Commission is publishing this notice to solicit comments on the proposed rule change from interested persons.

I. Self-Regulatory Organization's Statement of the Terms of Substance of the Proposed Rule Change

The Exchange filed a proposal to amend the operation of the Super Aggressive order instruction under paragraph (n)(2) of Exchange Rule 11.6.

The text of the proposed rule change is available at the Exchange's website at *www.markets.cboe.com*, at the principal office of the Exchange, and at the Commission's Public Reference Room.

¹15 U.S.C. 78s(b)(1).

² 17 CFR 240.19b-4.

³15 U.S.C. 78s(b)(3)(A).

⁴¹⁷ CFR 240.19b-4(f)(6).

II. Self-Regulatory Organization's Statement of the Purpose of, and Statutory Basis for, the Proposed Rule Change

In its filing with the Commission, the Exchange included statements concerning the purpose of and basis for the proposed rule change and discussed any comments it received on the proposed rule change. The text of these statements may be examined at the places specified in Item IV below. The Exchange has prepared summaries, set forth in Sections A, B, and C below, of the most significant parts of such statements.

A. Self-Regulatory Organization's Statement of the Purpose of, and Statutory Basis for, the Proposed Rule Change

1. Purpose

The Exchange proposes to amend the description of the Super Aggressive instruction under paragraph (n)(2) of Exchange Rule 11.6, Routing/Posting Instructions to: (i) Specify that an incoming order with a Post Only instruction that locks a resting order with a Super Aggressive instruction must include a Displayed instruction for the order with a Super Aggressive instruction to engage in a liquidity swap and execute against that incoming order; and (ii) modify language from the description of the Super Aggressive instruction that states if an order that does not contain a Super Aggressive instruction maintains higher priority than one or more Super Aggressive eligible orders, the Super Aggressive eligible order(s) with lower priority will not be converted and the incoming order with a Post Only instruction will be posted or cancelled in accordance with Exchange Rule 11.6(n)(4).⁵

Super Aggressive is an optional order instruction that directs the System ⁶ to route an order when an away Trading Center locks or crosses the limit price of the order resting on the EDGX Book.⁷ When an order with a Super Aggressive instruction is locked by an incoming order with a Post Only instruction that does not remove liquidity pursuant to Rule 11.6(n)(4),⁸ the order with a Super Aggressive instruction is converted to an executable order and will remove liquidity against such incoming order.

First, the Exchange proposes to modify the behavior of the Super Aggressive instruction to require that the incoming order with a Post Only instruction that locks a resting order with a Super Aggressive instruction must include a Displayed instruction for an execution to occur. The Super Aggressive instruction is generally utilized for best execution purposes because it enables the order to immediately attempt to access displayed liquidity on another Trading Center that is either priced equal to or better than the order with a Super Aggressive instruction's limit price. The Super Aggressive instruction also enables the order to execute against an equally priced incoming order with a Post Only instruction that would otherwise not execute by being willing to act as the liquidity remover in such a scenario. Today, the incoming order with a Post Only instruction may include either a Displayed or Non-Displayed instruction for it to engage in a liquidity swap with an order with a Super Aggressive instruction resting on the EDGX Book.

Consistent with the Super Aggressive instruction to access liquidity displayed on other Trading Centers, the Exchange proposes to amend the Super Aggressive instruction such that an order with such instruction will execute against an equally priced incoming order with a Post Only instruction only when such order is to be displayed on the EDGX Book. The order with a Super Aggressive instruction would continue to act as a liquidity remover in such a scenario. Should such an equally priced incoming order with a Post Only instruction not include a Displayed instruction, the resting order with a Super Aggressive instruction would remain on the EDGX Book and await an execution where it may act as a liquidity provider. The incoming order with a Post Only instruction and a Non-Displayed instruction would be posted to the EDGX Book at its limit price, creating an internally locked nondisplayed book. As is the case today, an execution would continue to occur where an incoming order with a Post Only instruction is priced more aggressively than the order with a Super

Aggressive instruction resting on the EDGX Book, regardless of whether the incoming order included a Displayed or Non-Displayed instruction.⁹

The Exchange notes that Users seeking to act as a liquidity remover once resting on the EDGX Book in all cases (i.e., seeking to execute against incoming Post Only orders regardless of the display instruction) may attach the Non-Displayed Swap ("NDS") instruction to their order.¹⁰ The NDS instruction is similar to the Super Aggressive instruction, in that it also is an optional order instruction that a User may include on an order that directs the Exchange to have such order, when resting on the EDGX Book, execute against an incoming order with a Post Only instruction rather than have it be locked by the incoming order. Today, because orders with either instruction (*i.e.*, Super Aggressive and NDS) will execute against incoming orders with a Post Only instruction regardless of whether the order is to be displayed, the instructions are currently identical with two exceptions. First, an order with a Super Aggressive instruction will not convert into a liquidity removing order and execute against an order with a Post Only instruction if there is an order on the order book with priority over such order that does not also contain a Super Aggressive instruction. As further described below, the Exchange is proposing to modify this feature of the Super Aggressive instruction. The second current distinction between the two instructions, which would remain, is that an order with a Super Aggressive instruction can be displayed on the Exchange whereas an order with the NDS instruction must be non-displayed. As amended, the additional distinction between the two instructions would be whether an order would become a liquidity removing order against any order with a Post Only instruction that would lock it (*i.e.*, NDS) or only when the order with a Post Only instruction that would lock it also contains a Displayed instruction (i.e., Super Aggressive).

The below examples illustrate the proposed behavior. Assume the National Best Bid and Offer ("NBBO") is \$10.00 by \$10.10. An order to buy is displayed on the EDGX Book at \$10.00 with a Super Aggressive instruction. There are no other orders resting on the EDGX Book. An order to sell at \$10.00 with a Post Only and Displayed instruction is entered. The incoming order to sell would execute against the resting order to buy at \$10.00, the

⁵ The Exchange also proposes to remove the extraneous word "solely" from the second sentence of Rule 11.6(n)(2). The removal of this word does not alter the operation of the Super Aggressive order instruction.

⁶ The term "System" is defined as "the electronic communications and trading facility designated by the Board through which securities orders of Users are consolidated for ranking, execution and, when applicable, routing away." *See* Exchange Rule 1.5(cc).

⁷ See Exchange Rule 1.5(d).

⁸ The Exchange will execute an order with a Post Only instruction priced at or above \$1.00 in certain circumstances where the value of such execution when removing liquidity equals or exceeds the value of such execution if the order instead posted to the EDGX Book and subsequently provided liquidity, including the applicable fees charged or rebates provided. *See* Exchange Rule 11.6(n)(4).

⁹ See id.

¹⁰ See Exchange Rule 11.6(n)(7).

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locking price, because the incoming order included a Displayed instruction. The order to buy would act as the liquidity remover and the order to sell would act as the liquidity adder. However, no execution would occur if the incoming order to sell included a Non-Displayed instruction. Instead, the incoming order to sell would be posted non-displayed to the EDGX Book at \$10.00, its limit price, causing the EDGX Book to be internally locked.

Second, the Exchange proposes to enable an incoming order with a Post Only instruction and Displayed instruction to execute against an equally priced non-displayed order with a Super Aggressive instruction where a non-displayed order without a Super Aggressive instruction maintains time priority over the Super Aggressive eligible order at that price. In such case, the non-displayed, non-Super Aggressive order seeks to remain a liquidity provider and would cede time priority to the order with a Super Aggressive instruction, which is willing to act as a liquidity remover to facilitate the execution. The Exchange proposes to effect this change by modifying language in the description of the Super Aggressive instruction to state that if an order displayed on the EDGX Book does not contain a Super Aggressive instruction and maintains higher priority than one or more Super Aggressive eligible orders, the Super Aggressive eligible order(s) with lower priority will not be converted and the incoming order with a Post Only instruction will be posted or cancelled in accordance with Exchange Rule 11.6(n)(4). Thus, an order with a Super Aggressive instruction, whether displayed on the Exchange or nondisplayed, will never execute ahead of a displayed order that maintains time priority.

The Super Aggressive instruction is designed to facilitate executions that would otherwise not occur due to the Post Only instruction requirement to not remove liquidity. Users entering orders with the Super Aggressive instruction tend to be fee agnostic because an order with a Super Aggressive instruction is willing to route to an away Trading Center displaying an equally or better priced order (i.e., pay a fee at such Trading Center). Meanwhile, an order without the Super Aggressive instruction elects to remain on the EDGX Book as the liquidity provider until it may execute against an incoming order that would act as the liquidity remover. Therefore, enabling the Super Aggressive order to execute against an incoming order, regardless of whether a non-displayed order without a Super

Aggressive instruction maintains priority, is consistent with the User's intent for both orders-one choses to remain the liquidity provider and forgo the execution while the other is willing to execute irrespective of whether it is the liquidity provider or remover. The Exchange notes that similar behavior occurs for orders utilizing the NDS instruction,¹¹ which also seeks to engage in a liquidity swap against incoming orders with a Post Only instruction. The Exchange, however, has proposed to retain the existing limitation with respect to orders displayed on the EDGX Book.

The following example illustrates the operation of an order with a Super Aggressive instruction under the proposed rule change. Assume the NBBO is \$10.00 by \$10.04. There is a non-displayed Limit Order to buy resting on the EDGX Book at \$10.03 ("Order A"). A second non-displayed Limit Order to buy at \$10.03 is then entered with a Super Aggressive instruction and has time priority behind the first Limit Order ("Order B"). An order to sell with a Post Only instruction priced at \$10.03 is entered. Under current behavior, the incoming sell order with a Post Only instruction would not execute against Order A and would post to the EDGX Book ¹² because the value of such execution against the resting buy order when removing liquidity does not equal or exceed the value of such execution if the order instead posted to the EDGX Book and subsequently provided liquidity, including the applicable fees charged or rebates provided. Further, the incoming sell order with a Post Only instruction could not execute against Order B because Order A is on the EDGX Book and maintains time priority over Order B. Under the proposed change, the incoming sell order, if it contained a Displayed instruction, would execute against Order B and Order B would become the remover of liquidity while the incoming sell order with a Post Only instruction would become the liquidity provider. In such case, Order A cedes priority to Order B because Order A did not also include a Super Aggressive

instruction 13 and thus the User that submitted the order did not indicate the preference to be treated as the remover of liquidity in favor of an execution; instead, by not using Super Aggressive, a User indicates the preference to remain posted on the EDGX Book as a liquidity provider. However, if the incoming sell order was priced at \$10.02, it would receive sufficient price improvement to execute upon entry against all resting buy Limit Orders in time priority at \$10.03.¹⁴ Also, if Order A was displayed on the EDGX Book, no execution would occur, as the proposed change would only apply to nondisplayed liquidity.

2. Statutory Basis

The Exchange believes that its proposal is consistent with Section 6(b) of the Act ¹⁵ in general, and furthers the objectives of Section 6(b)(5) of the Act ¹⁶ in particular, in that it is designed 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.

The proposed changes to the Super Aggressive order instruction are designed 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. The Super Aggressive instruction is an optional feature that is intended to reflect the order management practices of various market participants. The proposal to limit the execution of an order with a Super Aggressive instruction to execute against incoming orders with a Post Only instruction that also contain a Displayed instruction promotes just and equitable principles of trade because it enables Users to elect an order instruction consistent with their intent to execute only against displayed orders, in part, for best execution

¹¹ See Exchange Rule 11.6(n)(7). See also Securities Exchange Act Release No. 80841 (June 1, 2017), 82 FR 26559 (June 7, 2017) (SR–BatsEDGX– 2017–25) (including an example where an order cedes execution priority to an order with an NDS instruction).

 $^{^{12}}$ Such order would be posted to the EDGX Book in accordance with the Exchange's re-pricing instructions to comply with Rule 610(d) of Regulation NMS. See Exchange Rule 11.6(l)(1). See also 242 CFR 242.610(d).

¹³ This behavior is consistent with the operation of the Exchange's NDS instruction. *See supra* note 11.

¹⁴ The execution occurs here because the value of the execution against the buy order when removing liquidity exceeds the value of such execution if the order instead posted to the EDGX Book and subsequently provided liquidity, including the applicable fees charged or rebates provided. *See supra* note 8.

¹⁵ 15 U.S.C. 78f(b).

^{16 15} U.S.C. 78f(b)(5).

purposes. The amended Super Aggressive instruction would ensure executions at the best available price displayed on another Trading Center or against an incoming order that would have been displayed on the EDGX Book. Users seeking to act as a liquidity remover once resting on the EDGX Book and execute against an incoming order with a Post Only and Non-Displayed instruction may attach the NDS instruction to their order.¹⁷

The proposed change to the Super Aggressive instruction also removes impediments to and perfects the mechanism of a free and open market and a national market system because it is designed to facilitate executions that would otherwise not occur due to the Post Only instruction requirement to not remove liquidity. The proposal enables non-displayed Super Aggressive orders to execute against an incoming order, regardless of whether another nondisplayed order without a Super Aggressive instruction maintains priority consistent with the User's intent for both orders—one chooses to remain the liquidity provider and forgo the execution while the other is willing to execute irrespective of whether it is the liquidity provider or remover. The non-Super Aggressive order seeks to remain a liquidity provider and cede its time priority to the order with a Super Aggressive instruction, which is willing to act as a liquidity remover to facilitate the execution. It also enables an order without the Super Aggressive instruction to remain on the EDGX Book as a liquidity provider, consistent with the expected operation of their resting order. The Exchange notes that similar behavior occurs for orders utilizing the NDS¹⁸ instruction, which also seeks to engage in a liquidity swap against incoming orders with a Post Only instruction. Finally, by limiting the proposed change to non-displayed orders, the proposal remains consistent with NDS and also retains existing functionality with respect to the handling of displayed orders.

For the reasons set forth above, the Exchange believes the proposal removes impediments to and perfects the mechanism of a free and open market and a national market system, and, in general, protects investors and the public interest.

B. Self-Regulatory Organization's Statement on Burden on Competition

The Exchange does not believe that the proposed rule change will result in any burden on competition that is not

necessary or appropriate in furtherance of the purposes of the Act, as amended. On the contrary, the proposed changes to the Super Aggressive order instruction are intended to improve the usefulness of the instruction and to align its operation with the intention of the User, resulting in enhanced competition through increased usage and execution quality on the Exchange. Thus, to the extent the change is intended to improve functionality on the Exchange to encourage Users to direct their orders to the Exchange, the change is competitive, but the Exchange does not believe the proposed change will result in any burden on intermarket competition as it is a minor change to available functionality. The proposed changes to the Super Aggressive order instruction also promote intramarket competition because they will facilitate the execution of orders that would otherwise remain unexecuted consistent with the intent of the User entering the order, thereby increasing the efficient functioning of the Exchange. Further, the Super Aggressive order instruction will remain available to all Users in the same way it is today. Thus, Users can continue to choose between various optional order instructions, including Super Aggressive, NDS, and others, depending on the order handling they prefer the Exchange to utilize. Therefore, the Exchange does not believe the proposed rule change will result in any burden on intramarket competition that is not necessary or appropriate in furtherance of the purposes of the Act.

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 written comments on the proposed rule change.

III. Date of Effectiveness of the Proposed Rule Change and Timing for Commission Action

Because the foregoing 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 for 30 days from the date on which it was filed, or such shorter time as the Commission may designate, it has become effective pursuant to Section 19(b)(3)(A)(iii) of the Act ¹⁹ and subparagraph (f)(6) of Rule 19b–4 thereunder.²⁰

 20 17 CFR 240.19b–4(f)(6). In addition, Rule 19b–4(f)(6) requires a self-regulatory organization to give

A proposed rule change filed under Rule 19b-4(f)(6) normally does not become operative for 30 days after the date of the filing. However, Rule 19b-4(f)(6)(iii)²¹ permits the Commission to designate a shorter time if such action is consistent with the protection of investors and the public interest. In its filing, EDGX requested that the Commission waive the 30-day operative delay so that the Exchange can implement the proposed rule change promptly after filing. The Exchange stated that the proposal to allow an order with a Super Aggressive instruction to execute against an incoming Post Only order only if the Post Only order is displayable is consistent with the use of the Super Aggressive instruction to access liquidity displayed on other Trading Centers. Further, according to the Exchange, users seeking to execute against incoming non-displayable Post Only orders will continue to be able to attach the NDS order instruction, as well as other order instructions that may permit such executions. In addition, the Exchange stated that the proposed priority change where non-displayed orders without a Super Aggressive instruction would cede priority to nondisplayed orders with a Super Aggressive instruction is similar to, and consistent with, the Exchange's priority ceding functionality for orders with an NDS instruction and would facilitate executions that would otherwise not occur due to an incoming Post Only order's requirement not to remove liquidity. The Commission believes that waiver of the 30-day operative delay is consistent with the protection of investors and the public interest, as the proposed rule change relates to optional functionality that is consistent with existing functionality and, if selected by Exchange users, may enable them to better manage their orders and may increase order interaction on the Exchange. Accordingly, the Commission hereby waives the 30-day operative delay and designates the proposed rule change operative upon filing.²²

At any time within 60 days of the filing of the proposed rule change, the Commission summarily may temporarily suspend such rule change if

¹⁷ See Exchange Rule 11.6(n)(7).

¹⁸ See supra note 11.

¹⁹15 U.S.C. 78s(b)(3)(A)(iii).

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 Exchange has satisfied this requirement.

^{21 17} CFR 240.19b-4(f)(6)(iii).

²² For purposes only of waiving the 30-day operative delay, the Commission has also considered the proposed rule's impact on efficiency, competition, and capital formation. *See* 15 U.S.C. 78c(f).

it appears to the Commission that such action is: (i) Necessary or appropriate in the public interest; (ii) for the protection of investors; or (iii) otherwise in furtherance of the purposes of the Act. If the Commission takes such action, the Commission shall institute proceedings to determine whether the proposed rule should be approved or disapproved.

IV. Solicitation of Comments

Interested persons are invited to submit written data, views, and arguments concerning the foregoing, including whether the proposed rule change is consistent with the Act. Comments may be submitted by any of the following methods:

Electronic Comments

• Use the Commission's internet comment form (*http://www.sec.gov/ rules/sro.shtml*); or

• Send an email to *rule-comments*@ *sec.gov.* Please include File Number SR– CboeEDGX–2018–025 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-CboeEDGX-2018-025. 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–CboeEDGX–2018–025, and should be submitted on or before August 15, 2018.

For the Commission, by the Division of Trading and Markets, pursuant to delegated authority.²³

Eduardo A. Aleman,

Assistant Secretary. [FR Doc. 2018–15849 Filed 7–24–18; 8:45 am] BILLING CODE 8011–01–P

SECURITIES AND EXCHANGE COMMISSION

[Release No. 34-83678/July 20, 2018]

Securities Exchange Act of 1934; Order Scheduling Filing of Statements on Review; in the Matter of the Investors Exchange LLC; for an Order Granting the Approval of Proposed Rule Change To Establish a New Optional Listing Category on the Exchange, "LTSE Listings on IEX" (File No. SR-IEX-2018-06)

On March 15, 2018, Investors Exchange LLC (the "Exchange" or "IEX") filed with the Securities and Exchange Commission ("Commission"), pursuant to Section 19(b)(1) of the Securities Exchange Act of 1934 ¹ and Rule 19b–4 thereunder,² a proposed rule change to establish a new optional listing category on the Exchange, referred to as the "LTSE Listings on IEX" or "LTSE Listings." The proposed rule change was published for comment in the Federal Register on April 2, 2018.3 On May 11, 2018, the Division of Trading and Markets, for the Commission pursuant to delegated authority, extended the time period for Commission action on the proposed rule change.⁴ On June 27, 2018, the Exchange submitted Amendment No. 1 to the proposed rule change.⁵ On June 29, 2018, the Division of Trading and Markets, for the Commission pursuant to delegated authority,⁶ approved the proposed rule change, as modified by Amendment No. 1.7

³ See Securities Exchange Act Release No. 82948 (March 27, 2018), 83 FR 14074 (April 2, 2018) (SR– IEX–2018–06).

⁴ See Securities Exchange Act Release No. 83217 (May 11, 2018), 83 FR 22998 (May 17, 2018).

⁵ See letter from Claudia Crowley, Chief Regulatory Officer, Investors Exchange LLC, dated June 27, 2018, available at https://www.sec.gov/ comments/sr-iex-2018-06/iex201806-3956434-167066.pdf.

⁷ See Securities Exchange Act Release No. 83558 (June 29, 2018).

Pursuant to Commission Rule of Practice 431,⁸ the Commission is reviewing the delegated action, and the June 29, 2018 order is stayed.

Accordingly, *it is ordered*, pursuant to Commission Rule of Practice 431, that by August 20, 2018, any party or other person may file any additional statement.

It is further *ordered* that the June 29, 2018 order approving the proposed rule change, as modified by Amendment No. 1 (SR–IEX–2018–06) shall remain stayed pending further order of the Commission.

By the Commission.

Brent J. Fields,

Secretary.

[FR Doc. 2018–15926 Filed 7–24–18; 8:45 am] BILLING CODE 8011–01–P

SECURITIES AND EXCHANGE COMMISSION

Submission for OMB Review; Comment Request

Upon Written Request, Copies Available From: Securities and Exchange Commission, Office of FOIA Services, 100 F Street NE, Washington, DC 20549–2736

Extension:

Rule 17Ac2–2 and Form TA–2, SEC File No. 270–298, OMB Control No. 3235– 0337

Notice is hereby given that pursuant to the Paperwork Reduction Act of 1995 ("PRA") (44 U.S.C. 3501 *et seq.*), the Securities and Exchange Commission ("Commission") has submitted to the Office of Management and Budget ("OMB") a request for approval of the existing collection of information provided for in Rule 17Ac2–2 (17 CFR 240.17Ac2–2) and Form TA–2 under the Securities Exchange Act of 1934 (15 U.S.C. 78a *et seq.*) ("Exchange Act").

Rule 17Ac2–2 and Form TA–2 under the Exchange Act require transfer agents to file an annual report of their business activities with the Commission. These reporting requirements are designed to ensure that all registered transfer agents are providing the Commission with sufficient information on an annual basis about the transfer agent community and to permit the Commission to effectively monitor business activities of transfer agents.

The amount of time needed to comply with the requirements of amended Rule 17Ac2–2 and Form TA–2 varies. Of the total 373 registered transfer agents, approximately 9.2% (or 34 registrants)

²³ 17 CFR 200.30–3(a)(12) and (59).

¹15 U.S.C. 78s(b)(1).

² 17 CFR 240.19b-4.

^{6 17} CFR 200.30 3(a)(12).

^{8 17} CFR 201.431.

35301

would be required to complete only questions 1 through 3 and the signature section of amended Form TA-2, which the Commission estimates would take each registrant approximately 30 minutes, for a total burden of 17 hours $(34 \times .5 \text{ hours})$. Approximately 26.5% of registrants (or 99 registrants) would be required to answer questions 1 through 5, question 11 and the signature section, which the Commission estimates would take approximately 1 hour and 30 minutes, for a total of 148.5 hours (99 ×1.5 hours). Approximately 64.2% of the registrants (or 239 registrants) would be required to complete the entire Form TA-2, which the Commission estimates would take approximately 6 hours, for a total of 1,434 hours $(239 \times 6 \text{ hours})$. The aggregate annual burden on all 373 registered transfer agents is thus approximately 1,599.5 hours (17 hours + 148.5 hours + 1,434 hours) and the average annual burden per transfer agent is approximately 3.8 hours (1,434 ÷ 373).

This rule does not involve the collection of confidential information.

An agency may not conduct or sponsor, and a person is not required to respond to, a collection of information under the PRA unless it displays a currently valid OMB control number.

The public may view background documentation for this information collection at the following website: www.reginfo.gov. Comments should be directed to: (i) Desk Officer for the Securities and Exchange Commission, Office of Information and Regulatory Affairs, Office of Management and Budget, Room 10102, New Executive Office Building, Washington, DC 20503, or by sending an email to: *Shagufta* Ahmed@omb.eop.gov; and (ii) Pamela Dyson, Director/Chief Information Officer, Securities and Exchange Commission, c/o Candace Kenner, 100 F Street NE, Washington, DC 20549, or by sending an email to: PRA Mailbox@ sec.gov. Comments must be submitted to OMB within 30 days of this notice.

Dated: July 19, 2018.

Eduardo A. Aleman,

Assistant Secretary.

[FR Doc. 2018–15851 Filed 7–24–18; 8:45 am]

BILLING CODE 8011-01-P

SECURITIES AND EXCHANGE COMMISSION

[Release No. 34-83676; File No. SR-NYSEArca-2018-04]

Self-Regulatory Organizations; NYSE Arca, Inc.; Notice of Designation of a Longer Period for Commission Action on Proceedings To Determine Whether To Approve or Disapprove a Proposed Rule Change To Adopt a New NYSE Arca Rule 8.900–E and To List and Trade Shares of the Royce Pennsylvania ETF, Royce Premier ETF, and Royce Total Return ETF Under Proposed NYSE Arca Equities Rule 8.900–E

July 20, 2018.

On January 8, 2018, NYSE Arca, Inc. ("Exchange" or "NYSE Arca") filed with the Securities and Exchange Commission ("Commission"), pursuant to Section 19(b)(1) of the Securities Exchange Act of 1934 ("Act")¹ and Rule 19b–4 thereunder,² a proposed rule change to adopt new NYSE Arca Rule 8.900-E to permit it to list and trade Managed Portfolio Shares. The Exchange also proposed to list and trade shares of Royce Pennsylvania ETF, Royce Premier ETF, and Royce Total Return ETF under proposed NYSE Arca Rule 8.900–E. The proposed rule change was published for comment in the Federal Register on January 26, 2018.³ On March 7, 2018, pursuant to Section 19(b)(2) of the Act,⁴ the Commission designated a longer period within which to approve the proposed rule change, disapprove the proposed rule change, or institute proceedings to determine whether to disapprove the proposed rule change.⁵ The Commission received five comment letters on the proposed rule change.⁶ On April 26, 2018, the Commission instituted proceedings

³ See Securities Exchange Act Release No. 82549 (January 19, 2018), 83 FR 3846.

⁵ See Securities Exchange Act Release No. 82824, 83 FR 10934 (March 13, 2018). The Commission designated April 26, 2018, as the date by which the Commission shall approve or disapprove, or institute proceedings to determine whether to disapprove, the proposed rule change.

⁶ See letters from: (1) Terence W. Norman, Founder, Blue Tractor Group, LLC, dated February 6, 2018; (2) Simon P. Goulet, Co-Founder, Blue Tractor Group, LLC, dated February 13, 2018; (3) Todd J. Broms, Chief Executive Officer, Broms & Company LLC, dated February 16, 2018; (4) Kevin S. Haeberle, Associate Professor of Law, William & Mary Law School, dated February 16, 2018; and (5) Gary L. Gastineau, President, ETF Consultants.com, Inc., dated March 6, 2018. The comment letters are available at https://www.sec.gov/comments/srnysearca-2018-04/nysearca201804.htm. under Section 19(b)(2)(B) of the Act ⁷ to determine whether to approve or disapprove the proposed rule change.⁸ Since then, the Commission has received two additional comments on the proposed rule change.⁹

Section 19(b)(2) of the Act¹⁰ provides that, after initiating proceedings, the Commission shall issue an order approving or disapproving the proposed rule change not later than 180 days after the date of publication of notice of filing of the proposed rule change. The Commission, however, may extend the period for issuing an order approving or disapproving the proposed rule change by not more than 60 days if the Commission determines that a longer period is appropriate and publishes the reasons for such determination. The proposed rule change was published for notice and comment in the Federal **Register** on January 26, 2018.¹¹ July 25, 2018, is 180 days from that date, and September 23, 2018, is 240 days from that date.

The Commission finds it appropriate to designate a longer period within which to issue an order approving or disapproving the proposed rule change so that it has sufficient time to consider the proposed rule change and the issues raised in the comment letters that have been submitted in connection therewith. Accordingly, the Commission, pursuant to Section 19(b)(2) of the Act,¹² designates September 23, 2018, as the date by which the Commission should either approve or disapprove the proposed rule change (File No. SR– NYSEArca–2018–04).

For the Commission, by the Division of Trading and Markets, pursuant to delegated authority.¹³

Eduardo A. Aleman,

Assistant Secretary.

[FR Doc. 2018–15900 Filed 7–24–18; 8:45 am] BILLING CODE 8011–01–P

⁸ See Securities Exchange Act Release No. 83120, 83 FR 19371 (May 2, 2018).

⁹ See letters from: (1) Terence W. Norman, Founder, Blue Tractor Group, LLC, dated May 8, 2018 and (2) Kevin S. Haeberle, Associate Professor of Law, William & Mary Law School, dated June 6, 2018. The comment letters are available on the Commission's website at: https://www.sec.gov/ comments/sr-nysearca-2018-04/nysearca 201804.htm.

- 10 15 U.S.C. 78s(b)(2).
- ¹¹ See supra note 3.
- ¹² 15 U.S.C. 78s(b)(2).

¹15 U.S.C. 78s(b)(1).

² 17 CFR 240.19b-4.

⁴ 15 U.S.C. 78s(b)(2).

^{7 15} U.S.C. 78s(b)(2)(B).

^{13 17} CFR 200.30-3(a)(57).

SECURITIES AND EXCHANGE COMMISSION

[Release No. 34-83670; File No. SR-NASDAQ-2018-056]

Self-Regulatory Organizations; The Nasdaq Stock Market LLC; Notice of Filing and Immediate Effectiveness of Proposed Rule Change To Amend Rule 7015(b) To Provide for Port Connectivity the FINRA/Nasdaq Trade Reporting Facility Chicago

July 19, 2018.

Pursuant to Section 19(b)(1) of the Securities Exchange Act of 1934 ("Act"),¹ and Rule 19b–4 thereunder,² notice is hereby given that on July 6, 2018, The Nasdaq Stock Market LLC ("Nasdaq" or "Exchange") filed with the Securities and Exchange Commission ("Commission") the proposed rule change as described in Items I, II, and III below, which Items have been prepared by the Exchange. The Commission is publishing this notice to solicit comments on the proposed rule change from interested persons.

I. Self-Regulatory Organization's Statement of the Terms of Substance of the Proposed Rule Change

The Exchange proposes to amend the Exchange's transaction fees at Rule 7015(b) to provide for port connectivity [sic] the FINRA/Nasdaq Trade Reporting Facility Chicago, as described further below. The text of the proposed rule change is available on the Exchange's website at *http://nasdaq.cchwallstreet.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 Exchange included statements concerning the purpose of and basis for the proposed rule change and discussed any comments it received on the proposed rule change. The text of these statements may be examined at the places specified in Item IV below. The Exchange has prepared summaries, set forth in sections A, B, and C below, of the most significant aspects of such statements. A. Self-Regulatory Organization's Statement of the Purpose of, and Statutory Basis for, the Proposed Rule Change

1. Purpose

The Exchange proposes to amend Rules 7015(b) to establish fees for Financial Information Exchange or "FIX" Port connectivity to the FINRA/ Nasdaq Trade Reporting Facility Chicago ("FINRA/Nasdaq TRF Chicago"). The FINRA/Nasdaq TRF Chicago is a second iteration of the FINRA/Nasdaq Trade Reporting Facility (now known as the FINRA/Nasdaq Trade Reporting Facility Carteret or "FINRA/Nasdaq TRF Carteret") that the Commission approved on June 29, 2018.³ The FINRA/Nasdaq TRF Chicago is expected to launch in September 2018.

The proposal will amend Rule 7015(b), which presently charges a \$500 per port per month fee for FIX Ports to connect to the "FINRA/Nasdaq Trade Reporting Facility, ORF, and TRACE.' The proposal will amend this provision of the Rule to: (i) Refer to the FINRA/ Nasdaq Trade Facility by its new name, the "FINRA/Nasdaq TRF Carteret"; (ii) apply a \$500 per port per month fee to FIX Ports to connect to the FINRA/ Nasdaq TRF Chicago; and (3) waive this fee for FIX Port connections to the FINRA/Nasdaq TRF Chicago until November 1, 2018 so as to encourage firms to test connectivity to the new facility and also to provide them with a transition period to adjust to the new fees. As of November 1, 2018, the same fee that the Exchange charges for FIX Ports to connect to the FINRA/Nasdaq TRF Carteret will apply to FIX Port connections to the FINRA/Nasdag TRF Chicago.⁴

2. Statutory Basis

The Exchange believes that its proposal is consistent with Section 6(b) of the Act,⁵ in general, and furthers the objectives of Sections 6(b)(4) and 6(b)(5) of the Act,⁶ in particular, in that it provides for the equitable allocation of reasonable dues, fees and other charges among members and issuers and other persons using any facility, and is not designed to permit unfair discrimination between customers, issuers, brokers, or dealers.

The Exchange believes that the Exchange's proposal to charge a fee for FIX Ports that connect to the FINRA/ Nasdaq TRF Chicago is reasonable because the proposed fee accounts for the costs to the Exchange of developing and maintaining connectivity to the FINRA/Nasdaq TRF Chicago. The proposed fee is also reasonable because it mirrors a fee that the Exchange already charges for connections to the FINRA/Nasdaq TRF Carteret, which is the sister facility to the FINRA/Nasdaq TRF Chicago and to which the Chicago facility will be identical in all material respects.

The Exchange also believes that it is reasonable to waive the aforementioned fee for a brief transition period to allow participants to test and configure their connections to the FINRA/Nasdaq TRF Chicago and also to facilitate an adjustment to the new fees.

The Exchange believes that the proposal is an equitable allocation and is not unfairly discriminatory because the Exchange will apply the same fee and the same fee waiver—to all similarly situated members that choose to connect to the FINRA/Nasdaq TRF Chicago. It is also equitable to temporarily waive fees for connecting to the new facility because doing so will ease the burden of testing and configuring the connections.

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. In terms of inter-market competition, the Exchange notes that it operates in a highly competitive market in which market participants can readily favor competing venues if they deem fee levels at a particular venue to be excessive, or rebate opportunities available at other venues to be more favorable. In such an environment, the Exchange must continually adjust its fees to remain competitive with other exchanges and with alternative trading systems that have been exempted from compliance with the statutory standards applicable to exchanges. Because competitors are free to modify their own fees in response, and because market participants may readily adjust their order routing practices, the Exchange believes that the degree to which fee changes in this market may impose any burden on competition is extremely limited.

¹15 U.S.C. 78s(b)(1).

² 17 CFR 240.19b-4.

³ See Securities Exchange Act Release No. 83559 (June 29, 2018), 83 FR 31589 (July 6, 2018) (SR– FINRA–2018–013).

⁴For avoidance of doubt, the Exchange notes that a firm that pays a fee for a FIX Port to connect to the FINRA/Nasdaq TRF Carteret will also be liable for an additional fee to connect to the FINRA/ Nasdaq TRF Chicago.

⁵15 U.S.C. 78f(b).

⁶15 U.S.C. 78f(b)(4) and (5).

In this instance, the proposed changes do not impose a burden on competition because the proposed fee for connectivity to the FINRA/Nasdaq TRF Chicago will be the same as that which the Exchange presently charges to connect to the Chicago facility's sister facility, the FINRA/Nasdag TRF Carteret. Moreover, use of and connection to the FINRA/Nasdaq TRF Chicago is voluntary. If a firm does not wish to pay fees to connect to the FINRA/Nasdaq TRF Chicago, it may choose instead to connect to a competing trade reporting facility that charges lower fees.

Lastly, the proposed fee waiver does not burden competition because it will apply only for a brief transition period. Such transitional fee waivers are a commonly accepted means of facilitating the adoption, testing, and use of new functionalities and the attraction of new participants.⁷

C. Self-Regulatory Organization's Statement on Comments on the Proposed Rule Change Received From Members, Participants, or Others

No written comments were either solicited or received.

III. Date of Effectiveness of the Proposed Rule Change and Timing for Commission Action

The foregoing rule change has become effective pursuant to Section 19(b)(3)(A)(ii) of the Act.⁸

At any time within 60 days of the filing of the proposed rule change, the Commission summarily may temporarily suspend such rule change if it appears to the Commission that such action is: (i) Necessary or appropriate in the public interest; (ii) for the protection of investors; or (iii) otherwise in furtherance of the purposes of the Act. If the Commission takes such action, the Commission shall institute proceedings to determine whether the proposed rule should be approved or disapproved.

IV. Solicitation of Comments

Interested persons are invited to submit written data, views, and arguments concerning the foregoing, including whether the proposed rule change is consistent with the Act. Comments may be submitted by any of the following methods:

Electronic Comments

• Use the Commission's internet comment form (*http://www.sec.gov/rules/sro.shtml*); or

• Send an email to *rule-comments@ sec.gov.* Please include File Number SR– NASDAQ–2018–056 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-NASDAQ-2018-056. 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-NASDAQ-2018-056, and should be submitted on or before August 15, 2018.

For the Commission, by the Division of Trading and Markets, pursuant to delegated authority.⁹

Eduardo A. Aleman,

Assistant Secretary.

[FR Doc. 2018–15846 Filed 7–24–18; 8:45 am] BILLING CODE 8011–01–P

SECURITIES AND EXCHANGE COMMISSION

Submission for OMB Review; Comment Request

Upon Written Request, Copies Available From: Securities and Exchange Commission, Office of FOIA Services, 100 F Street NE, Washington, DC 20549–2736

Extension:

Form 1–E, Regulation E, SEC File No. 270– 221, OMB Control No. 3235–0232

Notice is hereby given that, pursuant to the Paperwork Reduction Act of 1995 (44 U.S.C. 3501 *et seq.*), the Securities and Exchange Commission (the "Commission") has submitted to the Office of Management and Budget a request for extension of the previously approved collection of information discussed below.

Form 1–E (17 CFR 239.200) under the Securities Act of 1933 (15 U.S.C. 77a et seq.) ("Securities Act") is the form that a small business investment company ("SBIC") or business development company ("BDC") uses to notify the Commission that it is claiming an exemption under Regulation E from registering its securities under the Securities Act. Rule 605 of Regulation E (17 CFR 230.605) under the Securities Act requires an SBIC or BDC claiming such an exemption to file an offering circular with the Commission that must also be provided to persons to whom an offer is made. Form 1-E requires an issuer to provide the names and addresses of the issuer, its affiliates, directors, officers, and counsel; a description of events which would make the exemption unavailable; the jurisdictions in which the issuer intends to offer the securities; information about unregistered securities issued or sold by the issuer within one year before filing the notification on Form 1–E; information as to whether the issuer is presently offering or contemplating offering any other securities; and exhibits, including copies of the rule 605 offering circular and any underwriting contracts.

The Commission uses the information provided in the notification on Form 1– E and the offering circular to determine whether an offering qualifies for the exemption under Regulation E. The Commission estimates that, each year, one issuer files one notification on Form 1–E, together with offering circulars, with the Commission.¹ Based on the

⁷ See, e.g., Securities Exchange Act Release No. 81095 (July 7, 2017), 82 FR 32409 (July 13, 2017) (SR–ISE–2017–62) (temporarily waiving port fees for connections to the re-platformed Nasdaq ISE Exchange).

^{8 15} U.S.C. 78s(b)(3)(A)(ii).

⁹¹⁷ CFR 200.30-3(a)(12).

 $^{^1}$ According to Commission records, one issuer filed two notifications on Form 1–E, together with offering circulars, during 2013 and 2014.

Commission's experience with disclosure documents, we estimate that the burden from compliance with Form 1–E and the offering circular requires approximately 100 hours per filing. The annual burden hours for compliance with Form 1–E and the offering circular would be 200 hours (2 responses × 100 hours per response). Estimates of the burden hours are made solely for the purposes of the PRA, and are not derived from a comprehensive or even a representative survey or study of the costs of SEC rules and forms.

Compliance with the information collection requirements of the rules is necessary to obtain the benefit of relying on the rules. The information provided on Form 1–E and in the offering circular will not be kept confidential. 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 public may view the background documentation for this information collection at the following website, www.reginfo.gov. Comments should be directed to: (i) Desk Officer for the Securities and Exchange Commission, Office of Information and Regulatory Affairs, Office of Management and Budget, Room 10102, New Executive Office Building, Washington, DC 20503, or by sending an email to: Shagufta Ahmed@omb.eop.gov; and (ii) Pamela Dyson, Director/Chief Information Officer, Securities and Exchange Commission, c/o Candace Kenner, 100 F Street NE, Washington, DC 20549 or send an email to: PRA Mailbox@ sec.gov. Comments must be submitted to OMB within 30 days of this notice.

Dated: July 19, 2018.

Eduardo A. Aleman,

Assistant Secretary.

[FR Doc. 2018–15855 Filed 7–24–18; 8:45 am] BILLING CODE 8011–01–P

SECURITIES AND EXCHANGE COMMISSION

Proposed Collection; Comment Request

Upon Written Request, Copies Available From: Securities and Exchange Commission, Office of FOIA Services, 100 F Street NE, Washington, DC 20549–2736

Extension:

Rule 10f–3; SEC File No. 270–237, OMB Control No. 3235–0226

Notice is hereby given that, pursuant to the Paperwork Reduction Act of 1995 (44 U.S.C. 3501–3520), the Securities and Exchange Commission ("Commission") is soliciting comments on the collections of information discussed below. The Commission plans to submit these existing collections of information to the Office of Management and Budget ("OMB") for extension and approval.

Section 10(f) of the Investment Company Act of 1940 (15 U.S.C. 80a) (the "Act") prohibits a registered investment company ("fund") from purchasing any security during an underwriting or selling syndicate if the fund has certain relationships with a principal underwriter for the security.¹ Congress enacted this provision in 1940 to protect funds and their shareholders by preventing underwriters from "dumping" unmarketable securities on affiliated funds.

Rule 10f-3 permits a fund to engage in a securities transaction that otherwise would violate section 10(f) if, among other things: (i) The fund's directors have approved procedures for purchases made in reliance on the rule, regularly review fund purchases to determine whether they comply with these procedures, and approve necessary changes to the procedures; and (ii) a written record of each transaction effected under the rule is maintained for six years, the first two of which in an easily accessible place.² The written record must state: (i) From whom the securities were acquired; (ii) the identity of the underwriting syndicate's members; (iii) the terms of the transactions; and (iv) the information or materials on which the fund's board of directors has determined that the purchases were made in compliance with procedures established by the board.

Rule 10f–3 also conditionally allows managed portions of fund portfolios to purchase securities offered in otherwise off-limits primary offerings. To qualify for this exemption, rule 10f-3 requires that the subadviser that is advising the purchaser be contractually prohibited from providing investment advice to any other portion of the fund's portfolio and consulting with any other of the fund's advisers that is a principal underwriter or affiliated person of a principal underwriter concerning the fund's securities transactions.

These requirements provide a mechanism for fund boards to oversee compliance with the rule. The required recordkeeping facilitates the Commission staff's review of rule 10f– 3 transactions during routine fund inspections and, when necessary, in connection with enforcement actions.

The staff estimates that approximately 236 funds engage in a total of approximately 2,928 rule 10f–3 transactions each year.³ Rule 10f–3 requires that the purchasing fund create a written record of each transaction that includes, among other things, from whom the securities were purchased and the terms of the transaction. The staff estimates ⁴ that it takes an average fund approximately 30 minutes per transaction and approximately 1,464 hours ⁵ in the aggregate to comply with this portion of the rule.

The funds also must maintain and preserve these transactional records in accordance with the rule's recordkeeping requirement, and the staff estimates that it takes a fund approximately 20 minutes per transaction and that annually, in the aggregate, funds spend approximately 976 hours ⁶ to comply with this portion of the rule.

In addition, fund boards must, no less than quarterly, examine each of these transactions to ensure that they comply with the fund's policies and procedures. The information or materials upon which the board relied to come to this determination also must be maintained and the staff estimates that it takes a fund 1 hour per quarter and, in the aggregate, approximately 944 hours ⁷ annually to comply with this rule requirement.

The staff estimates that reviewing and revising as needed written procedures for rule 10f-3 transactions takes, on average for each fund, two hours of a compliance attorney's time per year.⁸ Thus, annually, in the aggregate, the staff estimates that funds spend a total of approximately 472 hours ⁹ on monitoring and revising rule 10f–3 procedures.

Based on an analysis of fund filings, the staff estimates that approximately 299 fund portfolios enter into

⁴ Unless stated otherwise, the information collection burden estimates are based on conversations between the staff and representatives of funds.

⁵ This estimate is based on the following calculation: (0.5 hours \times 2,928 = 1,464 hours). ⁶ This estimate is based on the following

calculations: (20 minutes \times 2,928 transactions = 58,560 minutes; 58,560 minutes/60 = 976 hours).

⁷ This estimate is based on the following calculation: (1 hour per quarter × 4 quarters × 236

funds = 944 hours).

⁸ These averages take into account the fact that in most years, fund attorneys and boards spend little or no time modifying procedures and in other years, they spend significant time doing so.

 9 This estimate is based on the following calculation: (236 funds $\times 2$ hours = 472 hours).

^{1 15} U.S.C. 80a-10(f).

^{2 17} CFR 270.10f-3.

³ These estimates are based on staff extrapolations from filings with the Commission.

subadvisory agreements each year.¹⁰ Based on discussions with industry representatives, the staff estimates that it will require approximately 3 attorney hours to draft and execute additional clauses in new subadvisory contracts in order for funds and subadvisers to be able to rely on the exemptions in rule 10f-3. Because these additional clauses are identical to the clauses that a fund would need to insert in their subadvisory contracts to rely on rules 12d3-1, 17a-10, and 17e-1, and because we believe that funds that use one such rule generally use all of these rules, we apportion this 3 hour time burden equally to all four rules. Therefore, we estimate that the burden allocated to rule 10f-3 for this contract change would be 0.75 hours.¹¹ Assuming that all 299 funds that enter into new subadvisory contracts each year make the modification to their contract required by the rule, we estimate that the rule's contract modification requirement will result in 224 burden hours annually.12

The staff estimates, therefore, that rule 10f–3 imposes an information collection burden of 4,080 hours.¹³

Written comments are invited on: (a) Whether the collections of information are necessary for the proper performance of the functions of the Commission, including whether the information has practical utility; (b) the accuracy of the Commission's estimate of the burdens of the collections of information; (c) ways to enhance the quality, utility, and clarity of the information collected; and (d) ways to minimize the burdens of the collections of information on respondents, including through the use of automated collection techniques or other forms of information technology. Consideration will be given to comments and suggestions submitted in writing within 60 days of this publication.

Please direct your written comments to Pamela Dyson, Director/Chief Information Officer, Securities and Exchange Commission, C/O Candace Kenner, 100 F Street NE, Washington, DC 20549; or send an email to: *PRA_Mailbox@sec.gov.* Dated: July 19, 2018. Eduardo A. Aleman, Assistant Secretary. [FR Doc. 2018–15853 Filed 7–24–18; 8:45 am] BILLING CODE 8011–01–P

SECURITIES AND EXCHANGE COMMISSION

Submission for OMB Review; Comment Request

Upon Written Request, Copies Available From: Securities and Exchange Commission, Office of FOIA Services, 100 F Street NE, Washington, DC 20549–2736

Extension:

Interagency Statement on Sound Practices, SEC File No. 270–560, OMB Control No. 3235–0622

Notice is hereby given that pursuant to the Paperwork Reduction Act of 1995 ("PRA") (44 U.S.C. 3501 et seq.) the Securities and Exchange Commission ("Commission") has submitted to the Office of Management and Budget ("OMB") a request for approval of extension of the previously approved collection of information provided for in the Interagency Statement on Sound Practices Concerning Elevated Risk **Complex Structured Finance Activities** ("Statement") under the Securities Exchange Act of 1934 (15 U.S.C. 78a et seq.) ("Exchange Act") and the Investment Advisers Act of 1940 (15 U.S.C. 80b et seq.) ("Advisers Act").

The Statement was issued by the Commission, together with the Office of the Comptroller of the Currency, the Board of Governors of the Federal Reserve System, the Federal Deposit Insurance Corporation, and the Office of Thrift Supervision (together, the "Agencies"), in May 2006. The Statement describes the types of internal controls and risk management procedures that the Agencies believe are particularly effective in assisting financial institutions to identify and address the reputational, legal, and other risks associated with elevated risk complex structured finance transactions.

The primary purpose of the Statement is to ensure that these transactions receive enhanced scrutiny by the institution and to ensure that the institution does not participate in illegal or inappropriate transactions.

The Commission estimates that approximately 5 registered brokerdealers or investment advisers will spend an average of approximately 25 hours per year complying with the Statement. Thus, the total compliance burden is estimated to be approximately 125 burden-hours per year.

An agency may not conduct or sponsor, and a person is not required to respond to, a collection of information under the PRA unless it displays a currently valid OMB control number.

The public may view background documentation for this information collection at the following website, www.reginfo.gov. Comments should be directed to: (i) Desk Officer for the Securities and Exchange Commission, Office of Information and Regulatory Affairs, Office of Management and Budget, Room 10102, New Executive Office Building, Washington, DC 20503, or by sending an email to: *Shagufta* Ahmed@omb.eop.gov; and (ii) Pamela Dyson, Director/Chief Information Officer, Securities and Exchange Commission, c/o Candace Kenner 100 F Street NE Washington, DC 20549, or by sending an email to: PRA Mailbox@ sec.gov. Comments must be submitted to OMB within 30 days of this notice.

Dated: July 19, 2018.

Eduardo A. Aleman,

Assistant Secretary.

[FR Doc. 2018–15856 Filed 7–24–18; 8:45 am] BILLING CODE 8011–01–P

SECURITIES AND EXCHANGE COMMISSION

[Release No. 34–83672; File No. SR–CBOE– 2018–052]

Self-Regulatory Organizations; Cboe Exchange, Inc.; Notice of Filing and Immediate Effectiveness of a Proposed Rule Change To Extend the Credit Option Margin Pilot Program Through July 18, 2019

July 19, 2018.

Pursuant to Section 19(b)(1) of the Securities Exchange Act of 1934 (the ''Act''),¹ and Rule 19b–4 thereunder,² notice is hereby given that on July 18, 2018, Cboe Exchange, Inc. (the "Exchange" or "Cboe Options") filed with the Securities and Exchange Commission (the "Commission") the proposed rule change as described in Items I and II below, which Items have been prepared by the Exchange. The Exchange filed the proposal as a "noncontroversial" proposed rule change pursuant to Section 19(b)(3)(A)(iii) of the Act³ and Rule 19b-4(f)(6) thereunder.⁴ The Commission is publishing this notice to solicit

¹⁰ Based on information in Commission filings, we estimate that 38 percent of funds are advised by subadvisers.

¹¹ This estimate is based on the following calculation (3 hours \div 4 rules = .75 hours).

 $^{^{12}}$ These estimates are based on the following calculations: (0.75 hours \times 299 portfolios = 224 burden hours).

¹³ This estimate is based on the following calculation: (1,464 hours + 976 hours + 944 hours + 472 + 224 hours = 4,080 total burden hours).

¹15 U.S.C. 78s(b)(1).

² 17 CFR 240.19b–4.

^{3 15} U.S.C. 78s(b)(3)(A)(iii).

⁴17 CFR 240.19b-4(f)(6).

comments on the proposed rule change from interested persons.

I. Self-Regulatory Organization's Statement of the Terms of Substance of the Proposed Rule Change

The Exchange proposes to amend Rule 12.3 by extending the Credit Option Margin Pilot Program through July 18, 2019.

The text of the proposed rule change is available on the Exchange's website (http://www.cboe.com/AboutCBOE/ CBOELegalRegulatoryHome.aspx), at the Exchange's Office of the Secretary, 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 Exchange included statements concerning the purpose of and basis for the proposed rule change and discussed any comments it received on the proposed rule change. The text of these statements may be examined at the places specified in Item IV below. The Exchange has prepared summaries, set forth in sections A, B, and C below, of the most significant aspects of such statements.

A. Self-Regulatory Organization's Statement of the Purpose of, and Statutory Basis for, the Proposed Rule Change

1. Purpose

On February 2, 2011, the Commission approved the Exchange's proposal to establish a Credit Option Margin Pilot Program ("Program").⁵ The proposal became effective on a pilot basis to run on a parallel track with Financial Industry Regulatory Authority ("FINRA") Rule 4240 that similarly operates on an interim pilot basis.⁶

On January 17, 2012, the Exchange filed a rule change to, among other things, decouple the Program with the FINRA program and to extend the expiration date of the Program to

January 17, 2013.⁷ The Program, however, continues to be substantially similar to the provisions of the FINRA program. Subsequently, the Exchange filed rule changes to extend the program until January 17, 2014, January 16, 2015, January 15, 2016, January 17, 2017, and July 18, 2017, July 18, 2018 respectively.⁸ The Exchange believes that extending the expiration date of the Program further will allow for further analysis of the Program and a determination of how the Program should be structured in the future. Thus, the Exchange is now currently proposing to extend the duration of the Program for an additional year until July 18, 2019.

Additionally, the Exchange believes that it is in the public interest to extend the expiration date of the Program because it will continue to allow the Exchange to list Credit Options for trading. As a result, the Exchange will remain competitive with the Over-the-Counter Market with respect to swaps and security-based swaps. In the future, if the Exchange proposes an additional extension of the Credit Option Margin Pilot Program or proposes to make the Program permanent, then the Exchange will submit a filing proposing such amendments to the Program.

2. Statutory Basis

The Exchange believes the proposed rule change is consistent with the Securities Exchange Act of 1934 (the "Act") and the rules and regulations thereunder applicable to the Exchange and, in particular, the requirements of Section 6(b) of the Act.⁹ Specifically, the Exchange believes the proposed rule change is consistent with the Section $6(b)(5)^{10}$ requirements that the rules of an exchange be designed to prevent fraudulent and manipulative acts and practices, to promote just and equitable principles of trade, to foster cooperation and coordination with persons engaged in regulating, clearing, settling, processing information with respect to, and facilitation 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. Additionally, the Exchange believes the proposed rule change is consistent with the Section 6(b)(5)¹¹ requirement that the rules of an exchange not be designed to permit unfair discrimination between customers, issuers, brokers, or dealers.

In particular, the Exchange believes that the proposed rule change will further the purposes of the Act because, consistent with the goals of the Commission at the initial adoption of the program, the margin requirements set forth by the proposed rule change will help to stabilize the financial markets. In addition, the proposed rule change is substantially similar to existing FINRA Rule 4240.

B. Self-Regulatory Organization's Statement on Burden on Competition

The Exchange does not believe that the proposed rule change will impose any burden on competition that is not necessary or appropriate in furtherance of the purposes of the Act. Specifically, the Exchange believes that, by extending the expiration of the Program, the proposed rule change will allow for further analysis of the Program and a determination of how the Program shall be structured in the future. In doing so, the proposed rule change will also serve to promote regulatory clarity and consistency, thereby reducing burdens on the marketplace and facilitating investor protection.

C. Self-Regulatory Organization's Statement on Comments on the Proposed Rule Change Received From Members, Participants, or Others

The Exchange neither solicited nor received comments on the proposed rule change.

III. Date of Effectiveness of the Proposed Rule Change and Timing for Commission Action

Because the foregoing proposed rule change does not:

A. Significantly affect the protection of investors or the public interest;

B. impose any significant burden on competition; and

C. become operative for 30 days from the date on which it was filed, or such shorter time as the Commission may designate, it has become effective pursuant to Section 19(b)(3)(A) of the Act ¹² and Rule 19b-4(f)(6) ¹³ thereunder.

⁵ See Securities Exchange Act Release No. 63819 (February 2, 2011), 76 FR 6838 (February 8, 2011) order approving (SR-CBOE-2010-106). To implement the Program, the Exchange amended Rule 12.3(l), Margin Requirements, to make Cboe Option's margin requirements for Credit Options consistent with Financial Industry Regulatory Authority ("FINRA") Rule 4240, Margin Requirements for Credit Default Swaps. Cboe Options Credit Options (*i.e.*, Credit Default Options and Credit Default Basket Options) are analogous to credit default swaps.

⁶ See Securities Exchange Act Release No. 59955 (May 22, 2009), 74 FR 25586 (May 28, 2009) (Notice of Filing and Order Granting Accelerated Approval of Proposed Rule Change; SR–FINRA–2009–012).

 ⁷ See Securities Exchange Act Release No. 66163
 (January 17, 2012), 77 FR 3318 (January 23, 2012)
 (SR-CBOE–2012–007).

⁸ See Securities Exchange Act Release Nos. 68539 (December 27, 2012), 78 FR 138 (January 2, 2013) (SR-CBOE-2012-125), 71124 (December 18, 2013), 78 FR 77754 (December 24, 2013) (SR-CBOE-2013-123), 73837 (December 15, 2014), 79 FR 75850 (December 19, 2014) (SR-CBOE-2014-091), 76824 (January 5, 2016), 81 FR 1255 (January 11, 2016) (SR-CBOE-2015-118), 79621 (December 14, 2016) 81 FR 95236 (December 27, 2016) (SR-CBOE-2016-089), and 81083 (July 6, 2017) 82 FR 32219 (July 12, 2017) (SR-CBOE-2017-051).

⁹15 U.S.C. 78f(b).

^{10 15} U.S.C. 78f(b)(5).

¹¹ Id.

¹² 15 U.S.C. 78s(b)(3)(A).

The Exchange has asked the Commission to waive the 30-day operative delay so that the proposal may become operative immediately upon filing. The Exchange states that waiver of the 30-day operative delay will allow it to maintain the status quo, thereby reducing market disruption. The Commission believes that waiving the 30-day operative delay is consistent with the protection of investors and the public interest, as it will allow the Program to continue uninterrupted, thereby avoiding investor confusion that could result from a temporary interruption of the Program. For this reason, the Commission designates the proposed rule change to be operative upon filing.14

At any time within 60 days of the filing of the proposed rule change, the Commission summarily may temporarily suspend such rule change if it appears to the Commission that such action is necessary or appropriate in the public interest, for the protection of investors, or otherwise in furtherance of the purposes of the Act. If the Commission takes such action, the Commission will institute proceedings 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– CBOE–2018–052 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–CBOE–2018–052. 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–CBOE–2018–052 and should be submitted on or before August 15, 2018.

For the Commission, by the Division of Trading and Markets, pursuant to delegated authority.¹⁵

Eduardo A. Aleman,

Assistant Secretary.

[FR Doc. 2018–15847 Filed 7–24–18; 8:45 am] BILLING CODE 8011–01–P

DEPARTMENT OF STATE

[Public Notice 10477]

Notice of Determinations: Culturally Significant Objects Imported for Exhibition Determinations: "Islam and the Classical Heritage" Exhibition

SUMMARY: Notice is hereby given of the following determinations: I hereby determine that certain objects to be included in the exhibition "Islam and the Classical Heritage," imported from abroad for temporary exhibition within the United States, are of cultural significance. The objects are imported pursuant to a loan agreement with the foreign owner or custodian. I also determine that the exhibition or display

of the exhibit objects at the Fine Arts Museums of San Francisco, Legion of Honor, in San Francisco, California, from on or about August 25, 2018, until on or about January 27, 2019, and at possible additional exhibitions or venues yet to be determined, is in the national interest. I have ordered that Public Notice of these determinations be published in the **Federal Register**. **FOR FURTHER INFORMATION CONTACT:** Julie Simpson, Attorney-Adviser, Office of the Legal Adviser, U.S. Department of State (telephone: 202–632–6471; email: *section2459@state.gov*). The mailing

20522–0505. **SUPPLEMENTARY INFORMATION:** The foregoing determinations were made pursuant to the authority vested in me by the Act of October 19, 1965 (79 Stat. 985; 22 U.S.C. 2459), E.O. 12047 of March 27, 1978, the Foreign Affairs Reform and Restructuring Act of 1998 (112 Stat. 2681, *et seq.*; 22 U.S.C. 6501 note, *et seq.*), Delegation of Authority No. 234 of October 1, 1999, Delegation of Authority No. 236–3 of August 28, 2000, and Delegation of Authority No. 236–10 of July 6, 2018.

address is U.S. Department of State, L/

PD, SA-5, Suite 5H03, Washington, DC

Jennifer Z. Galt,

Principal Deputy Assistant Secretary for Educational and Cultural Affairs, Department of State.

[FR Doc. 2018–15833 Filed 7–24–18; 8:45 am] BILLING CODE 4710–05–P

DEPARTMENT OF STATE

[Public Notice: 10478]

In the Matter of the Review of the Designation of al-Shabaab (and Other Aliases) as a Foreign Terrorist Organization Pursuant to Section 219 of the Immigration and Nationality Act, as Amended

Based upon a review of the Administrative Record assembled pursuant to Section 219(a)(4)(C) of the Immigration and Nationality Act, as amended (8 U.S.C. 1189(a)(4)(C)) ("INA"), and in consultation with the Attorney General and the Secretary of the Treasury, I conclude that the circumstances that were the basis for the designation of the aforementioned organization as a Foreign Terrorist Organization have not changed in such a manner as to warrant revocation of the designation and that the national security of the United States does not warrant a revocation of the designation.

Therefore, I hereby determine that the designation of the aforementioned organization as a Foreign Terrorist

the Commission with written notice of its intent to file the proposed rule change, along with a brief description and the text of the proposed rule change, at least five business days prior to the date of the filing of the proposed rule change, or such shorter time as designated by the Commission.

¹⁴ For purposes only of waiving the 30-day operative delay, the Commission has also considered the proposed rule's impact on efficiency, competition, and capital formation. *See* 15 U.S.C. 78c(f).

^{15 17} CFR 200.30-3(a)(12).

Organization, pursuant to Section 219 of the INA (8 U.S.C. 1189), shall be maintained.

This determination shall be published in the **Federal Register**.

Dated: July 9, 2018.

Michael Pompeo,

Secretary of State.

[FR Doc. 2018–15914 Filed 7–24–18; 8:45 am] BILLING CODE 4710–AD–P

DEPARTMENT OF STATE

[Public Notice: 10471]

In the Matter of the Review of the Designation of al-Shabaab (and Other Aliases) as a Foreign Terrorist Organization Pursuant to Section 219 of the Immigration and Nationality Act, as Amended

Based upon a review of the Administrative Record assembled pursuant to Section 219(a)(4)(C) of the Immigration and Nationality Act, as amended (8 U.S.C. 1189(a)(4)(C)) ("INA"), and in consultation with the Attorney General and the Secretary of the Treasury, I conclude that the circumstances that were the basis for the designation of the aforementioned organization as a Foreign Terrorist Organization have not changed in such a manner as to warrant revocation of the designation and that the national security of the United States does not warrant a revocation of the designation.

Therefore, I hereby determine that the designation of the aforementioned organization as a Foreign Terrorist Organization, pursuant to Section 219 of the INA (8 U.S.C. 1189), shall be maintained.

This determination shall be published in the **Federal Register**.

Dated: July 9, 2018.

Michael Pompeo,

Secretary of State.

[FR Doc. 2018–15917 Filed 7–24–18; 8:45 am] BILLING CODE 4710–AD–P

DEPARTMENT OF TRANSPORTATION

Federal Aviation Administration

Agency Information Collection Activities: Requests for Comments; Clearance of Renewed Approval of Information Collection: Disclosure of Seat Dimensions To Facilitate the Use of Child Safety Seats on Airplanes During Passenger-Carrying Operations

AGENCY: Federal Aviation Administration (FAA), DOT.

ACTION: Notice and request for comments.

SUMMARY: In accordance with the Paperwork Reduction Act of 1995, FAA invites public comments about our intention to request the Office of Management and Budget (OMB) approval to renew an information collection. The collection involves each passenger carrying air carrier operating under the Code of Federal Regulations to post on the internet website of the air carrier the maximum dimensions of a child safety seat that can be used on those aircraft. The information to be collected will be used to facilitate the use of child restraint systems onboard airplanes and is required by section 412 of the FAA Modernization and Reform Act of 2012.

DATES: Written comments should be submitted by September 24, 2018. **ADDRESSES:** Send comments to the FAA at the following address: Barbara Hall, Federal Aviation Administration, ASP–110, 10101 Hillwood Parkway, Fort Worth, TX 76177.

Public Comments Invited: You are asked to comment on any aspect of this information collection, including (a) Whether the proposed collection of information is necessary for FAA's performance; (b) the accuracy of the estimated burden: (c) ways for FAA to enhance the quality, utility and clarity of the information collection; and (d) ways that the burden could be minimized without reducing the quality of the collected information. The agency will summarize and/or include your comments in the request for OMB's clearance of this information collection. FOR FURTHER INFORMATION CONTACT:

Barbara Hall by email at: Barbara.L.Hall@faa.gov; phone: 940–

594–5913.

SUPPLEMENTARY INFORMATION:

OMB Control Number: 2120–0760. Title: Disclosure of Seat Dimensions to Facilitate the Use of Child Safety Seats on Airplanes During Passenger-Carrying Operations.

Form Numbers: There are no forms associated with this collection.

Type of Review: Renewal. *Background:* Section 412 of the FAA

Modernization and Reform Act of 2012 (Pub. L. 112–95) specifically required the Federal Aviation Administration (FAA) to conduct rulemaking "[T]o require each air carrier operating under part 121 of title 14, Code of Federal Regulations to post on the internet website of the air carrier the maximum dimensions of a child safety seat that can be used on each aircraft operated by the air carrier to enable passengers to

determine which child safety seats can be used on those aircraft." As a result, the FAA amended 14 CFR 121.311, which requires passenger carrying air carriers to make available on their websites the width of the widest passenger seat in each class of service for each make, model and series of airplane used in passenger-carrying operations (80 FR 58575). Section 412 of Public Law 112-95 requires that all air carriers provide this required information on their internet websites. The vast majority of this burden occurred on a one-time basis as air carriers initially provided information on their websites in order to comply with the regulation. After initial implementation, the only time air carriers need to update their websites after initial implementation is when a new airplane make, model, or series is introduced to an air carrier's fleet, or when an air carrier replaces the widest or narrowest seats installed on an existing airplane make, model, or series with wider or narrower seats. The purpose of this collection is to facilitate the use of child restraint systems onboard airplanes by providing greater information to caregivers to help them determine whether a particular child restraint system will fit in an airplane seat

Respondents: 50 part 121 air carriers. *Frequency:* On occasion.

Estimated Average Burden per Response: 7 hours.

Estimated Total Annual Burden: 350 hours.

Issued in Washington, DC, on July 19, 2018.

Karen Shutt,

Manager, Performance, Policy, and Records Management Branch, ASP–110. [FR Doc. 2018–15913 Filed 7–24–18; 8:45 am]

BILLING CODE 4910-13-P

DEPARTMENT OF TRANSPORTATION

Federal Highway Administration

[Docket No. FHWA-2018-0038]

Agency Information Collection Activities: Request for Comments for the Renewal of a Previously Approved Information Collection

AGENCY: Federal Highway Administration (FHWA), DOT. **ACTION:** Notice and request for comments.

SUMMARY: In compliance with the Paperwork Reduction Act (PRA) of 1995, this notice announces that FHWA will submit the collection of information described below to the Office of Management and Budget (OMB) for review and comment. The **Federal Register** Notice with a 60-day comment period soliciting comments on the following collection of information was published on May 4, 2018. The PRA submission describes the nature of the information collection and its expected cost and burden.

DATES: Please submit comments by August 24, 2018.

ADDRESSES: You may submit comments identified by DOT Docket ID Number FHWA 2018–0038, by any of the following methods:

Website: For access to the docket to read background documents or comments received go to the Federal eRulemaking Portal: Go to *http:// www.regulations.gov.* Follow the online instructions for submitting comments.

Fax: 1-202-493-2251.

Mail: Docket Management Facility, U.S. Department of Transportation, West Building Ground Floor, Room W12–140, 1200 New Jersey Avenue SE, Washington, DC 20590–0001.

Hand Delivery or Courier: U.S. Department of Transportation, West Building Ground Floor, Room W12–140, 1200 New Jersey Avenue SE, Washington, DC 20590, between 9 a.m. and 5 p.m. ET, Monday through Friday, except Federal holidays.

FOR FURTHER INFORMATION CONTACT: Jim Sinnette, Office of Innovative Program Delivery, 202–366–1561, *james.sinnette@dot.gov*, Federal Highway Administration, Department of Transportation, 1200 New Jersey Avenue SE, Washington, DC 20590. Office hours are from 8 a.m. to 4:30 p.m., Monday through Friday, except Federal holidays.

SUPPLEMENTARY INFORMATION:

Title: FHWA Major Project Financial Plans and Project Management Plans.

Background: Major projects are defined in section 106(h) of title 23, United States Code (U.S.C.), as projects receiving Federal financial assistance with an estimated total cost of \$500,000,000, or other projects as may be identified by the Secretary. Major projects are typically large, complex projects designed to address major highway needs and require the investment of significant financial resources. Project sponsors of major projects are required to submit a project management plan and an annual financial plan to FHWA.

The preparation of the project management plan, as required by 23 U.S.C. 106(h)(2), ensures that clearly defined roles, responsibilities, procedures and processes are in effect to provide timely information to the project decisionmakers to effectively manage the scope, costs, schedules, quality of, and the Federal requirements applicable to, the project. The project management plan serves as a guide for implementing the major project and documents assumptions and decisions regarding communication, management processes, execution and overall project control.

The preparation of the annual financial plan, as required by 23 U.S.C. 106(h)(3), ensures that the necessary financial resources are identified, available, and monitored throughout the life of the project. An annual financial plan is a comprehensive document that reflects the project's scope, schedule, cost estimate, and funding structure to provide reasonable assurance that there will be sufficient funding available to implement and complete the entire project, or a fundable phase of the project, as planned.

Respondents: Approximately 100 project sponsors per year.

Frequency: The financial plan is submitted annually. The first financial plan is submitted prior to the authorization of Federal funds for construction and updates are submitted each year until construction completion.

The project management plan is first submitted prior to the start of construction and then updated as significant changes to the project occur during construction.

Estimated Average Burden per Response: Approximately 40 hours for the initial submittal of each plan and 20 hours for each update.

Estimated Total Annual Burden Hours: Approximately 20 initial plans and 80 plan updates are submitted each year. For a total of approximately, 2,400 hours each year.

Public Comments Invited: You are asked to comment on any aspect of this information collection, including: (1) Whether the proposed collection is necessary for the FHWA's performance; (2) the accuracy of the estimated burdens; (3) ways for the FHWA to enhance the quality, usefulness, and clarity of the collected information; and (4) ways that the burden could be minimized, including the use of electronic technology, without reducing the quality of the collected information. The agency will summarize and/or include your comments in the request for OMB's clearance of this information collection.

Authority: The Paperwork Reduction Act of 1995; 44 U.S.C. Chapter 35, as amended; and 49 CFR 1.48.

Issued On: July 19, 2018. **Michael Howell,** *Information Collection Officer.* [FR Doc. 2018–15880 Filed 7–24–18; 8:45 am] **BILLING CODE 4910–22–P**

DEPARTMENT OF TRANSPORTATION

Maritime Administration

[Docket No. MARAD-2018-0119]

Requested Administrative Waiver of the Coastwise Trade Laws: Vessel INDECENT PROPOSAL IV; Invitation for Public Comments

AGENCY: Maritime Administration, DOT. **ACTION:** Notice.

SUMMARY: The Secretary of Transportation, as represented by the Maritime Administration (MARAD), is authorized to grant waivers of the U.S.build requirement of the coastwise laws under certain circumstances. A request for such a waiver has been received by MARAD. The vessel, and a brief description of the proposed service, is listed below.

DATES: Submit comments on or before August 24, 2018.

ADDRESSES: Comments should refer to docket number MARAD-2018-0119. Written comments may be submitted by hand or by mail to the Docket Clerk. U.S. Department of Transportation, Docket Operations, M-30, West Building Ground Floor, Room W12–140, 1200 New Jersey Avenue SE, Washington, DC 20590. You may also send comments electronically via the internet at http://www.regulations.gov. All comments will become part of this docket and will be available for inspection and copying at the above address between 10:00 a.m. and 5:00 p.m., Monday through Friday, except federal holidays. An electronic version of this document and all documents entered into this docket is available at http://www.regulations.gov.

FOR FURTHER INFORMATION CONTACT:

Bianca Carr, U.S. Department of Transportation, Maritime Administration, 1200 New Jersey Avenue SE, Room W23–453, Washington, DC 20590. Telephone 202– 366–9309, Email *Bianca.carr@dot.gov.*

SUPPLEMENTARY INFORMATION: As described by the applicant the intended service of the vessel INDECENT PROPOSAL IV is:

 —INTENDED COMMERCIAL USE OF VESSEL: "The Vessel will be used for limited high end guest charter."
 —GEOGRAPHIC REGION: "California" The complete application is given in DOT docket MARAD-2018-0119 at http://www.regulations.gov. Interested parties may comment on the effect this action may have on U.S. vessel builders or businesses in the U.S. that use U.S.flag vessels. If MARAD determines, in accordance with 46 U.S.C. 12121 and MARAD's regulations at 46 CFR part 388, that the issuance of the waiver will have an unduly adverse effect on a U.S.vessel builder or a business that uses U.S.-flag vessels in that business, a waiver will not be granted. Comments should refer to the docket number of this notice and the vessel name in order for MARAD to properly consider the comments. Comments should also state the commenter's interest in the waiver application, and address the waiver criteria given in section 388.4 of MARAD's regulations at 46 CFR part 388.

Privacy Act

In accordance with 5 U.S.C. 553(c), DOT/MARAD solicits comments from the public to better inform its rulemaking process. DOT/MARAD posts these comments, without edit, to www.regulations.gov, as described in the system of records notice, DOT/ALL-14 FDMS, accessible through www.dot.gov/privacy. In order to facilitate comment tracking and response, we encourage commenters to provide their name, or the name of their organization; however, submission of names is completely optional. Whether or not commenters identify themselves, all timely comments will be fully considered. If you wish to provide comments containing proprietary or confidential information, please contact the agency for alternate submission instructions.

Authority: 49 CFR 1.93(a), 46 U.S.C. 55103, 46 U.S.C. 12121.

Dated: July 20, 2018. By Order of the Maritime Administrator. **T. Mitchell Hudson, Jr.**,

Secretary, Maritime Administration.

[FR Doc. 2018–15864 Filed 7–24–18; 8:45 am] BILLING CODE 4910–81–P

DEPARTMENT OF TRANSPORTATION

Maritime Administration

[Docket No. MARAD-2018-0115]

Requested Administrative Waiver of the Coastwise Trade Laws: Vessel CYNDERELLA; Invitation for Public Comments

AGENCY: Maritime Administration, DOT. **ACTION:** Notice.

SUMMARY: The Secretary of Transportation, as represented by the Maritime Administration (MARAD), is authorized to grant waivers of the U.S.build requirement of the coastwise laws under certain circumstances. A request for such a waiver has been received by MARAD. The vessel, and a brief description of the proposed service, is listed below.

DATES: Submit comments on or before August 24, 2018.

ADDRESSES: Comments should refer to docket number MARAD-2018-0115. Written comments may be submitted by hand or by mail to the Docket Clerk, U.S. Department of Transportation, Docket Operations, M-30, West Building Ground Floor, Room W12–140, 1200 New Jersey Avenue SE, Washington, DC 20590. You may also send comments electronically via the internet at *http://www.regulations.gov*. All comments will become part of this docket and will be available for inspection and copying at the above address between 10:00 a.m. and 5:00 p.m., Monday through Friday, except federal holidays. An electronic version of this document and all documents entered into this docket is available at http://www.regulations.gov.

FOR FURTHER INFORMATION CONTACT: Bianca Carr, U.S. Department of Transportation, Maritime Administration, 1200 New Jersey Avenue SE, Room W23–453, Washington, DC 20590. Telephone 202– 366–9309, Email *Bianca.carr@dot.gov.*

SUPPLEMENTARY INFORMATION: As described by the applicant the intended service of the vessel CYNDERELLA is:

- —Intended Commercial Use of Vessel:
 "Carrying passengers for hire"
 —Geographic Region: "Florida,
- Maryland, Delaware, New Jersey, New York (excluding New York Harbor), Connecticut, Rhode Island, Massachusetts, New Hampshire, Maine''

The complete application is given in DOT docket MARAD-2018-0115 at *http://www.regulations.gov.* Interested parties may comment on the effect this action may have on U.S. vessel builders or businesses in the U.S. that use U.S.flag vessels. If MARAD determines, in accordance with 46 U.S.C. 12121 and MARAD's regulations at 46 CFR part 388, that the issuance of the waiver will have an unduly adverse effect on a U.S.vessel builder or a business that uses U.S.-flag vessels in that business, a waiver will not be granted. Comments should refer to the docket number of this notice and the vessel name in order for MARAD to properly consider the

comments. Comments should also state the commenter's interest in the waiver application, and address the waiver criteria given in section 388.4 of MARAD's regulations at 46 CFR part 388.

Privacy Act

In accordance with 5 U.S.C. 553(c), DOT/MARAD solicits comments from the public to better inform its rulemaking process. DOT/MARAD posts these comments, without edit, to www.regulations.gov, as described in the system of records notice, DOT/ALL-14 FDMS, accessible through www.dot.gov/privacy. In order to facilitate comment tracking and response, we encourage commenters to provide their name, or the name of their organization; however, submission of names is completely optional. Whether or not commenters identify themselves, all timely comments will be fully considered. If you wish to provide comments containing proprietary or confidential information, please contact the agency for alternate submission instructions.

(Authority: 49 CFR 1.93(a), 46 U.S.C. 55103, 46 U.S.C. 12121)

Dated: July 20, 2018.

By Order of the Maritime Administrator.

T. Mitchell Hudson, Jr.,

Secretary, Maritime Administration. [FR Doc. 2018–15863 Filed 7–24–18; 8:45 am] BILLING CODE 4910–81–P

DEPARTMENT OF TRANSPORTATION

Maritime Administration

[Docket No. MARAD-2018-0118]

Requested Administrative Waiver of the Coastwise Trade Laws: Vessel LA PEREGRINA; Invitation for Public Comments

AGENCY: Maritime Administration, DOT. **ACTION:** Notice.

SUMMARY: The Secretary of Transportation, as represented by the Maritime Administration (MARAD), is authorized to grant waivers of the U.S.build requirement of the coastwise laws under certain circumstances. A request for such a waiver has been received by MARAD. The vessel, and a brief description of the proposed service, is listed below.

DATES: Submit comments on or before August 24, 2018.

ADDRESSES: Comments should refer to docket number MARAD–2018–0118. Written comments may be submitted by

hand or by mail to the Docket Clerk, U.S. Department of Transportation, Docket Operations, M-30, West Building Ground Floor, Room W12–140, 1200 New Jersey Avenue SE, Washington, DC 20590. You may also send comments electronically via the internet at http://www.regulations.gov. All comments will become part of this docket and will be available for inspection and copying at the above address between 10:00 a.m. and 5:00 p.m., Monday through Friday, except federal holidays. An electronic version of this document and all documents entered into this docket is available at http://www.regulations.gov.

FOR FURTHER INFORMATION CONTACT:

Bianca Carr, U.S. Department of Transportation, Maritime Administration, 1200 New Jersey Avenue SE, Room W23–453, Washington, DC 20590. Telephone 202– 366–9309, Email *Bianca.carr@dot.gov.*

SUPPLEMENTARY INFORMATION: As

described by the applicant the intended service of the vessel LA PEREGRINA is:

- —Intended Commercial Use of Vessel: "Crewed charter sailing trips; *i.e.*, commercial transport of up to six passengers."
- -Geographic Region: "Texas; Louisiana; Mississippi; Alabama; Florida; Georgia; South Carolina; North Carolina; Virginia; Maryland; Delaware; New Jersey; New York (excluding New York Harbor); Connecticut, Rhode Island, Massachusetts; New Hampshire; Maine"

The complete application is given in DOT docket MARAD-2018-0118 at http://www.regulations.gov. Interested parties may comment on the effect this action may have on U.S. vessel builders or businesses in the U.S. that use U.S.flag vessels. If MARAD determines, in accordance with 46 U.S.C. 12121 and MARAD's regulations at 46 CFR part 388, that the issuance of the waiver will have an unduly adverse effect on a U.S.vessel builder or a business that uses U.S.-flag vessels in that business, a waiver will not be granted. Comments should refer to the docket number of this notice and the vessel name in order for MARAD to properly consider the comments. Comments should also state the commenter's interest in the waiver application, and address the waiver criteria given in section 388.4 of MARAD's regulations at 46 CFR part 388.

Privacy Act

In accordance with 5 U.S.C. 553(c), DOT/MARAD solicits comments from the public to better inform its

rulemaking process. DOT/MARAD posts these comments, without edit, to www.regulations.gov, as described in the system of records notice, DOT/ALL-14 FĎMS, accessible through www.dot.gov/privacy. In order to facilitate comment tracking and response, we encourage commenters to provide their name, or the name of their organization; however, submission of names is completely optional. Whether or not commenters identify themselves, all timely comments will be fully considered. If you wish to provide comments containing proprietary or confidential information, please contact the agency for alternate submission instructions.

(Authority: 49 CFR 1.93(a), 46 U.S.C. 55103, 46 U.S.C. 12121.)

Dated: July 20, 2018. By Order of the Maritime Administrator.

T. Mitchell Hudson, Jr.,

Secretary, Maritime Administration. [FR Doc. 2018–15865 Filed 7–24–18; 8:45 am] BILLING CODE 4910–81–P

DEPARTMENT OF TRANSPORTATION

Maritime Administration

[Docket No. MARAD-2018-0116]

Requested Administrative Waiver of the Coastwise Trade Laws: Vessel BUEN CAMINO; Invitation for Public Comments

AGENCY: Maritime Administration, DOT. **ACTION:** Notice.

SUMMARY: The Secretary of Transportation, as represented by the Maritime Administration (MARAD), is authorized to grant waivers of the U.S.build requirement of the coastwise laws under certain circumstances. A request for such a waiver has been received by MARAD. The vessel, and a brief description of the proposed service, is listed below.

DATES: Submit comments on or before August 24, 2018.

ADDRESSES: Comments should refer to docket number MARAD–2018–0116. Written comments may be submitted by hand or by mail to the Docket Clerk, U.S. Department of Transportation, Docket Operations, M–30, West Building Ground Floor, Room W12–140, 1200 New Jersey Avenue SE, Washington, DC 20590. You may also send comments electronically via the internet at *http://www.regulations.gov*. All comments will become part of this docket and will be available for inspection and copying at the above address between 10:00 a.m. and 5:00 p.m., Monday through Friday, except federal holidays. An electronic version of this document and all documents entered into this docket is available at *http://www.regulations.gov.*

FOR FURTHER INFORMATION CONTACT:

Bianca Carr, U.S. Department of Transportation, Maritime Administration, 1200 New Jersey Avenue SE, Room W23–453, Washington, DC 20590. Telephone 202– 366–9309, Email *Bianca.carr@dot.gov*.

SUPPLEMENTARY INFORMATION: As described by the applicant the intended service of the vessel BUEN CAMINO is:

—INTENDED COMMERCIAL USE OF VESSEL: "Local scenic tours" —GEOGRAPHIC REGION: "California"

The complete application is given in DOT docket MARAD-2018-0116 at http://www.regulations.gov. Interested parties may comment on the effect this action may have on U.S. vessel builders or businesses in the U.S. that use U.S.flag vessels. If MARAD determines, in accordance with 46 U.S.C. 12121 and MARAD's regulations at 46 CFR part 388, that the issuance of the waiver will have an unduly adverse effect on a U.S.vessel builder or a business that uses U.S.-flag vessels in that business, a waiver will not be granted. Comments should refer to the docket number of this notice and the vessel name in order for MARAD to properly consider the comments. Comments should also state the commenter's interest in the waiver application, and address the waiver criteria given in section 388.4 of MARAD's regulations at 46 CFR part 388.

Privacy Act

In accordance with 5 U.S.C. 553(c), DOT/MARAD solicits comments from the public to better inform its rulemaking process. DOT/MARAD posts these comments, without edit, to www.regulations.gov, as described in the system of records notice, DOT/ALL-14 FDMS, accessible through www.dot.gov/privacy. In order to facilitate comment tracking and response, we encourage commenters to provide their name, or the name of their organization; however, submission of names is completely optional. Whether or not commenters identify themselves, all timely comments will be fully considered. If you wish to provide comments containing proprietary or confidential information, please contact the agency for alternate submission instructions.

(Authority: 49 CFR 1.93(a), 46 U.S.C. 55103, 46 U.S.C. 12121)

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Dated: July 20, 2018. By Order of the Maritime Administrator. **T. Mitchell Hudson, Jr.**,

Secretary, Maritime Administration. [FR Doc. 2018–15862 Filed 7–24–18; 8:45 am] BILLING CODE 4910–81–P

DEPARTMENT OF TRANSPORTATION

Maritime Administration

[Docket No. MARAD-2018-0121]

Requested Administrative Waiver of the Coastwise Trade Laws: Vessel SCARLET; Invitation for Public Comments

AGENCY: Maritime Administration, DOT. **ACTION:** Notice.

SUMMARY: The Secretary of Transportation, as represented by the Maritime Administration (MARAD), is authorized to grant waivers of the U.S.build requirement of the coastwise laws under certain circumstances. A request for such a waiver has been received by MARAD. The vessel, and a brief description of the proposed service, is listed below.

DATES: Submit comments on or before August 24, 2018.

ADDRESSES: Comments should refer to docket number MARAD-2018-0121. Written comments may be submitted by hand or by mail to the Docket Clerk, U.S. Department of Transportation, Docket Operations, M-30, West Building Ground Floor, Room W12–140. 1200 New Jersey Avenue SE, Washington, DC 20590. You may also send comments electronically via the internet at http://www.regulations.gov. All comments will become part of this docket and will be available for inspection and copying at the above address between 10:00 a.m. and 5:00 p.m., Monday through Friday, except federal holidays. An electronic version of this document and all documents entered into this docket is available at http://www.regulations.gov.

FOR FURTHER INFORMATION CONTACT:

Bianca Carr, U.S. Department of Transportation, Maritime Administration, 1200 New Jersey Avenue SE, Room W23–453, Washington, DC 20590. Telephone 202– 366–9309, Email *Bianca.carr@dot.gov.*

SUPPLEMENTARY INFORMATION: As

described by the applicant the intended service of the vessel SCARLET is:

- —Intended Commercial Use Of Vessel: "passenger yacht charters"
- —Geographic Region: ''Florida, Georgia, South Carolina, North Carolina, Virginia, Delaware, Massachusetts,

New Hampshire, Maine, Alabama, Louisiana, Texas''

The complete application is given in DOT docket MARAD-2018-0121 at http://www.regulations.gov. Interested parties may comment on the effect this action may have on U.S. vessel builders or businesses in the U.S. that use U.S.flag vessels. If MARAD determines, in accordance with 46 U.S.C. 12121 and MARAD's regulations at 46 CFR part 388, that the issuance of the waiver will have an unduly adverse effect on a U.S.vessel builder or a business that uses U.S.-flag vessels in that business, a waiver will not be granted. Comments should refer to the docket number of this notice and the vessel name in order for MARAD to properly consider the comments. Comments should also state the commenter's interest in the waiver application, and address the waiver criteria given in section 388.4 of MARAD's regulations at 46 CFR part 388.

Privacy Act

In accordance with 5 U.S.C. 553(c), DOT/MARAD solicits comments from the public to better inform its rulemaking process. DOT/MARAD posts these comments, without edit, to www.regulations.gov, as described in the system of records notice, DOT/ALL-14 FDMS, accessible through www.dot.gov/privacy. In order to facilitate comment tracking and response, we encourage commenters to provide their name, or the name of their organization; however, submission of names is completely optional. Whether or not commenters identify themselves, all timely comments will be fully considered. If you wish to provide comments containing proprietary or confidential information, please contact the agency for alternate submission instructions.

(Authority: 49 CFR 1.93(a), 46 U.S.C. § 55103, 46 U.S.C. § 12121)

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Dated: July 20, 2018. By Order of the Maritime Administrator.

T. Mitchell Hudson, Jr.,

Secretary, Maritime Administration. [FR Doc. 2018–15867 Filed 7–24–18; 8:45 am] BILLING CODE 4910–81–P

DEPARTMENT OF TRANSPORTATION

Maritime Administration

[[Docket No. MARAD-2018-0117]

Requested Administrative Waiver of the Coastwise Trade Laws: Vessel REEL NAUTI; Invitation for Public Comments

AGENCY: Maritime Administration, DOT. **ACTION:** Notice.

SUMMARY: The Secretary of Transportation, as represented by the Maritime Administration (MARAD), is authorized to grant waivers of the U.S.build requirement of the coastwise laws under certain circumstances. A request for such a waiver has been received by MARAD. The vessel, and a brief description of the proposed service, is listed below.

DATES: Submit comments on or before August 24, 2018.

ADDRESSES: Comments should refer to docket number MARAD-2018-0117. Written comments may be submitted by hand or by mail to the Docket Clerk, U.S. Department of Transportation, Docket Operations, M-30, West Building Ground Floor, Room W12–140, 1200 New Jersey Avenue SE, Washington, DČ 20590. You may also send comments electronically via the internet at http://www.regulations.gov. All comments will become part of this docket and will be available for inspection and copying at the above address between 10:00 a.m. and 5:00 p.m., Monday through Friday, except federal holidays. An electronic version of this document and all documents entered into this docket is available at http://www.regulations.gov.

FOR FURTHER INFORMATION CONTACT:

Bianca Carr, U.S. Department of Transportation, Maritime Administration, 1200 New Jersey Avenue SE, Room W23–453, Washington, DC 20590. Telephone 202– 366–9309, Email *Bianca.carr@dot.gov*.

SUPPLEMENTARY INFORMATION: As described by the applicant the intended service of the vessel REEL NAUTI is: —Intended Commercial Use Of Vessel:

The complete application is given in DOT docket MARAD–2018–0117 at *http://www.regulations.gov.* Interested parties may comment on the effect this action may have on U.S. vessel builders or businesses in the U.S. that use U.S.flag vessels. If MARAD determines, in accordance with 46 U.S.C. 12121 and MARAD's regulations at 46 CFR part 388, that the issuance of the waiver will have an unduly adverse effect on a U.S.vessel builder or a business that uses U.S.-flag vessels in that business, a waiver will not be granted. Comments should refer to the docket number of this notice and the vessel name in order for MARAD to properly consider the comments. Comments should also state the commenter's interest in the waiver application, and address the waiver criteria given in section 388.4 of MARAD's regulations at 46 CFR part 388.

Privacy Act

In accordance with 5 U.S.C. 553(c), DOT/MARAD solicits comments from the public to better inform its rulemaking process. DOT/MARAD posts these comments, without edit, to www.regulations.gov, as described in the system of records notice, DOT/ALL-14 FDMS, accessible through www.dot.gov/privacy. In order to facilitate comment tracking and response, we encourage commenters to provide their name, or the name of their organization; however, submission of names is completely optional. Whether or not commenters identify themselves, all timely comments will be fully considered. If you wish to provide comments containing proprietary or confidential information, please contact the agency for alternate submission instructions.

(Authority: 49 CFR 1.93(a), 46 U.S.C. 55103, 46 U.S.C. 12121) *

Dated: July 20, 2018. By Order of the Maritime Administrator.

T. Mitchell Hudson, Jr., Secretary, Maritime Administration. [FR Doc. 2018-15866 Filed 7-24-18; 8:45 am]

BILLING CODE 4910-81-P

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DEPARTMENT OF TRANSPORTATION

Maritime Administration

[Docket No. MARAD-2018-0120]

Requested Administrative Waiver of the Coastwise Trade Laws: Vessel VINTAGE; Invitation for Public Comments

AGENCY: Maritime Administration, DOT. **ACTION:** Notice.

SUMMARY: The Secretary of Transportation, as represented by the Maritime Administration (MARAD), is authorized to grant waivers of the U.S.build requirement of the coastwise laws under certain circumstances. A request for such a waiver has been received by MARAD. The vessel, and a brief

description of the proposed service, is listed below.

DATES: Submit comments on or before August 24, 2018.

ADDRESSES: Comments should refer to docket number MARAD-2018-0120. Written comments may be submitted by hand or by mail to the Docket Clerk, U.S. Department of Transportation, Docket Operations, M-30, West Building Ground Floor, Room W12-140, 1200 New Jersey Avenue SE, Washington, DC 20590. You may also send comments electronically via the internet at http://www.regulations.gov. All comments will become part of this docket and will be available for inspection and copying at the above address between 10:00 a.m. and 5:00 p.m., Monday through Friday, except federal holidays. An electronic version of this document and all documents entered into this docket is available at http://www.regulations.gov.

FOR FURTHER INFORMATION CONTACT:

Bianca Carr, U.S. Department of Transportation, Maritime Administration, 1200 New Jersey Avenue SE, Room W23-453, Washington, DC 20590. Telephone 202-366–9309, Email Bianca.carr@dot.gov.

SUPPLEMENTARY INFORMATION: As described by the applicant the intended service of the vessel VINTAGE is:

- VESSEL: To charter the vessel on Lake Michigan and Chicago River (inner city of Chicago). -GEOGRAPHIC REGIÓN: ''Illinois,
- Michigan, and Wisconsin"

The complete application is given in DOT docket MARAD-2018-0120 at http://www.regulations.gov. Interested parties may comment on the effect this action may have on U.S. vessel builders or businesses in the U.S. that use U.S.flag vessels. If MARAD determines, in accordance with 46 U.S.C. 12121 and MARAD's regulations at 46 CFR part 388, that the issuance of the waiver will have an unduly adverse effect on a U.S.vessel builder or a business that uses U.S.-flag vessels in that business, a waiver will not be granted. Comments should refer to the docket number of this notice and the vessel name in order for MARAD to properly consider the comments. Comments should also state the commenter's interest in the waiver application, and address the waiver criteria given in section 388.4 of MARAD's regulations at 46 CFR part 388.

Privacy Act

In accordance with 5 U.S.C. 553(c), DOT/MARAD solicits comments from the public to better inform its

rulemaking process. DOT/MARAD posts these comments, without edit, to www.regulations.gov, as described in the system of records notice, DOT/ALL-14 FĎMS, accessible through www.dot.gov/privacy. In order to facilitate comment tracking and response, we encourage commenters to provide their name, or the name of their organization; however, submission of names is completely optional. Whether or not commenters identify themselves, all timely comments will be fully considered. If you wish to provide comments containing proprietary or confidential information, please contact the agency for alternate submission instructions.

(Authority: 49 CFR 1.93(a), 46 U.S.C. 55103, 46 U.S.C. 12121)

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Dated: July 20, 2018. By Order of the Maritime Administrator.

T. Mitchell Hudson, Jr.,

Secretary, Maritime Administration. [FR Doc. 2018-15868 Filed 7-24-18; 8:45 am] BILLING CODE 4910-81-P

DEPARTMENT OF TRANSPORTATION

Pipeline and Hazardous Materials Safety Administration

[Docket No. PHMSA-2017-0158]

Pipeline Safety: Request for Special Permit: Empire Pipeline—a National **Fuel Gas Company**

AGENCY: Pipeline and Hazardous Materials Safety Administration (PHMSA); DOT. **ACTION:** Notice.

SUMMARY: PHMSA is publishing this notice to seek public comments on a request for a special permit from a natural gas pipeline operator that seeks relief from compliance with certain requirements in the Federal pipeline safety regulations to operate at an alternative maximum allowable operating pressure (MAOP) of up to 80 percent of the pipe's specified minimum yield strength (SMYS) on an existing 24inch diameter pipeline. 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 August 24, 2018.

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 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.Reglations.gov.* Comments, including any personal information provided, are posted without changes or edits to *http:// www.Regulations.gov.*

FOR FURTHER INFORMATION CONTACT:

General: Ms. Kay McIver by telephone at 202–366–0113, or email at *kay.mciver@dot.gov.*

Technical: Mr. Steve Nanney by telephone at 713–628–7479, or by email at *Steve.Nanney@dot.gov.*

SUPPLEMENTARY INFORMATION: Empire Pipeline, owned by National Fuel Gas Company, has requested a special permit for 49 Code of Federal Regulations (CFR) 192.112(c)(1) and (2), 192.112(f)(3), 192.328(a), and 192.328(e) for the Empire Connector Pipeline (ECP) to be able to operate at alternative MAOP of up to 80 percent SMYS of the pipe. To operate a natural gas pipeline at alternative MAOP, an operator must design, construct, and operate the pipeline in accordance with the Federal pipeline safety regulations of 49 CFR 192.112, 192.328, and 192.620.

Empire Pipeline is the operator of ECP. ECP is an interstate natural gas pipeline with 76.6 miles of 24-inch diameter pipe. The ECP runs north to south, from Victor to Coring, New York, through the counties of Ontario, Yates, Schuyler, Chemung and Steuben. The special permit requested segments of

ECP total 69.8 miles and are in Class 1 and 2 locations and includes some high consequence areas. The ECP special permit segments are mostly in rural areas though agricultural fields, open pastures, wooden areas, and mostly flat to rolling terrain. The ECP construction began in 2007 and the line was placed in service on December 10, 2008. The ECP presently has a MAOP of 1,290 pounds per square inch gauge (psig) and has operated at, or below the MAOP for the life of the pipeline. ECP proposed to utilize alternative MAOP to allow increasing the pipeline MAOP from 1,290 psig up to 1,440 psig. The ECP has 6.5 miles of Class 3 locations that are designed for the alternative MAOP. The Class 3 locations will be required to meet the special permit conditions. The Class 3 locations are proposed to be included in the special permit for a total mileage of 76.6 miles.

A draft environmental assessment (DEA) and proposed special permit conditions for ECP's operations at alternative MAOP are provided in the docket at http://www.Regulations.gov. In the DEA, Empire proposes alternative measures and activities that will be taken to mitigate safety and environmental risks in the continued operation of the ECP at the alternative MAOP. The proposed special permit conditions are a draft of operational measures that would be implemented by Empire throughout the life of the ECP special permit to maintain safety at the alternative MAOP.

We invite interested persons to participate by reviewing the special permit request, DEA, and proposed special permit conditions at *http:// www.Regulations.gov*, and by submitting written comments, data, or other views. Please include any comments on potential safety and environmental impacts that may result if the special permit is granted.

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 we receive in making our decision to grant or deny the request.

Issued in Washington, DC, on July 20, 2018, under authority delegated in 49 CFR 1.97.

Alan K. Mayberry,

Associate Administrator for Pipeline Safety. [FR Doc. 2018–15895 Filed 7–24–18; 8:45 am] BILLING CODE 4910–60–P

DEPARTMENT OF THE TREASURY

Multiemployer Pension Plan Application To Reduce Benefits

AGENCY: Department of the Treasury. **ACTION:** Notice of availability; request for comments.

SUMMARY: The Board of Trustees of the Toledo Roofers Local No. 134 Pension Plan, a multiemployer pension plan, has submitted an application to reduce benefits under the plan in accordance with the Multiemployer Pension Reform Act of 2014 (MPRA). The purpose of this notice is to announce that the application submitted by the Board of Trustees of the Toledo Roofers Local No. 134 Pension Plan has been published on the website of the Department of the Treasury (Treasury), and to request public comments on the application from interested parties, including participants and beneficiaries, employee organizations, and contributing employers of the Toledo Roofers Local No. 134 Pension Plan.

DATES: Comments must be received by September 10, 2018.

ADDRESSES: You may submit comments electronically through the Federal eRulemaking Portal at *http:// www.regulations.gov*, in accordance with the instructions on that site. Electronic submissions through *www.regulations.gov* are encouraged.

Comments may also be mailed to the Department of the Treasury, MPRA Office, 1500 Pennsylvania Avenue NW, Room 1224, Washington, DC 20220, Attn: Danielle Norris. Comments sent via facsimile or email will not be accepted.

Additional Instructions. All comments received, including attachments and other supporting materials, will be made available to the public. Do not include any personally identifiable information (such as your Social Security number, name, address, or other contact information) or any other information in your comment or supporting materials that you do not want publicly disclosed. Treasury will make comments available for public inspection and copying on www.regulations.gov or upon request. Comments posted on the internet can be retrieved by most internet search engines.

FOR FURTHER INFORMATION CONTACT: For information regarding the application from the Toledo Roofers Local No. 134 Pension Plan, please contact Treasury at (202) 622–1534 (not a toll-free number).

SUPPLEMENTARY INFORMATION: MPRA amended the Internal Revenue Code to

permit a multiemployer plan that is projected to have insufficient funds to reduce pension benefits payable to participants and beneficiaries if certain conditions are satisfied. In order to reduce benefits, the plan sponsor is required to submit an application to the Secretary of the Treasury, which must be approved or denied in consultation with the Pension Benefit Guaranty Corporation (PBGC) and the Department of Labor.

On June 25, 2018, the Board of Trustees of the Toledo Roofers Local No. 134 Pension Plan submitted an application for approval to reduce benefits under the plan. As required by MPRA, that application has been published on Treasury's website at *https://www.treasury.gov/services/ Pages/Plan-Applications.aspx.* Treasury is publishing this notice in the **Federal Register**, in consultation with PBGC and the Department of Labor, to solicit public comments on all aspects of the Toledo Roofers Local No. 134 Pension Plan application.

Comments are requested from interested parties, including participants and beneficiaries, employee organizations, and contributing employers of the Toledo Roofers Local No. 134 Pension Plan. Consideration will be given to any comments that are timely received by Treasury.

Dated: July 18, 2018.

David Kautter,

Assistant Secretary for Tax Policy. [FR Doc. 2018–15881 Filed 7–24–18; 8:45 am] BILLING CODE 4810–25–P

DEPARTMENT OF THE TREASURY

Multiemployer Pension Plan Application To Reduce Benefits

AGENCY: Department of the Treasury. **ACTION:** Notice of availability; request for comments.

SUMMARY: The Board of Trustees of the Southwest Ohio Regional Council of Carpenters Pension Plan, a multiemployer pension plan, has submitted an application to reduce benefits under the plan in accordance with the Multiemployer Pension Reform Act of 2014 (MPRA). The purpose of this notice is to announce that the application submitted by the Board of Trustees of the Southwest Ohio **Regional Council of Carpenters Pension** Plan has been published on the website of the Department of the Treasury (Treasury), and to request public comments on the application from interested parties, including participants and beneficiaries, employee organizations, and contributing employers of the Southwest Ohio Regional Council of Carpenters Pension Plan.

DATES: Comments must be received by September 10, 2018.

ADDRESSES: You may submit comments electronically through the Federal eRulemaking Portal at *http:// www.regulations.gov,* in accordance with the instructions on that site. Electronic submissions through *www.regulations.gov* are encouraged.

Comments may also be mailed to the Department of the Treasury, MPRA Office, 1500 Pennsylvania Avenue NW, Room 1224, Washington, DC 20220, Attn: Danielle Norris. Comments sent via facsimile or email will not be accepted.

Additional Instructions. All comments received, including attachments and other supporting materials, will be made available to the public. Do not include any personally identifiable information (such as your Social Security number, name, address, or other contact information) or any other information in your comment or supporting materials that you do not want publicly disclosed. Treasury will make comments available for public inspection and copying on www.regulations.gov or upon request. Comments posted on the internet can be retrieved by most internet search engines.

FOR FURTHER INFORMATION CONTACT: For information regarding the application from the Southwest Ohio Regional Council of Carpenters Pension Plan, please contact Treasury at (202) 622–1534 (not a toll-free number).

SUPPLEMENTARY INFORMATION: MPRA amended the Internal Revenue Code to permit a multiemployer plan that is projected to have insufficient funds to reduce pension benefits payable to participants and beneficiaries if certain conditions are satisfied. In order to reduce benefits, the plan sponsor is required to submit an application to the Secretary of the Treasury, which must be approved or denied in consultation with the Pension Benefit Guaranty Corporation (PBGC) and the Department of Labor.

On June 29, 2018, the Board of Trustees of the Southwest Ohio Regional Council of Carpenters Pension Plan submitted an application for approval to reduce benefits under the plan. As required by MPRA, that application has been published on Treasury's website at *https:// www.treasury.gov/services/Pages/Plan-Applications.aspx.* Treasury is publishing this notice in the **Federal** **Register**, in consultation with PBGC and the Department of Labor, to solicit public comments on all aspects of the Southwest Ohio Regional Council of Carpenters Pension Plan application.

Comments are requested from interested parties, including participants and beneficiaries, employee organizations, and contributing employers of the Southwest Ohio Regional Council of Carpenters Pension Plan. Consideration will be given to any comments that are timely received by Treasury.

Dated: July 18, 2018.

David Kautter,

Assistant Secretary for Tax Policy. [FR Doc. 2018–15889 Filed 7–24–18; 8:45 am] BILLING CODE 4810–25–P

DEPARTMENT OF THE TREASURY

Multiemployer Pension Plan Application To Reduce Benefits

AGENCY: Department of the Treasury. **ACTION:** Notice of availability; request for comments.

SUMMARY: The Board of Trustees of the Local 807 Labor-Management Pension Plan, a multiemployer pension plan, has submitted an application to reduce benefits under the plan in accordance with the Multiemployer Pension Reform Act of 2014 (MPRA). The purpose of this notice is to announce that the application submitted by the Board of Trustees of the Local 807 Labor-Management Pension Plan has been published on the website of the Department of the Treasury (Treasury), and to request public comments on the application from interested parties, including participants and beneficiaries, employee organizations, and contributing employers of the Local 807 Labor-Management Pension Plan.

DATES: Comments must be received by September 10, 2018.

ADDRESSES: You may submit comments electronically through the Federal eRulemaking Portal at *http:// www.regulations.gov*, in accordance with the instructions on that site. Electronic submissions through *www.regulations.gov* are encouraged.

Comments may also be mailed to the Department of the Treasury, MPRA Office, 1500 Pennsylvania Avenue NW, Room 1224, Washington, DC 20220, Attn: Danielle Norris. Comments sent via facsimile or email will not be accepted.

Additional Instructions. All comments received, including attachments and other supporting materials, will be made available to the public. Do not include any personally identifiable information (such as your Social Security number, name, address, or other contact information) or any other information in your comment or supporting materials that you do not want publicly disclosed. Treasury will make comments available for public inspection and copying on *www.regulations.gov* or upon request. Comments posted on the internet can be retrieved by most internet search engines.

FOR FURTHER INFORMATION CONTACT: For information regarding the application from the Local 807 Labor-Management Pension Plan, please contact Treasury at (202) 622–1534 (not a toll-free number).

SUPPLEMENTARY INFORMATION: MPRA amended the Internal Revenue Code to permit a multiemployer plan that is projected to have insufficient funds to reduce pension benefits payable to participants and beneficiaries if certain conditions are satisfied. In order to reduce benefits, the plan sponsor is required to submit an application to the Secretary of the Treasury, which must be approved or denied in consultation with the Pension Benefit Guaranty Corporation (PBGC) and the Department of Labor.

On June 29, 2018, the Board of Trustees of the Local 807 Labor-Management Pension Plan submitted an application for approval to reduce benefits under the plan. As required by MPRA, that application has been published on Treasury's website at *https://www.treasury.gov/services/ Pages/Plan-Applications.aspx.* Treasury is publishing this notice in the **Federal Register**, in consultation with PBGC and the Department of Labor, to solicit public comments on all aspects of the Local 807 Labor-Management Pension Plan application.

Comments are requested from interested parties, including participants and beneficiaries, employee organizations, and contributing employers of the Local 807 Labor-Management Pension Plan. Consideration will be given to any comments that are timely received by Treasury. Dated: July 18, 2018. David Kautter, Assistant Secretary for Tax Policy. [FR Doc. 2018–15886 Filed 7–24–18; 8:45 am] BILLING CODE 4810–25–P

DEPARTMENT OF THE TREASURY

Multiemployer Pension Plan Application To Reduce Benefits

AGENCY: Department of the Treasury. **ACTION:** Notice of availability; request for comments.

SUMMARY: The Board of Trustees of the Mid-Jersey Trucking Industry and Local No. 701 Pension Fund, a multiemployer pension plan, has submitted an application to reduce benefits under the plan in accordance with the Multiemployer Pension Reform Act of 2014 (MPRA). The purpose of this notice is to announce that the application submitted by the Board of Trustees of the Mid-Jersey Trucking Industry and Local No. 701 Pension Fund has been published on the website of the Department of the Treasury (Treasury), and to request public comments on the application from interested parties, including participants and beneficiaries, employee organizations, and contributing employers of the Mid-Jersey Trucking Industry and Local No. 701 Pension Fund.

DATES: Comments must be received by September 10, 2018.

ADDRESSES: You may submit comments electronically through the Federal eRulemaking Portal at *http:// www.regulations.gov,* in accordance with the instructions on that site. Electronic submissions through *www.regulations.gov* are encouraged.

Comments may also be mailed to the Department of the Treasury, MPRA Office, 1500 Pennsylvania Avenue NW, Room 1224, Washington, DC 20220, Attn: Danielle Norris. Comments sent via facsimile or email will not be accepted.

Additional Instructions. All comments received, including attachments and other supporting materials, will be made available to the public. Do not include any personally identifiable information (such as your Social Security number, name, address, or other contact information) or any other information in your comment or supporting materials that you do not want publicly disclosed. Treasury will make comments available for public inspection and copying on *www.regulations.gov* or upon request. Comments posted on the internet can be retrieved by most internet search engines.

FOR FURTHER INFORMATION CONTACT: For information regarding the application from the Mid-Jersey Trucking Industry and Local No. 701 Pension Fund, please contact Treasury at (202) 622–1534 (not a toll-free number).

SUPPLEMENTARY INFORMATION: MPRA amended the Internal Revenue Code to permit a multiemployer plan that is projected to have insufficient funds to reduce pension benefits payable to participants and beneficiaries if certain conditions are satisfied. In order to reduce benefits, the plan sponsor is required to submit an application to the Secretary of the Treasury, which must be approved or denied in consultation with the Pension Benefit Guaranty Corporation (PBGC) and the Department of Labor.

On June 27, 2018, the Board of Trustees of the Mid-Jersey Trucking Industry and Local No. 701 Pension Fund submitted an application for approval to reduce benefits under the plan. As required by MPRA, that application has been published on Treasury's website at *https://* www.treasury.gov/services/Pages/Plan-Applications.aspx. Treasury is publishing this notice in the Federal Register, in consultation with PBGC and the Department of Labor, to solicit public comments on all aspects of the Mid-Jersey Trucking Industry and Local No. 701 Pension Fund application.

Comments are requested from interested parties, including participants and beneficiaries, employee organizations, and contributing employers of the Mid-Jersey Trucking Industry and Local No. 701 Pension Fund. Consideration will be given to any comments that are timely received by Treasury.

Dated: July 18, 2018.

David Kautter,

Assistant Secretary for Tax Policy. [FR Doc. 2018–15888 Filed 7–24–18; 8:45 am] BILLING CODE 4810–25–P



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Part II

Department of Health and Human Services

Secretarial Review and Publication of the National Quality Forum 2017 Annual Report to Congress and the Secretary of the Department of Health and Human Services Submitted by the Consensus-Based Entity Regarding Performance Measurement; Notice

DEPARTMENT OF HEALTH AND HUMAN SERVICES

[CMS-3348-N]

Secretarial Review and Publication of the National Quality Forum 2017 Annual Report to Congress and the Secretary of the Department of Health and Human Services Submitted by the Consensus-Based Entity Regarding Performance Measurement

AGENCY: Office of the Secretary of Health and Human Services, HHS. **ACTION:** Notice.

SUMMARY: This notice acknowledges the Secretary of the Department of Health and Human Services' (the Secretary) receipt and review of the National Quality Forum 2017 Annual Report to Congress and the Secretary submitted by the consensus-based entity under contract with the Secretary in accordance with the Social Security Act. The Secretary has reviewed and is publishing the report in the **Federal Register** together with the Secretary's comments on the report not later than 6 months after receiving the report in accordance with the Act.

FOR FURTHER INFORMATION CONTACT: Sophia Chan, (410) 786–5050. SUPPLEMENTARY INFORMATION:

I. Background

The United States Department of Health and Human Services (HHS) has long recognized that a high functioning health care system that provides higher quality care requires accurate, valid, and reliable measurement of quality and efficiency. The Medicare Improvements for Patients and Providers Act of 2008 (MIPPA) (Pub. L. 110-275) added section 1890 of the Social Security Act (the Act), which requires the Secretary of the Department of Health and Human Services (the Secretary) to contract with the consensus-based entity (CBE) to perform multiple duties designed to help improve performance measurement. Section 3014 of the Patient Protection and Affordable Care Act (the Affordable Care Act) (Pub. L. 111-148) expanded the duties of the CBE to help in the identification of gaps in available measures and to improve the selection of measures used in health care programs.

HHS awarded a competitive contract to the National Quality Forum (NQF) in January 2009 to fulfill the requirements of section 1890 of the Act. A second, multi-year contract was awarded to NQF after an open competition in 2012. A third, multi-year contract was awarded again to NQF after an open competition in 2017. Section 1890(b) of the Act requires the following:

Priority Setting Process: Formulation of a National Strategy and Priorities for Health Care Performance Measurement. The CBE must synthesize evidence and convene key stakeholders to make recommendations on an integrated national strategy and priorities for health care performance measurement in all applicable settings. In doing so, the CBE is to give priority to measures that: (1) Address the health care provided to patients with prevalent, high-cost chronic diseases; (2) have the greatest potential for improving quality, efficiency, and patient-centered health care; and (3) may be implemented rapidly due to existing evidence, standards of care, or other reasons. Additionally, the CBE must take into account measures that: (1) May assist consumers and patients in making informed health care decisions; (2) address health disparities across groups and areas; and (3) address the continuum of care across multiple providers, practitioners and settings.

Endorsement of Measures: The ČBE must provide for the endorsement of standardized health care performance measures. This process must consider whether measures are evidence-based, reliable, valid, verifiable, relevant to enhanced health outcomes, actionable at the caregiver level, feasible to collect and report, responsive to variations in patient characteristics such as health status, language capabilities, race or ethnicity, and income level, and are consistent across types of health care providers, including hospitals and physicians.

Maintenance of CBE Endorsed Measures: The CBE is required to establish and implement a process to ensure that endorsed measures are updated (or retired if obsolete) as new evidence is developed.

Review and Endorsement of an Episode Grouper Under the Physician Feedback Program: The CBE must provide for the review and, as appropriate, the endorsement of the episode grouper developed by the Secretary on an expedited basis.

Convening Multi-Stakeholder Groups: The CBE must convene multistakeholder groups to provide input on: (1) The selection of certain categories of quality and efficiency measures, from among such measures that have been endorsed by the entity; (2) such measures that have not been considered for endorsement by such entity but are used or proposed to be used by the Secretary for the collection or reporting of quality and efficiency measures; and (3) national priorities for improvement

in population health and in the delivery of health care services for consideration under the national strategy. The CBE provides input on measures for use in certain specific Medicare programs, for use in programs that report performance information to the public, and for use in health care programs that are not included under the Act. The multistakeholder groups provide input on quality and efficiency measures for various federal health care quality reporting and quality improvement programs including those that address certain Medicare services provided through hospices, hospital inpatient and outpatient facilities, physician offices, cancer hospitals, end stage renal disease (ESRD) facilities, inpatient rehabilitation facilities, long-term care hospitals, psychiatric hospitals, and home health care programs.

Transmission of Multi-Stakeholder Input: Not later than February 1 of each year, the CBE must transmit to the Secretary the input of multi-stakeholder groups.

Annual Report to Congress and the Secretary: Not later than March 1 of each year, the CBE is required to submit to Congress and the Secretary an annual report. The report must describe:

• The implementation of quality and efficiency measurement initiatives and the coordination of such initiatives with quality and efficiency initiatives implemented by other payers;

• Recommendations on an integrated national strategy and priorities for health care performance measurement;

• Performance of the CBE's duties required under its contract with the Secretary;

• Gaps in endorsed quality and efficiency measures, including measures that are within priority areas identified by the Secretary under the national strategy established under section 399HH of the Public Health Service Act (National Quality Strategy), and where quality and efficiency measures are unavailable or inadequate to identify or address such gaps;

• Areas in which evidence is insufficient to support endorsement of quality and efficiency measures in priority areas identified by the Secretary under the National Quality Strategy, and where targeted research may address such gaps; and

• The convening of multi-stakeholder groups to provide input on: (1) The selection of quality and efficiency measures from among such measures that have been endorsed by the CBE and such measures that have not been considered for endorsement by the CBE but are used or proposed to be used by the Secretary for the collection or reporting of quality and efficiency measures; and (2) national priorities for improvement in population health and the delivery of health care services for consideration under the National Quality Strategy.

The statutory requirements for the CBE to annually report to Congress and the Secretary of HHS also specify that the Secretary must review and publish the CBE's annual report in the **Federal Register**, together with any comments of the Secretary on the report, not later than 6 months after receiving it.

This **Federal Register** notice complies with the statutory requirement for Secretarial review and publication of the CBE's annual report. NQF submitted a report on its 2017 activities to the Secretary on March 1, 2018. Comments from the Secretary on the report are presented in section II of this notice, and the National Quality Forum 2017 Annual Report to Congress and the Secretary of the Department of Health and Human Services is provided, as submitted to HHS, in the addendum to this **Federal Register** notice in section III.

II. Secretarial Comments on the National Quality Forum 2017 Annual Report to Congress and the Secretary of the Department of Health and Human Services

Once again, we thank NQF and the many stakeholders who participate in NQF projects for helping to advance the science and utility of health care quality measurement. As part of their annual recurring work to maintain a strong portfolio of endorsed measures for use across varied settings of care and health conditions, NQF reports that in 2017 it updated its measure portfolio by reviewing and endorsing or re-endorsing 120 measures and removing 109 measures. Endorsed measures are developed and implemented with input from numerous stakeholders. These measures undergo rigorous testing to ensure they are evidence-based, reliable, and valid. Continuous refinement of the measures portfolio through the measures maintenance process ensures that quality measures remain aligned with current field practices and health care goals. HHS, with the help of our partners, is committed to implementing measures that provide value to payers and actionable information that can be used to improve the health of patients.

NQF also undertook and continued a number of targeted projects dealing with

difficult quality measurement issues. In particular, NOF has worked to help HHS address the unique challenges faced by rural communities. Nearly one in five Americans reside in rural communities.¹ HHS recognizes the unique challenges facing rural America, and with the support of partners like NQF, we are leveraging quality measurement to improve access and quality for healthcare providers serving rural patients. NQF recently completed several projects that focused on rural health, including Performance Measurement for Rural Low-Volume Providers² and Creating a Framework to Support Measure Development for Telehealth.³ Our reforms in the area of rural health are part of our overall strategy to update our programs and improve access to high quality services.

In 2017, recognizing the need to strengthen representation of rural stakeholders in the pre-rulemaking process, HHS tasked NQF to establish a Measures Application Partnership (MAP) Rural Health Workgroup. The membership of the MAP Rural Health Workgroup, comprised of 18 organizational members, seven subject matter experts, and three federal liaisons, which reflects the diversity of rural providers and residents and allows for input from those most affected and most knowledgeable about rural measurement challenges and potential solutions. The MAP Rural Health Workgroup represents a continuation of HHS' effort to address rural health. With valuable input from our partners and stakeholders, HHS can continue to improve health care in rural America.

The MAP Rural Health Workgroup has focused on identifying a core set of the best available, "rural-relevant" measures to address the needs of the rural population. The MAP Rural Health Workgroup is also working to identify measurement gaps with respect to rural communities and provide recommendations regarding alignment and coordination of measurement efforts across both public and private programs, care settings, specialties, and sectors (both public and private). Additionally, the MAP Rural Health Workgroup provides guidance for the MAP to ensure that measures under consideration address rural provider and resident needs and challenges. The MAP Rural Health Workgroup's recommendations are also helping to address specific barriers to quality reporting faced by rural clinicians. Furthermore, the MAP Rural Health Workgroup has provided a space for rural clinicians to broadly share their valuable input. Rural physicians contribute unique and valuable perspectives critical to addressing national challenges, such as the opioid epidemic. However, rural physicians are often isolated from national discussions on relevant measures that could identify areas of need and gauge prevalence. Highlighting the valuable input from rural clinicians opens collaboration opportunities between rural providers and providers in other settings as HHS works to integrate new measures concerning the prevention and treatment of opioid and substance use disorders.

Addressing the needs of rural health communities is just one of many areas in which NQF partners with HHS in enhancing and protecting the health and well-being of all Americans. HHS greatly appreciates the ability to collaborate with diverse stakeholders and partners to help develop the strongest possible approaches to quality measurement as a key component to health care delivery system reform.

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.*).

IV. Addendum

In this Addendum, we are publishing the NQF Report on 2017 Activities to Congress and the Secretary of the Department of Health and Human Services, as submitted to HHS.

Dated: June 21, 2018.

Alex M. Azar II,

Secretary, Department of Health and Human Services.

BILLING CODE 4120-01-P

¹U.S. Census Bureau, 2010 Census, Table GCTPH1.

² https://www.qualityforum.org/Publications/ 2015/09/Rural_Health_Final_Report.aspx.

³ http://www.qualityforum.org/Publications/2017/ 08/Creating_a_Framework_to_Support_Measure_ Development_for_Telehealth.aspx.



NQF Report on 2017 Activities to Congress and the Secretary of the Department of Health and Human Services

Advance Copy, February 2018

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I. Executive Summary

Quality measurement is an essential cornerstone of the national movement to achieve high-value healthcare that ensures meaningful outcomes for patients and reduces spending. The strong, bipartisan support in the public and private sectors reflects a continued national commitment to invest in quality measurement as a means to ensure high-quality, cost-effective care and to align healthcare system priorities to drive greater improvement and reduce unnecessary administrative burden on providers. Current initiatives to achieve these goals all rely on good, evidence-based quality measures, which help to identify areas for improvement, gauge success of efforts, reduce provider burden, and support transparency so that Americans can know that the care they are receiving is safe and effective.

The National Quality Forum (NQF) is an independent organization that brings together public- and private-sector stakeholders from across the healthcare system to determine the high-value measures that can best drive improvement in the nation's health and healthcare. NQF facilitates private-sector recommendations on quality measures proposed for use in federal programs, advances the science of performance measurement, and identifies and provides direction to address critical clinical, cross-cutting areas, called gaps, where quality measures are underdeveloped or nonexistent.

This annual report, *NQF Report on 2017 Activities to Congress and the Secretary of the Department of Health and Human Services*, highlights and summarizes the work that NQF performed between January 1 and December 31, 2017 under contract with the U.S. Department of Health and Human Services (HHS) in the following six areas:

- Recommendations on the National Quality Strategy and Priorities;
- Quality and Efficiency Measurement Initiatives (Performance Measures);
- Stakeholder Recommendations on Quality and Efficiency Measures;
- Gaps on Endorsed Quality and Efficiency Measures across HHS Programs;
- Gaps in Evidence and Targeted Research Needs; and
- Coordination with Measurement Initiatives by Other Payers.

Through two federal statutes and several extensions, Congress has recognized the role of a "consensus based entity" (CBE), currently NQF, in helping to forge agreement across the public and private sectors about what to measure and improve in healthcare. The 2008 Medicare Improvements for Patients and Providers Act (MIPPA) (PL 110-275) established the responsibilities of the consensus-based entity by creating section 1890 of the Social Security Act. The 2010 Patient Protection and Affordable Care Act (ACA) (PL 111-148) modified and added to the consensus-based entity's responsibilities. The American Taxpayer Relief Act of 2012 (PL 112-240) extended funding under the MIPPA statute to the consensus-based entity through fiscal year 2013. The Protecting Access to Medicare Act of 2014 (PL 113-93) extended funding under the MIPPA and ACA statutes to the consensus-based entity through March 31, 2015. Section 207 of the Medicare Access and CHIP Reauthorization Act of 2015 (MACRA) (PL 114-10) extended funding under section 1890(d)(2) of the Social Security Act for quality measure endorsement, input, and selection for fiscal years 2015 through 2017. Bipartisan action by numerous Congresses over several years has reinforced the importance of the role of the CBE.

In accordance with section 1890 of the Social Security Act, NQF, in its designation as the CBE, is charged to report annually on its work to Congress and the HHS Secretary.

As amended by the above laws, the Social Security Act (the Act)—specifically section 1890(b)(5)(A) mandates that the entity report to Congress and the Secretary of the Department of Health and Human Services (HHS) no later than March 1st of each year.

The report must include descriptions of:

1) how NQF has implemented quality and efficiency measurement initiatives under the Act and coordinated these initiatives with those implemented by other payers;

2) NQF's recommendations with respect to an integrated national strategy and priorities for healthcare performance measurement in all applicable settings;

3) NQF's performance of the duties required under its contract with HHS (Appendix A);

4) gaps in endorsed quality and efficiency measures, including measures that are within priority areas identified by the Secretary under HHS' national strategy, and where quality and efficiency measures are unavailable or inadequate to identify or address such gaps;

5) areas in which evidence is insufficient to support endorsement of measures in priority areas identified by the National Quality Strategy, and where targeted research may address such gaps; and

6) matters related to convening multistakeholder groups to provide input on: a) the selection of certain quality and efficiency measures, and b) national priorities for improvement in population health and in the delivery of healthcare services for consideration under the National Quality Strategy.¹

The deliverables NQF produced under contract with HHS in 2017 are referenced throughout this report, and a full list is included in <u>Appendix A</u>. Immediately following is a summary of NQF's work in 2017 in each of the six aforementioned areas. These topics are discussed in further detail in the body of the report.

Recommendations on the National Quality Strategy and Priorities

NQF brought together organizations in the public and private sectors to help shape national healthcare priorities in the National Quality Strategy (NQS) that HHS released in 2011. Supporting these priorities, in 2017, NQF began or concluded work in several areas of importance, including rural health quality, healthcare disparities, strategies to address social determinants of health in state Medicaid programs, and measurement guidance for Medicaid and CHIP.

NQF's multistakeholder Rural Health Committee currently is exploring quality measurement challenges facing rural providers and will identify a core set of the best available "rural-relevant" measures to address the healthcare needs of the rural population. In a project that concluded in 2017, NQF's Disparities Standing Committee created a roadmap for how providers and payers can reduce healthcare disparities and promote health equity using performance measurement and its associated policy levers. In another project, NQF developed a framework for state Medicaid programs to better integrate health

and nonhealth services, using food insecurity and housing instability as examples. NQF also continued to provide guidance to strengthen core measure sets for Medicaid and CHIP programs.

Quality and Efficiency Measurement Initiatives (Performance Measures)

Healthcare performance measures establish important standards of care and are key to enhancing healthcare value. NQF's portfolio of endorsed measures contains the most accurate and effective measures across a variety of clinical and cross-cutting topic areas. Public- and private-sector programs can use these measures for quality improvement and payment knowing that the measures have met criteria of scientific acceptability, usability, and feasibility—and can accurately discern the quality of provider performance.

In 2017, NQF endorsed 120 measures and removed 109 from its portfolio, across 18 endorsement projects focused on driving the healthcare system to be more responsive to patient and family needs (e.g., person- and family-centered care, care coordination, pediatrics, and palliative and end-of-life care), improving care for highly prevalent conditions (e.g., cardiovascular care; renal care; behavioral health; musculoskeletal health; eye care and ear, nose, and throat conditions; infectious disease; pediatrics; and cancer), and emphasizing cross-cutting areas to foster better care and coordination (e.g., behavioral health, patient safety, cost and resource use, health and well-being, and all-cause admissions and readmissions).

With input from dozens of public and private stakeholders, NQF continued to refine and improve its measure endorsement process and implemented significant changes to enhance and streamline processes. NQF also concluded a two-year trial looking at the impact of including social risk in the risk-adjustment models for certain measures, revealing opportunities as well as challenges. In addition, NQF began a new project to continue to advance understanding of attribution and potential best practices in quality reporting and value-based payment models.

Stakeholder Recommendations on Quality and Efficiency Measures

The Measure Applications Partnership (MAP) is a public-private partnership convened by NQF that provides input to HHS on the selection of quality and efficiency measures for pay-for-performance and quality reporting programs. The private sector also frequently adopts MAP's recommendations. MAP comprises more than 150 representatives from 90 private-sector stakeholder organizations and seven federal agencies—ensuring that the federal government receives varied and thoughtful input on the selection and continued use of performance measures in quality reporting and payment programs.

MAP's work fosters the use of more uniform measurement across federal programs and the public and private sectors. Alignment, or use of the same measures, helps better focus providers on key areas in which to improve quality; reduces wasteful data collection for hospitals, physicians, and nurses; and helps to curb the proliferation of similar, redundant measures that can confuse patients and payers.

For the 2016-2017 pre-rulemaking process, MAP convened three care setting-specific workgroups— Clinician, Hospital, and Post-Acute Care/Long-Term Care (PAC/LTC)—to review proposed measures for use in Medicare programs. MAP reviewed 74 measures—recommending 65 either for use in a federal

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program or for continued development. MAP workgroups convened again in late 2017 to review 35 measures for the 2017-2018 pre-rulemaking process.

Gaps on Endorsed Quality and Efficiency Measures across HHS Programs

NQF is committed to measurement that drives meaningful improvement in the healthcare system. In addition to endorsing high-value measures and recommending measures for use in federal programs, NQF standing committees and MAP, as well as the Medicaid task forces and workgroups, also identify measure gaps—areas in healthcare where high-value measures are too few or nonexistent—to drive improvement. These activities alert stakeholders, including measure developers and policymakers, about pressing measurement needs. The gaps identified in 2017 span conditions, settings, and issues, from care for costly and prevalent diseases to access to care to patient experience, and more. One common thread in discussions about gaps was the need for more outcome measures, particularly those that assess patient-reported outcomes.

Gaps in Evidence and Targeted Research Needs

Several NQF projects completed in 2017, as well as one that is underway, create needed strategic approaches to measure quality in areas critical to improving health and healthcare for the nation. NQF's foundational work in these important areas underpins future efforts to improve quality through measurement and ensure safer, patient-centered, cost-effective care that reflects current science and evidence.

NQF completed projects to create strategic measurement approaches for assessing the quality of telehealth, diagnostic safety and accuracy, and transitions of care into and out of emergency departments. NQF also developed a measurement structure for assessing progress toward interoperability, an important area for advancing care that continues to present significant challenges to healthcare organizations. In other work, NQF continued its efforts to support structured reporting of patient safety events in hospitals and other care settings. NQF also began a new project to identify measure concepts that can be used to improve the quality and safety of care in ambulatory care settings.

Coordination with Measurement Initiatives by Other Payers

NQF completed a project to identify measures to support states' efforts to reform Medicaid payment and service delivery. The Medicaid Innovation Accelerator project authorized under the ACA section 3021 provided the CMS Center for Medicaid and Children's Health Insurance Program (CHIP) Services. (CMCS) with aligned measure sets across multiple states to support efforts in four high-cost, high-need areas of care for the Medicaid population: reducing substance use disorders, improving care for beneficiaries with complex care needs and high costs, promoting community integration through community-based, long-term care services and supports, and supporting the integration of physical and mental health.

Adding to NQF's efforts to encourage the use of more meaningful measures and reduce measure burden on providers, NQF in 2017 continued to contribute technical guidance to the Core Quality Measures Collaborative workgroups. The initiative, led by America's Health Insurance Plans (AHIP), and which also

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involves the Centers for Medicare & Medicaid Services (CMS), brought together private- and publicsector payers to reach consensus on core performance measures. In 2017, the Collaborative added pediatrics measures to its sets of clinician-level core measures intended to promote alignment of measure sets across payers.

II. Recommendations on the National Quality Strategy and Priorities

Section 1890(b)(1) of the Social Security Act (the Act), mandates that the consensus-based entity (entity) shall "synthesize evidence and convene key stakeholders to make recommendations . . . on an integrated national strategy and priorities for health care performance measurement in all applicable settings. In making such recommendations, the entity shall ensure that priority is given to measures: (i) that address the health care provided to patients with prevalent, high-cost chronic diseases; (ii) with the greatest potential for improving the quality, efficiency, and patient-centeredness of health care; and (iii) that may be implemented rapidly due to existing evidence, standards of care, or other reasons." In addition, the entity is to "take into account measures that: (i) may assist consumers and patients in making informed health care decisions; (ii) address health disparities across groups and areas; and (iii) address the continuum of care a patient receives, including services furnished by multiple health care providers or practitioners and across multiple settings."²

Additionally, section 1890(b)(5)(A)(vi) of the Social Security Act, requires that this report describe matters related to multistakeholder input on national priorities for improvement in population health and in delivery of health care services for consideration under the National Quality Strategy.

In 2010, at the request of HHS, the NQF-convened National Priorities Partnership (NPP) provided input that helped shape the national healthcare priorities in the initial version of the National Quality Strategy (NQS) that HHS released in March 2011.³ The Centers for Medicare & Medicaid Services (CMS) continues to align its work with the priorities of making care safer, strengthening person and family engagement, promoting effective communication, promoting effective prevention and treatment of chronic disease, working with communities to promote best practices of healthy living, and making care affordable in partnership with public and private healthcare stakeholders across the country.

Annually, NQF has continued to endorse measures reflective of these national priorities and convene diverse stakeholder groups to reach consensus on key strategies for performance measurement and quality improvement. In 2017, NQF completed or began work in key areas of importance that address healthcare priorities. This work includes projects to improve measurement of care quality in rural settings, reduce healthcare disparities, address social determinants of health, and recommend measures to evaluate care for the population enrolled in Medicaid and CHIP. These initiatives are described below. Additional projects to develop measurement structures to assess the quality of telehealth, progress toward interoperability, transitions of care from emergency departments, and the quality and safety of diagnoses are described in another section of this report, "Gaps in Evidence and Targeted Research Needs."

Priority Initiative to Improve Rural Healthcare

More than 59 million Americans—approximately 19 percent of the U.S. population—live in rural areas.⁴ Statistics indicate that rural residents may be more disadvantaged overall than those in urban or suburban areas, particularly with respect to sociodemographic factors, health status and behaviors, and access to the healthcare delivery system. For example, rural Americans are more likely to be older; have chronic health conditions; engage in poor health behaviors such as smoking; and have higher rates of social disadvantages, such as low income, high unemployment, and lower educational attainment.^{5,6} Rural Americans are also more likely to experience difficulties accessing primary care, dental, and mental healthcare, given the shortage of providers in rural areas.⁷ The continuing trend of rural hospital closures has also affected rural Americans' ability to access care in their communities.⁸

Rural hospitals and clinicians participate in a variety of private-sector, state, and a limited number of federal quality measurement and improvement efforts. In a 2015 HHS-funded project, NQF convened a multistakeholder Rural Health Committee to explore in depth the quality measurement challenges facing rural providers.

Multiple and disparate demands (e.g., direct patient care, business and operational responsibilities) compete for the time and attention of providers who serve in small rural hospitals, and providers in rural clinical practices often have limited time, staff, and finances available for quality improvement activities. In addition, some rural areas may lack information technology (IT) capabilities altogether and/or IT professionals who can leverage those capabilities for quality measurement and improvement efforts. The heterogeneity of residents in many rural areas, such as a disproportionate number of vulnerable residents, has particular implications for healthcare performance measurement, including limited applicability of measures and potentially, the need for modifications in the risk-adjustment approach for certain measures.⁹ Moreover, depending on the particular performance measure, rural providers may not have enough patients to achieve reliable and valid measurement results. While urban areas may experience many of these same difficulties, in rural areas they likely pose greater challenges for, and have greater impact on, quality measurement and improvement activities.

Some measurement challenges are unique to rural providers. For example, many do not participate in current CMS quality programs because they don't exist, or participate—in the case of Critical Access Hospitals (CAHs)—only on a voluntary basis, and thus may have limited experience in collecting data and reporting on healthcare performance measures. Also, claims-based performance measures may not provide valid results for those rural providers who do not submit comprehensive data because they do not rely on claims reimbursements for payment.

The NQF Rural Health Committee made a series of recommendations to CMS, particularly in the context of pay-for-performance programs and improving quality in rural areas. The Committee's overarching recommendation¹⁰ was to integrate rural healthcare providers into federal quality programs. The Committee noted that rural providers' nonparticipation in federal quality programs may affect the ability of these providers to identify and address opportunities for improvement, as well as demonstrate how they perform compared to their nonrural counterparts.

The Committee's remaining recommendations were intended to help ease the transition of rural providers to mandatory participation in CMS quality programs. These recommendations include: to develop rural-relevant measures (e.g., to address topics such as patient hand-offs and transitions, address the low case-volume challenge, and include appropriate risk adjustment); align measurement efforts (including measures themselves, data collection efforts, and informational resources); consider rural-specific challenges during the measure-selection process, create a rural health workgroup to advise the Measure Applications Partnership (MAP); and address the design and implementation of pay-for-performance programs.

In 2017, recognizing the lack of representation from rural stakeholders in the pre-rulemaking process, CMS tasked NQF to implement the 2015 Rural Health Workgroup's recommendation to establish a MAP Rural Health Workgroup (see <u>Appendix G</u>). This Workgroup, comprised of 18 organizational members, seven subject matter experts, and three federal liaisons, was seated in November 2017. Because Workgroup members reflect the diversity of rural providers and residents, it includes the perspectives of those most affected and those most knowledgeable about rural measurement challenges and potential solutions. Input from such rural experts will allow the setting-specific MAP Workgroups and Coordinating Committee to consider measurement challenges that rural providers face, including the limitations of current or proposed measures.

A major task of the MAP Rural Health Workgroup will be to identify a core set of the best available, "rural-relevant" measures to address the needs of the rural population. During its first year, the Workgroup will focus on measures that are potentially applicable to CMS' hospital inpatient and outpatient quality reporting programs and its clinician-focused quality reporting programs. The Workgroup also will identify rural-relevant gaps in measurement and provide recommendations regarding alignment and coordination of measurement efforts across both public and private programs, care settings, specialties, and sectors (both public and private). Additionally, the Workgroup will provide guidance to address a measurement topic relevant to vulnerable individuals in rural areas and will provide input on Measures Under Consideration (MUC) specific to the needs and challenges of rural providers and residents. NQF will issue a final report on this work in September 2018. In future years, if it is funded to continue its work, the Workgroup will shift attention to measures applicable in post-acute and long-term care settings.

Quality Roadmap to Reduce Healthcare Disparities and Promote Health Equity

Widespread recognition of health and healthcare disparities has prompted HHS as well as many other organizations in the public and private sectors to prioritize health equity as a key component of healthcare quality improvement. Disparities are differences caused by inequities that are linked to social, economic, and/or environmental disadvantages, and these differences persist despite overall improvements in public health and medicine. Achieving health equity requires eliminating disparities in healthcare delivery and outcomes by addressing social risk factors that adversely affect excluded or marginalized groups.

Performance measurement is an essential tool for monitoring health disparities and assessing the level to which research-based interventions are employed to reduce disparities. Measures can help to

pinpoint where people with social risk factors do not receive the care they need or receive care that is lower quality. However, there was no comprehensive approach for HHS and other stakeholders to use measurement to eliminate disparities and promote health equity.

In 2016, HHS funded NQF to convene the Disparities Standing Committee, a multistakeholder group of experts (e.g., payers, providers, researchers, and patients) to develop recommendations for how performance measurement, and its associated policy levers, can be used to reduce disparities in health and healthcare. NQF documented the project through three interim reports published in 2017, each of which examines disparities based on social risk factors identified in the 2016 National Academy of Medicine (NAM) report, *Accounting for Social Risk Factors in Medicare Payment: Identifying Social Risk Factors*, ¹¹ e.g., socioeconomic position, race, ethnicity, residential and community context, and sexual orientation.

The first interim report, *Disparities in Healthcare and Health Outcomes in Selected Conditions*, ¹² documented disparities in health and healthcare among leading causes of morbidity and mortality for certain conditions from a review of published literature. These conditions include cardiovascular diseases, cancer, diabetes and chronic kidney disease, infant mortality/low birthweight, and mental illness. The report documents significant disparities across all of the selected conditions and highlights the urgent need for a systematic approach to eliminate disparities through measurement. The report includes examples of interventions that were successful in reducing disparities, such as improving outcomes in diabetes and cardiovascular disease. It also cites the *2016 National Healthcare Quality and Disparities Report*, ¹³ which documents smaller disparities for 20 percent of measures (e.g., care coordination, patient safety, and affordability) between African Americans and Non-Hispanic Whites.

The second interim report, *Effective Interventions in Reducing Disparities in Healthcare and Health Outcomes in Selected Conditions*,¹⁴ identified interventions (e.g., patient education, lifestyle modification, and culturally tailored programs) that could be used to address disparities documented in the first interim report. The Disparities Standing Committee and NQF staff reviewed the research on interventions that have effectively reduced disparities. They found that interventions to reduce disparities currently are focused largely on reducing disparities based on race and ethnicity. In addition, interventions are usually implemented to address disparities in one condition or to address disparities for one social risk factor. The findings indicate potential for multitarget interventions that could address disparities across conditions and for multiple social factors.

The third interim report, An Environmental Scan of Health Equity Measures and a Conceptual Framework for Measure Development,¹⁵ documented 886 performance measures that can be used either to monitor disparities within the selected conditions explored in the first interim report or to assess the use of evidence-based interventions identified in the second interim report. Most measures evaluated processes or outcomes of healthcare, and few gauged the use of evidence-based interventions. The environmental scan pointed to several gaps in measurement and areas for future research. The Disparities Standing Committee used the outcomes of each interim report to inform its final recommendations. Published September 2017, the final report, *A Roadmap for Promoting Health Equity and Eliminating Disparities*, ¹⁶ outlines how the U.S. healthcare system (e.g., providers and payers) can build on existing standards of care, measurement practices, and payment models to address disparities. It also identifies areas where collaboration between health and nonhealth sectors and community linkages can be used to expand the healthcare system's role to better address the upstream causes of disparities.

The Roadmap provides guidance for addressing a wide spectrum of disparities based on age, gender, income, race, ethnicity, nativity, language, sexual orientation, gender identity, disability, geographic location, and other social risk factors. It emphasizes the importance of cultural competence, community engagement, and cross-sector partnerships to reduce disparities. In particular, the Roadmap addresses measurement beyond clinical settings, structures, and processes of care. For example, it includes the assessment of collaboration between healthcare and other sectors (e.g., schools, social services, transportation, housing, etc.) to reduce the impact of social risk factors and achieve health equity.

The Roadmap suggests actions that healthcare stakeholders can employ to reduce disparities, including:

Prioritize measures that can help to identify and monitor disparities (disparities-sensitive measures). Measure implementers should prioritize the use of measures that are sensitive to disparities in health and healthcare. Disparities-sensitive measures detect differences in quality across institutions or in relation to certain benchmarks, but also differences in quality among population or social groups. The Roadmap specifies criteria to assist with the prioritization of disparities-sensitive measures.

Implement evidence-based interventions to reduce disparities. Stakeholders should implement evidence-based interventions to reduce disparities at every level of the healthcare system (i.e., government, community, organization, and individual levels).

Invest in the development and use of measures to assess interventions that reduce disparities (health equity measures). The Committee identified five domains of measurement that should be used together to reduce disparities and advance health equity. These domains assess the extent to which the healthcare system:

- Collaborates and partners with other organizations or agencies that influence the health of individuals (e.g., neighborhoods, transportation, housing, education, etc.) to address social needs.
- Adopts and implements a culture of equity. A culture of equity recognizes and prioritizes the
 elimination of disparities through genuine respect; fairness; cultural competency; the
 creation of environments where all individuals, particularly those from diverse and/or
 stigmatized backgrounds, feel safe in addressing difficult topics, e.g., racism; and advocating
 for public and private policies that advance equity.
- Creates structures that support a culture of equity. These structures include policies and
 procedures that institutionalize values that promote health equity, commit adequate
 resources for the reduction of disparities, and enact systematic collection of data to monitor
 and provide transparency and accountability for the outcomes of individuals with social risk
 factors.

- Ensures equitable access to healthcare. Equitable access means that individuals with social
 risk factors are able to easily get care. It also means care is affordable, convenient, and able
 to meet the needs of individuals with social risk factors.
- Ensures high-quality care that continuously reduces disparities. Performance measures should be routinely stratified by social risk to identify disparities in care. In addition, performance measures should be used to create accountability for reducing, and ultimately, eliminating disparities through effective interventions.

Provide incentives to reduce disparities. Providers and other stakeholders should be incentivized to reduce disparities through recognition, payment, or additional resources. For example, public and private payers can adjust payments to providers based on social risk factors or offer additional payments for primary care or disease management programs (e.g., in-home monitoring of blood pressure).

The Committee suggested ways for sectors of the healthcare system to pursue specific actions, including that:

- Hospitals and health plans identify and prioritize reducing disparities and distinguish which they
 can address in the short- and long-term;
- Clinicians implement evidence-based interventions by connecting patients to community-based services or culturally tailored programs shown to mitigate the drivers of disparities;
- Measure developers work with patients to translate concepts of equity into performance measures that can directly assess health equity; and
- Policymakers and payers incentivize the reduction of disparities and the promotion of health
 equity by building health equity measures into new and existing healthcare payment models.

The Committee developed a set of 10 recommendations to support reducing disparities and promoting health equity. Among its recommendations, the Committee supports providing primary care practices incentives to support preventive activities for patients with social risk factors. Equitable access starts with unconstrained access to primary care. Robust systems of primary care are associated with improved population health and reduced disparities. Primary care plays a unique role in promoting equity through its comprehensive and biopsychosocial focus, longitudinal personal relationships, and its capacity to align intensity of care management with patient needs. The Committee's complete list of recommendations follows:

Recommendation 1: Collect social risk factor data.

Data are the bedrock of all measurement activities; however, data on social risk factors are currently limited. As such, stakeholders must invest in the necessary infrastructure to support data collection. There is a general need for data collection related to social risks like housing instability, food insecurity, gender identity, sexual orientation, language, continuity of insurance coverage, etc.

Recommendation 2: Use and prioritize stratified health equity outcome measures.

Stakeholders should first conduct a needs assessment to identify the extent to which they are meeting the goals outlined in the Roadmap. The domains of measurement should be considered as a whole rather than aiming to make progress in only one area. Stakeholders must actively identify and decommission measures that have reached ceiling levels of performance and where there are insignificant gaps in performance.

Recommendation 3: Prioritize measures in the domains of Equitable Access and Equitable High-Quality Care for accountability purposes.

Some measures within the domains of measurement are more suitable for accountability and others, for quality improvement. The majority of measures that fall within the domains of *Culture for Equity*, *Structure for Equity*, and *Collaboration and Partnerships* should be used primarily for quality improvement initiatives and are less appropriate for accountability. Measures that are aligned with the domains of *Equitable Access to Care* and *Equitable High-Quality Care* may be more suitable for accountability.

Recommendation 4: Invest in preventive and primary care for patients with social risk factors.

Equitable access starts with unconstrained access to primary care. People with low health literacy, limited access to social networks for reliable information, or who are challenged with navigating a fragmented healthcare system often rely on continuity with a trusted primary care provider. Primary care's capacity to care for people (rather than diseases) across medical, behavioral, and psychosocial dimensions while providing resources and services to align with these needs is vital to improving health equity. Ultimately, incentives are needed to prioritize support for traditionally underfunded preventive activities.

Recommendation 5: Redesign payment models to support health equity.

Payment models designed to promote health equity have the potential to have a large impact on reducing disparities. For example, health plans can provide upfront payments to fund infrastructure for achieving equity and addressing the social determinants of health. Health plans also can implement pay-for-performance payment models that reward providers for reducing disparities in quality and access to care. The Committee noted that purchasers could use mixed model approaches, combining payment models based on their specific goals (e.g., upfront payments and pay-for-performance to reduce disparities). Payment models can also be phased, using pay-for-reporting, then pay-for-performance incentives.

Recommendation 6: Link health equity measures to accreditation programs.

Integrating health equity measures into accreditation programs can increase accountability for reducing disparities and promoting health equity. These measures can be linked to quality improvement-related equity building activities. Organizations like the National Committee for Quality Assurance (NCQA) and URAC have already aligned with this strategy.

Recommendation 7: Support outpatient and inpatient services with additional payment for patients with social risk factors.

Social risk factors are like clinical risk factors in the sense that they require more time and effort on the part of providers in specific encounters to achieve the same results. If an office visit is more complex (and billed and paid at a higher level) because of clinical complexity in a patient, the same concept could extend to the incorporation of social risk factors and "social complexity" as a payment concept.

Recommendation 8: Ensure organizations disproportionately serving individuals with social risk can compete in value-based purchasing programs.

Payers should consider additional payments to assist organizations in developing the infrastructure to provide high-quality care for people with social risk factors. There is a need to adjust for social risk factors as well as stratify performance scores by social risk to ensure transparency and drive improvement. In addition, relevant stakeholders should prospectively monitor the financial impact of value-based purchasing programs on organizations caring for individuals with social risk factors.

Recommendation 9: Fund care delivery and payment reform demonstration projects to reduce disparities.

The evidence base for many care delivery and payment reform interventions to reduce healthcare disparities is still limited. There is a need to better understand what work is being done to reduce disparities, what interventions are effective, and how these interventions can be replicated in practice (e.g., implementation science). Future research and demonstration projects should be conducted in partnership with researchers to ensure they are rigorous and scientifically sound.

Recommendation 10: Assess economic impact of disparities from multiple perspectives.

There is limited understanding of the economic impact of disparities. Quantifying the costs in terms such as lost productivity, quality-adjusted life years, readmission rates, emergency department use, etc., could help organizations understand the imperative to invest in health equity.

A Framework for Medicaid to Address Social Determinants of Health

State Medicaid programs are making significant advances in addressing social determinants of health (SDOH) to improve health outcomes.^{17,18,19} Evidence is growing that SDOH—such as where people live, how much money they earn, and their level of education—have significant impact on health and wellbeing.²⁰ Several states have implemented waivers and new financing mechanisms to support the collection of SDOH data and coordination of care based on SDOH.²¹ However, the evidence-base for screening and addressing social needs is still developing. Numerous organizations have called for a framework to help state Medicaid programs make strategic investments in the collection and use of SDOH data.

Funded by CMS, NQF convened an Expert Panel to develop a framework for state Medicaid programs to better integrate health and nonhealth services, using food insecurity and housing instability as illustrative examples. The Expert Panel included a variety of stakeholder groups such as clinicians, researchers, health plans, health systems, and consumer advocates. Food insecurity and housing instability were selected as key areas where state Medicaid programs can support data collection efforts in the short term.

To support this work, NQF conducted a literature review on the impact of food insecurity and housing instability on health outcomes, an environmental scan of measures (e.g., screening tools, performance measures, scales, assessments, etc.), and key informant interviews. Key informants represented organizations working to reduce the incidence of food insecurity and housing instability. The interviews offered insights into barriers and opportunities. For example, many informants cited a lack of resources

in communities such as food deserts, areas without food banks, and long waiting lists for housing supports.

The Expert Panel identified a framework that builds on the hub-and-spoke model by Taylor et al., and on work from the Social Interventions Research & Evaluation Network at the University of California San Francisco.^{22,23} The framework positions Medicaid programs at the "hub" as a primary health care entity that connects healthcare to nonhealth services that can address social needs (the "spokes") to the healthcare system. The "spokes" include services like housing supports, food and nutritional supports, home and community-based services, and employment services. The framework illustrates the role of Medicaid programs in supporting SDOH Informed Healthcare, using information on social needs in clinical decision making for Medicaid beneficiaries, and SDOH Targeted Healthcare—connecting individuals to nonhealth services that can address SDOH (e.g., Temporary Assistance of Needy Families, Head Start, and homelessness assistance programs).

In its final report, completed December 2017, the Expert Panel shared a set of six recommendations to support the implementation of the framework:

- 1. Acknowledge Medicaid has a role in addressing social determinants of health
- 2. Create a comprehensive, accessible, routinely updated list of community resources
- 3. Harmonize tools that assess social determinants of health
- Create standards for inputting and extracting social needs data from electronic health records
- 5. Increase information sharing between government agencies
- 6. Expand the use of waivers and demonstration projects to learn what works best for screening and addressing SDOH

2017 Measurement Guidance for Medicaid and CHIP

Medicaid is the largest health insurance program in the United States, serving 74 million individuals. Nearly 36 million, or almost half of the people enrolled in Medicaid and CHIP are children.²⁴ As the primary health insurance program for the nation's low-income population,²⁵ Medicaid covers many individuals with a high need for medical and healthcare services, including the growing population of more than 11 million individuals who are dually eligible for both Medicare and Medicaid.²⁶ Medicaid beneficiaries with complex care needs account for roughly 54 percent of total Medicaid expenditures, despite comprising just 5 percent of all Medicaid beneficiaries.²⁷ Moreover, Medicaid covers nearly 50 percent of all births as well as 40 percent of children's healthcare.²⁸ Understanding the needs of adults and children who rely on Medicaid for their healthcare is imperative for improving their health and the quality of their care.

In 2017, NQF continued its efforts to improve healthcare for the population enrolled in Medicaid and CHIP by recommending standardized measures to evaluate quality of care across states in key areas. NQF issued its recommendations on Medicaid's core measures in a series of three reports.

Strengthening the Core Set of Healthcare Quality Measures for Adults Enrolled in Medicaid, 2017²⁹ Section 1139B of the Social Security Act (amended by the ACA) called for the creation of a Core Set of Health Care Quality Measures for Adults Enrolled in Medicaid (the Adult Core Set) to assess the quality of care for adults enrolled in Medicaid. HHS established the Adult Core Set to standardize the measurement of healthcare quality across state Medicaid programs, assist states in collecting and reporting on the measures, and facilitate use of the measures for quality improvement.³⁰ In January 2012, HHS published the initial Adult Core Set of measures in partnership with a subcommittee to the AHRQ's National Advisory Council.³¹ The 2017 Adult Core Set contained 30 healthcare quality measures.

NQF's Medicaid Adult Task Force recommended improvements to the Adult Core Set annually. The Task Force also has identified high-priority gaps where more or better quality measures are needed. In its fifth set of recommendations on the Adult Core Set, published in August 2017, the Task Force recommended the addition of four measures to address care of patients with asthma, patients' feedback about the quality of long-term services received in a community setting, opioid use, and contraceptive use. The Task Force supported the removal of two measures from the Adult Core Set, citing states' reporting challenges regarding data collection for one measure and encouraging the addition of a more meaningful replacement for the other that focused on counting office visits, rather than the content of the visits, to address patient outcomes.

Thirty-nine states reported on at least one of the Adult Core Set measures for federal fiscal year (FFY) 2015.³² State reporting increased for 20 of the 25 measures included in both the 2014 and 2015 Adult Core Sets.³³ The gradual addition of measures to the Core Set has allowed states to build their measure-reporting infrastructure, as evidenced by the increase in the number of states voluntarily reporting on measures. The Task Force suggested optimizing data connections between data systems and among organizations, as well as improving integration across local, state, and federal health entities as some of the ways states could improve quality and Adult Core Set reporting.

NQF has begun its next annual review of the Adult Core Set with the appointment of a new, multistakeholder Medicaid Adult Workgroup. The results are due to CMS by the end of August 2018.

Strengthening the Core Set of Healthcare Quality Measures for Children Enrolled in Medicaid and CHIP, 2017³⁴

The Children's Health and Insurance Program Reauthorization Act of 2009 (CHIPRA) required HHS to develop standards to measure the quality of children's healthcare. This legislative mandate led to the identification of the Core Set of Health Care Quality Measures for Children Enrolled in Medicaid and CHIP (the Child Core Set). CMS released the initial Child Core Set in 2010. Measures in the Child Core Set are relevant to children ages 0-20 as well as pregnant women because these measures address both prenatal and postpartum quality-of-care issues. CHIPRA also required CMS to recommend updates to the initial Child Core Set annually beginning in January 2013. The 2017 Child Core Set contained 27 healthcare quality measures.

NQF's Medicaid Child Task Force has recommended improvements to the Child Core Set annually. The Task Force also has identified high-priority gaps where more or better quality measures are needed. In

its fourth set of annual recommendations on the Child Core Set, published in August 2017, the Task Force recommended the addition of five measures to address access to care, behavioral health, and care of patients with asthma. The Task Force supported the removal of five measures, citing the need for better measures that focus on care quality, not frequency of services.

Every state reported on at least some of the Child Core Set measures for FFY 2015.³⁵ State reporting increased for 16 of the 23 measures included in both the 2014 and 2015 Child Core Set.³⁶ As with the Adult Core Set, the gradual addition of measures to the Child Core Set has allowed states to build their measure-reporting infrastructure, as evidenced by the increase in the number of states voluntarily reporting on measures. The Task Force suggested optimizing data connections between data systems and among organizations, as well as improving integration across local, state, and federal health entities as some of the ways states could improve quality and Child Core Set reporting.

NQF has begun its next annual review of the Child Core Set with the appointment of a new, multistakeholder Medicaid Child Workgroup. The results are due to CMS by the end of August 2018.

Promoting Integrated and Coordinated Care that Addresses Social Risk for the Dual Eligible Beneficiary Population³⁷

Dual eligible beneficiaries are a growing population with complex needs that require high levels of services and supports.³⁸ Dual eligible beneficiaries comprise 20 percent of Medicare beneficiaries but account for 34 percent of annual spending, at approximately \$187 billion. Similarly, dual eligible beneficiaries comprise 15 percent of Medicaid beneficiaries but account for 33 percent of annual spending at approximately \$119 billion.³⁹ NQF's Dual Eligible Workgroup was established six years ago to address the unique challenges of caring for the nation's most vulnerable population. The Workgroup identified a core set of healthcare quality measures for this population, the Dual Eligible Beneficiaries Family of Measures (the Family of Measures), which it has annually reviewed and updated. The 2017 Family of Measures contained 71 healthcare quality measures. The Starter Set, a subset of the Family of Measures.

In its 2017 review of the Family of Measures, the Workgroup recommended the addition of measures addressing functional change, hospital discharges to community settings, patients' feedback about the quality of long-term services received in a community setting, and population-level HIV viral load suppression. The Workgroup supported the removal of eight measures from the Family of Measures because they are no longer NQF-endorsed.

The Workgroup discussed the need for better coordination and integration of efforts to include various stakeholders, such as federal agencies and community organizations, along with effective use of available measurement tools. To accomplish these objectives, the Workgroup recommended that HHS develop a collaboration strategy for federal agencies and work with community-based organizations.

The Workgroup discussed the need for a paradigm shift in measure conceptualization and development. Workgroup members suggested that future measure development should start at the individual beneficiary level to address the population's needs and gap areas. The Workgroup also encouraged

measurement that has an expanded focus on quality, for example, to help connect medical and social care.

The Workgroup emphasized the need for a population-based measurement framework that recognizes and measures the effects of social risk factors on health outcomes. The Workgroup identified 11 social risk factors that underscore the complexity of the dual eligible population, including social support, residential and community context, and socioeconomic position, status, and income.

HHS has not funded NQF in 2018 to review the Family of Measures. However, NQF will continue its efforts to improve the quality of care for vulnerable individuals by incorporating the needs of dual eligible beneficiaries across all of its work, including measure review and endorsement, review of Medicaid core measure sets, and the work of its Disparities Standing Committee. NQF also will continue to explore opportunities to re-engage the Duals Workgroup in the future.

III. Quality and Efficiency Measurement Initiatives (Performance Measurement)

Section 1890(b)(2) and (3) of the Social Security Act requires the consensus-based entity (CBE) to endorse standardized healthcare performance measures. The endorsement process must consider whether measures are evidence-based, reliable, valid, verifiable, relevant to enhanced health outcomes, actionable at the caregiver level, feasible for collecting and reporting, responsive to variations in patient characteristics, and consistent across types of healthcare providers. In addition, the CBE must establish and implement a process to ensure that measures endorsed are updated (or retired if obsolete) as new evidence is developed.⁴⁰

Working with multistakeholder committees to build consensus, NQF reviews and endorses healthcare performance measures. Measures help clinicians, hospitals, and other providers understand whether the care they provide their patients is optimal, and appropriate, and if not, where to focus improvement efforts. The federal government, states, and private-sector organizations use NQF-endorsed measures to evaluate performance; inform employers, patients, and their families; and drive quality improvement. Together, NQF-endorsed measures serve to enhance healthcare value by ensuring that consistent, high-quality performance data are available, which allows for comparisons across providers as well as the ability to benchmark performance. Currently, NQF has a portfolio of 628 NQF-endorsed measures. Subsets of this portfolio apply to particular settings and levels of analysis.

Important Changes to NQF Measure Endorsement

NQF is committed to making measure endorsement more efficient, fostering innovation, and enabling greater access to NQF's technical assistance.

NQF's measure endorsement process, also referred to as the Consensus Development Process (CDP), provides the nation, including HHS' public reporting and pay-for-performance initiatives, with a portfolio of measures that meet rigorous evaluation criteria and that are reflective of the current evidence, reliable and valid, useful for accountability and quality improvement, and feasible to implement.

Since NQF approved the first version of the CDP in July 2000, NQF has continuously refined its process to address the needs of the healthcare industry. Many of these refinements have been incremental and others more substantive, requiring pilot testing and significant operational changes. With CMS funding, NQF hosted its most recent process improvement event May 18-19, 2017, which involved thoroughly examining how NQF endorses measures, specifically to make the process more agile and reduce the cycle time for measure submission and review. More than 40 private- and public-sector stakeholders—including experts from CMS and other federal agencies, members of NQF standing committees, and representatives of organizations that develop measures—also provided input, as did NQF members and the public. The resulting changes are outlined in the *2017 Consensus Development Process Redesign*⁴¹ report.

Increased Opportunities for Measure Submission

Among the most significant changes is that NQF standing committees can now evaluate measures for endorsement twice a year. Previously, standing committees reviewed a select few new and current measures each year, contingent on funding. With this change to more frequent endorsement review, NQF aims to reduce standing committee downtime and be more responsive to the rapidly evolving healthcare system. However, NQF now limits the number of measures that may be evaluated by its standing committees in one measure review cycle to a maximum of 12, including up to eight measures undergoing maintenance review and up to four measures being evaluated for initial endorsement. Limiting the number of measures reviewed in a cycle ensures that the standing committees have the capacity to provide each measure with a thorough, efficient, and rigorous review.

Consolidated Measure Review Topical Areas

To optimize the evaluation of NQF's library of measures, NQF consolidated or modified some of its committees. These modifications help to balance measure portfolios and grouped cross-cutting clinical areas, such as Primary Care and Chronic Illness and Geriatrics and Palliative Care. NQF's measure portfolio now comprises 15 topical areas, including:

- All-Cause Admissions/Readmissions
- Behavioral Health and Substance Use
- Cancer
- Cardiovascular
- Cost and Efficiency
- Geriatric and Palliative Care
- Neurology
- Patient Experience and Function
- Patient Safety
- Pediatrics
- Perinatal and Women's Health
- Prevention and Population Health
- Primary Care and Chronic Illness
- Renal
- Surgery

Individual standing committees will no longer convene for the following topical areas: Person- and Family-Centered Care; Ears, Eyes, Nose, and Throat Conditions; Endocrine; Musculoskeletal; Infectious Diseases; Care Coordination; Gastrointestinal; and Genitourinary.

Intent to Submit

NQF now requires measure developers and stewards to submit measure specifications and testing information along with an Intent to Submit form at least three months prior to the measure submission deadline. This advance notification will allow NQF to adequately plan for measures in the pipeline and maintenance measures ready for re-evaluation in the various topic areas. NQF also encourages measure developers to seek technical assistance from NQF staff during this time.

Technical Review: NQF Scientific Methods Panel

In September 2017, NQF established the Scientific Methods Panel (SMP) (see <u>Appendix C</u>) to assist in conducting methodological reviews of measures being reviewed for endorsement. The Panel's creation was in response to feedback from key stakeholders who took part in NQF's 2017 process improvement event. These stakeholders noted the challenges many standing committee members face conducting technical reviews of measures when their background is not in statistics or measure development. Stakeholders recommended that NQF shift the responsibility of scientific review of measures from the committees to an SMP and NQF staff. Their intent was to allow consumers, patients, purchasers, and other members of NQF standing committees to focus on bringing their expertise to the subject matter under consideration and to be more engaged throughout the evaluation process.

The SMP consists of 24 individuals with methodological expertise. Panel members are appointed to an initial two- or three-year term, with an optional three-year term to follow. NQF issues a transparent and public call for nominations from statisticians, epidemiologists, psychometricians, economists, performance measure methodologists, and experts in eMeasures as well as disparities in healthcare who also have relevant knowledge and/or proficiency in methodology, implementation of measures, and/or broad clinical expertise that would lend itself to the evaluation of complex measures. After a public comment period of the proposed SMP roster, NQF senior leadership approved the Panel slate.

The SMP conducts evaluations of scientific acceptability for selected, complex measures. Specifically, the SMP reviews the "must-pass" subcriteria of reliability and validity using NQF's standard measure evaluation criteria⁴² for new and maintenance measures. The SMP provides a preliminary recommendation to NQF staff and the standing committees. NQF staff will continue to provide a preliminary analysis of all measures under review, including a methods review for noncomplex measures. The following measures are considered complex and may require an evaluation by the SMP:

- Outcome measures, including intermediate clinical outcomes
- Instrument-based measures (e.g., patient-reported outcome performance measures)
- Cost/resource use measures
- Efficiency measures (those combining concepts of resource use and quality)
- Composite measures

In addition to evaluating submitted measures for scientific acceptability in NQF's measure endorsement process, the SMP will serve in an advisory capacity to NQF on methodologic issues related to measure testing, risk adjustment, and measurement approaches. As measures have become more complex, a myriad of issues have emerged related to measure testing, data sources, and assessment of reliability and validity. The Panel will help to ensure that NQF's testing requirements adjust to changes in measurement science.

Additional Changes

Expanding the measure evaluation commenting period for the public and NQF members to 15+ consecutive weeks. NQF will have one continuous public commenting period for measures under review. Reflecting NQF's commitment to transparency, this expanded commenting period replaces two separate commenting periods (a 14-day pre-meeting comment period and 30-day post-meeting comment period). Standing committees will review all submitted comments, and all submitted comments will receive a written response from the standing committee, measure developer or steward, or NQF staff, as appropriate.

Allowing only NQF members to signal support for measures under review. Process improvement event participants recommended that NQF members should no longer vote on measure endorsement decisions during a separate 15-day voting period to inform standing committees' recommendations. NQF members can now express their support ('Support' or 'Do Not Support') for measures during the 15+ week continuous public commenting period. This opportunity for NQF members to express support/nonsupport for measures is intended to promote and facilitate their engagement and feedback in the endorsement process.

Simplifying the structure and content of NQF measure evaluation reports. These changes are intended to minimize the length and density of technical reports on measure evaluations. Reports will be streamlined to include an executive summary that indicates the endorsement decision, brief summaries of each measure reviewed, details of committee deliberations on each measure against NQF measure evaluation criteria, and full measure specifications. In addition, NQF will create an annual cross-cutting report across all the topic areas that will summarize trends and performance, high-priority gap areas in measurement for future development, and measure concepts submitted during the solicitation process for measures.

Enhancing education and training for stakeholder participation and engagement. NQF will expand and strengthen the current range of educational resources offered to specific audiences, including committee members, developers, and staff. Feedback received from participants in NQF's process improvement activity mentioned the need for more accessible and tailored resources for stakeholders engaged at various points of the CDP. In response, NQF will develop more on-demand, virtual, education resources that provide technical and other assistance. These and other recommendations to enhance stakeholder education and training are being implemented through a phased process and timeline that began in the summer of 2017.

Improving access to and exchange of measure information between the measure endorsement process and the Measure Applications Partnership (MAP). Process improvement event participants noted that there is significant overlap between NQF's two separate review processes (measure endorsement through the CDP and input on measure selection and use through MAP) and called for a centralized resource to access comprehensive and longitudinal information on measures. NQF is advancing initiatives to aggregate data from MAP reviews on measure selection and use as well as to consolidate existing information from endorsement review reports to make it easier for users to access measure information.

Future, additional and strategic changes may be implemented to the NQF CDP with direction from NQF's Consensus Standards Approval Committee (CSAC) and Board of Directors. For example, process improvement participants recommended changing how final endorsement decisions are made. Specifically, they recommended that standing committees, not NQF's Consensus Standards Approval Committee (CSAC),⁴³ make final endorsement decisions without ratification from the CSAC. Their rationale was that the CSAC rarely overturns standing committee measure endorsement recommendations. Additionally, process improvement participants recommended that the CSAC, and not the NQF Appeals Board, adjudicate appeals of decisions to endorse or not endorse measures. Given important strategic considerations, NQF will assess the newly designed CDP over time to determine whether these changes will enhance the process during future iterations.

Cross-Cutting Project to Improve the Measurement Process

In 2017, NQF's measurement science work continued to advance understanding of attribution and potential best practices in quality reporting and value-based payment models. Attribution is the methodology used to assign patients, and the quality or costs of their healthcare, to specific organizations or providers.

As healthcare payers and consumers increasingly seek greater value from healthcare services, determining which physicians or other providers are ultimately responsible for the quality and outcomes of the care patients receive is paramount. Attribution models are essential parts of policy and program design as well as measure development and implementation. Currently, a wide range of such models are in use across the nation, and, in some cases, limited information about the specifics of these models exists. The lack of standardization and specificity has prompted concerns from providers and other accountable entities that some models may inaccurately assign accountability for patients or outcomes.

In its role as the CBE, NQF continues its work to address these issues, which are fundamental to achieving a value-based healthcare system. In work that began September 2017, NQF has convened a multistakeholder advisory panel to build on the foundational guidance provided in NQF's 2016 report on attribution and its accompanying Attribution Model Selection Guide. The goal for the new work of the Improving Attribution Models Advisory Panel is to address notable attribution challenges, including the development and selection of attribution models to link health outcomes or costs to individual providers or teams of providers that include nonclinicians and care for patients with complex medical needs. The Panel also will share guidance on evaluating attribution models for health outcomes among specific patient populations, including pediatric patients or those with comorbidities. The Panel also will weigh in

on the role of attribution for NQF's measure endorsement and Measure Applications Partnership processes. A final report with the Panel's recommendations is expected in August 2018.

Social Risk Trial

Value-based purchasing and alternative payment models aim to reduce healthcare spending while improving quality by tying provider payments to performance on cost and quality measures (e.g., readmission rates, complication rates, or mortality rates). HHS has stated a goal to tie 90 percent of Medicare fee-for-service payments to performance on quality measures by the end of 2018.⁴⁴ CMS operationalizes this goal through federal accountability programs such as the Merit-Based Payment System, Hospital Readmissions Reduction Program, and Hospital Value-Based Purchasing Program.

Public- and private-sector payers also are increasingly using outcome measures as the performance metrics in value-based purchasing programs. However, healthcare outcomes are not solely the result of the quality of care received and can be influenced by factors outside a provider's control, such as a patient's comorbid conditions or severity of illness. Because patients are not randomly assigned to providers, performance measures should account for these underlying differences in patients' health risk to ensure performance measures make fair conclusions about provider quality. Risk adjustment (also known as case-mix adjustment) refers to statistical methods to control or account for patient-related factors when computing performance measure scores.

Risk adjusting outcome measures to account for differences in patient health status and clinical factors (e.g., comorbidities, severity of illness) that are present at the start of care is widely accepted. However, there is a growing evidence base that a person's social risk factors (i.e., socioeconomic and demographic factors) can also affect health outcomes.⁴⁵ Previous NQF policy did not allow for measure developers to include social risk factors in the risk-adjustment models of measures being submitted for NQF review and endorsement. This policy was developed because of concerns that including these factors in the risk-adjustment models of reasures could mask disparities or create lower standards of care for people with social risk factors. However, the increased use of performance measures for public reporting and payment purposes underscores the need to ensure that these measures fairly and accurately assess quality. As a result, stakeholders and policymakers have called for the federal government to examine impact of social factors on the results of performance measures.

In August 2014, an NQF-convened Expert Panel recommended that NQF allow the inclusion of social risk factors in the risk-adjustment models of endorsed measures where there is both a conceptual basis (i.e., a logical theory or rationale) and empirical evidence that show social risk factors can influence the outcomes assessed in the measures. The Expert Panel also recommended that performance measures adjusted for social risk be stratified by social and demographic factors to identify disparities. However, concerns remained about the appropriateness and feasibility of allowing NQF-endorsed measures to be adjusted for social risk. To address these concerns, the NQF Board of Directors suspended NQF's policy prohibiting the inclusion of social risk factors in risk-adjustment models and instituted a two-year trial to assess how and when it is appropriate to adjust performance measures for social risk. NQF's Disparities Standing Committee provided oversight and guidance on the evaluation of the results of the trial.

In April 2017, NQF concluded this self-funded two-year trial period during which measure developers were required to explore the impact of social risk factors on the results of their measures and could include social risk factors in the risk-adjustment models of measures submitted for endorsement review if there was a conceptual basis and empirical evidence to support doing so. NQF's work, as well as recent reports from the <u>National Academies of Science</u>, Engineering, and <u>Medicine⁴⁶</u> and the <u>Office of the Assistant Secretary for Planning and Evaluation</u>,⁴⁷ adds to growing evidence that individuals' social risk factors affect their health and healthcare.

The trial period included all measures submitted for review from April 2015 through April 2017. During this two-year period, NQF reviewed 303 performance measures across 16 topical areas. Out of the 303 measures submitted for endorsement, 93 included some form of risk adjustment. The measure developers found—and the standing committees reviewing these measures agreed—that 65 of these 93 risk-adjusted measures had a conceptual basis for including social risk factors in the model. This relationship was demonstrated empirically for 21 out of these 65 measures. Ultimately, 17 out of these 21 measures were <u>NQF-endorsed with a social risk factor included</u> in their risk-adjustment model.

The trial period highlighted challenges to adjusting measures for social risk factors. First, the trial revealed challenges in obtaining data on social risk factors, including data granular enough to reflect individuals' social risk accurately. Next, the trial found that social risk factors had variable impacts on performance scores, reaffirming the Expert Panel's guidance that each measure must be assessed individually to determine if there is an empirical basis for social risk factor adjustment. In July 2017, NQF issued a report of its findings⁴⁸ from the trial, highlighting key conclusions and areas where further study may be needed.

Throughout the trial period, stakeholders expressed varying views on whether or not including social risk factors would worsen healthcare disparities. Some stakeholders reiterated concerns about masking disparities or creating different standards of care. However, others cautioned that using measures that are not adjusted for social risk factors for payment purposes disproportionately penalizes safety-net provides and could worsen disparities by threatening access to care.

To allow for monitoring of potential disparities in care, NQF requires the developers of measures that include social risk factors in their risk-adjustment models to also submit specifications to calculate a version of the measure that only includes clinical risk factors and which can be stratified by social risk. This would allow measure users to compare the measure when adjusted for social risk and when only adjusted for clinical risk to better understand the effects of adjustment for social risk.

In July 2017, the NQF Board of Directors approved a three-year extension of the policy allowing measure developers to include social risk factors in risk-adjustment models for outcome measures submitted for endorsement. NQF staff will review the risk-adjustment approach during the preliminary analysis of each measure. Additionally, NQF's Scientific Methods Panel⁴⁹ will review all outcome measures and provide guidance on the appropriateness of the risk-adjustment methods. NQF standing committees will continue to review the conceptual basis and the appropriateness of social and clinical risk factors included in each measure's risk-adjustment model.

Current State of NQF Measure Portfolio: Responding to Evolving Needs

Working with multistakeholder committees,⁵⁰ NQF maintains its endorsed measure portfolio to keep it relevant. This maintenance may include removing endorsement for measures that no longer meet rigorous criteria, facilitating measure harmonization among competing or similar measures, or retiring measures that no longer provide significant opportunities for improvement. NQF encourages measure developers to submit measures that can drive more meaningful improvements in care, such as measures of patient-reported outcomes. While NQF pursues strategies to make its measure portfolio appropriately lean and responsive to real-time changes in evidence, it also proactively seeks measures from the field that will help to fill known measure gaps and that align with the NQS goals.

NQF worked on 18 quality measure endorsement projects in 2017. Across these HHS-funded endorsement projects, NQF endorsed 120 measures and removed 109 measures from its portfolio. NQF's measure portfolio contains high-value measures across a variety of clinical and cross-cutting topic areas. Forty-two percent of the measures in NQF's portfolio are outcomes measures. NQF's multistakeholder committees—which include providers, payers, and other experts from across healthcare, as well as patients and consumers—review both previously endorsed and new measures using rigorous evaluation criteria. The committees make recommendations for NQF to endorse or not endorse measures. In 2017, NQF's Board completed its service as the ratifying body for endorsement decisions of the CSAC. The CSAC now makes all final endorsement decisions.

Measure Endorsement and Maintenance Accomplishments

All measures are evaluated by subject matter and measurement expert committees against the following NQF criteria:

- 1. Importance to Measure and Report
- 2. Reliability and Validity Scientific Acceptability of Measure Properties
- 3. Feasibility
- 4. Usability and Use
- 5. Comparison to Related or Competing Measures

More information is available in the Measure Evaluation Criteria and Guidance for Evaluating Measures for Endorsement.⁵¹

<u>Appendix A</u> lists the types of measures reviewed in 2017 and the results of the review. Below are summaries of endorsement and maintenance projects completed in 2017, as well as projects that began but were not completed during the year.

Completed Projects

All-Cause Admissions and Readmissions

High rates of readmissions are costly to the healthcare system and can indicate low-quality care during a hospital stay and poor-quality care coordination. Unnecessary hospitalizations can prolong the illness of patients, increase their time away from home and family, expose them to potential harms, and add to

their costs. A 2013 Medicare Payment Advisory Commission (MedPAC) report suggests that reducing avoidable readmissions by 10 percent could achieve a savings of \$1 billion or more.⁵²

Successful efforts to drive down readmissions are being applied beyond inpatient hospital stays to postacute care settings and across the entire continuum of care.^{53,54} NQF currently has 47 endorsed all-cause and condition-specific admissions and readmissions measures addressing numerous settings. Many of these measures are used in various private and federal quality reporting and value-based purchasing programs, including CMS' Hospital Readmission Reduction Program (HRRP).

NQF undertook two projects to review admissions and readmissions measures in 2017. The first phase began in 2015. The Board of Directors finalized the endorsement decisions of measures in this first phase in December 2016. However, because NQF received appeals of the endorsement decision for some measures, the project did not conclude until April 2017. NQF considers an endorsement project complete after adjudication of any appeals received and issuance of the final report.

During the 2015-2017 phase of work, NQF's All-Cause Admissions and Readmissions Standing Committee evaluated 11 new measures and six measures undergoing maintenance review. Sixteen measures were endorsed, and one was not endorsed. Endorsed measures assessed issues such as hospitalization and emergency department use from home health settings and 30-day readmissions for various conditions. These measures were included in NQF's groundbreaking trial to determine whether NQF should permanently change its policy and allow measures to be adjusted for social risk factors. Ultimately, one measure, NQF #2858 *Discharge to Community*, was found to have both a conceptual basis and empirical evidence to adjust the measure for social risk. One social risk factor, marital status, was included in the risk-adjustment model of this measure. This project phase concluded in April 2017.

In the most recent 2017 phase of work, the Committee evaluated two additional measures. Both measures were endorsed. One of these measures, which assesses unplanned readmissions for cancer patients, was endorsed with one social risk factor in its risk-adjustment model (dual eligibility for Medicare and Medicaid). This project phase concluded in September 2017.

Behavioral Health

About 43.8 million people in the United States—nearly one in five—experience a mental illness in a given year.⁵⁵ In addition, 20.2 million U.S. adults had a substance use disorder, of which 50.5 percent had both a mental disorder and a substance use disorder.⁵⁶ In 2013, the United States spent \$201 billion for mental healthcare, and that number is expected to continue rising.⁵⁷ Given the extent and impact of mental illness and substance use disorders, performance measurement in this area needs to remain operational and current.

This multiphase project endorsed measures for improving the delivery of behavioral health services, achieving better behavioral health outcomes, and improving the behavioral health of the U.S. population, especially those with mental illness and substance abuse. Prior phases of this project concluded with endorsement of 46 measures. NQF's behavioral health portfolio currently contains 54 measures.

In the 2016-2017 project phase, NQF's Behavioral Health Standing Committee examined measures of tobacco use, alcohol and substance use, attention deficit hyperactivity disorder (ADHD), depression, medication continuation and reconciliation, and follow-up after hospitalization for mental illness. The Committee evaluated seven new measures and six measures undergoing maintenance review. Nine measures were endorsed, three were not endorsed, and one measure undergoing maintenance review was deferred for future, continued endorsement consideration. This project concluded in August 2017.

Cancer

Cancer is the second most common cause of death in the United States, exceeded only by heart disease.⁵⁸ The National Cancer Institute estimates that 595,690 people died from cancer in 2016.⁵⁹ Nearly half of all men and one-third of all women in the U.S. will develop cancer during their lifetime.⁶⁰ The National Cancer Institute estimated that in 2010 the costs for cancer care in the United States totaled nearly \$157 billion and could reach \$174 billion in 2020.⁶¹

The complexity of cancer and the many care settings and providers involved in its treatment underscore the need for quality measures that address the value and efficiency of care for patients and their families. NQF's portfolio of 34 cancer measures includes measures for breast cancer, colon cancer, hematology, lung and thoracic cancer, prostate cancer, and other general cancer measures. These measures address cancer screening, appropriate treatment (including surgery, chemotherapy, and radiation therapy), and morbidity and mortality.

NQF's Cancer Standing Committee evaluated three new measures and 15 measures undergoing maintenance review. Thirteen measures were endorsed, two measures received inactive endorsement with reserve status, and three measures were not endorsed. The purpose of inactive endorsement with reserve status is to retain endorsement of reliable and valid quality performance measures that have overall high levels of performance with little variability, so that performance may be monitored as necessary to ensure that it does not decline. This project concluded in January 2017.

Cardiovascular

Cardiovascular disease (CVD) is the leading cause of death in the United States. It kills nearly one in four Americans and costs \$312 billion per year, more than 10 percent of annual health expenditures.⁶² Considering the overall toll of cardiovascular disease, measures that assess clinical care performance and patient outcomes are paramount to reducing the negative impacts of CVD.

This multiphase project has built up a portfolio of 54 cardiovascular measures, covering primary prevention and screening, coronary artery disease (CAD), ischemic vascular disease (IVD), acute myocardial infarction (AMI), cardiac catheterization, percutaneous catheterization intervention (PCI), heart failure (HF), rhythm disorders, implantable cardioverter-defibrillators (ICDs), cardiac imaging, cardiac rehabilitation, and high blood pressure.

In the 2016-2017 project phase, NQF's Cardiovascular Standing Committee evaluated two new measures and four measures undergoing maintenance review. Four measures were endorsed, and two were not endorsed. One of the endorsed measures, NQF #0076 *Optimal Vascular Care*, included a social risk

factor, status and type of insurance, in its risk adjustment model. This project concluded in February 2017.

Care Coordination

The coordination of care is essential to reduce preventable hospitalizations, achieve better patient outcomes, and lower costs in today's healthcare system. Reducing preventable hospitalizations is a significant factor in controlling healthcare costs.⁶³ In 2010, preventable hospital admissions accounted for nearly \$32 billion in costs for adults with selected chronic and acute diseases.⁶⁴

This multiphase project focused on healthcare coordination across episodes of care and care transitions. The NQF portfolio for care coordination includes 14 measures, covering emergency department transfers, plan of care, e-prescribing, timely transitions, medication management, and transition records.

In the 2016-2017 project phase, NQF's Care Coordination Standing Committee evaluated two new measures and five measures undergoing maintenance review. One measure was endorsed, and six were not endorsed. Endorsement was removed from four previously endorsed measures. This project concluded in August 2017.

Cost and Resource Use

In 2015, healthcare spending in the United States reached \$3.2 trillion—a 5.8 percent increase over 2014 spending,⁶⁵ but the United States continues to rank below other developed countries for health outcomes, including lower life expectancy and greater prevalence of chronic diseases.⁶⁶ The United States is also falling behind other developed countries in the quality domains of effective care, safe care, coordinated care, and patient-centered care.⁶⁷ Improving efficiency has the potential to simultaneously reduce the rate of cost growth and improve the quality of care provided.

The NQF cost and resource use portfolio includes six measures. The 2016-2017 project was the latest phase of NQF's work on evaluating and endorsing cost and resource use measures, initially begun in 2010. The prior three phases of work focused on the evaluation of both condition-specific and noncondition-specific measures of total cost, using per capita or per hospitalization episode approaches.

In this fourth phase, NQF's Cost and Resource Use Standing Committee evaluated three existing noncondition-specific measures of cost and resource use. All three measures received continued endorsement. These measures were included in NQF's social risk trial; therefore, the measure developers were asked to evaluate the impact of social risk factors on the outcome of their measures. The developers of all three measures found a conceptual basis to potentially include social risk factors in the risk-adjustment models of their measures. However, when these factors were tested empirically, their inclusion did not significantly improve the performance of the risk-adjustment model and did not result in statistically significant changes in measure scores for nearly all providers. As a result, these measures were not endorsed with adjustment for social risk. This project concluded in August 2017.

Eye Care and Ear, Nose, and Throat Conditions

More than 3.4 million (3 percent) of Americans 40 years of age or older are either blind or visually impaired, and millions more are at risk for developing vision impairment and blindness.⁶⁸ At a cost of \$139 billion in 2013, eye disorders and vision loss are among the costliest health conditions currently facing the United States.⁶⁹ Hearing loss affects 1 in 10 Americans. In 2010, there were an estimated 20 million visits to otolaryngologists in America, and one-fifth of these visits were made by people under age 15.⁷⁰

NQF's Eye Care, Ear, Nose, and Throat (EENT) Standing Committee identifies and endorses measures in areas related to glaucoma, macular degeneration, cataracts, hearing screening and evaluation, and ear infections. The NQF EENT measure portfolio includes 21 measures. In 2017, the Committee evaluated two new measures. One measure was endorsed, and the other was not endorsed. This project concluded September 2017.

Health and Well-Being

Medical care has a relatively small influence on overall health when compared with behaviors such as smoking and poor diet, physical environmental hazards, and social factors like low educational achievement and poverty.⁷¹ Social, environmental, economic, and behavioral factors all play a significant role in maintaining and improving health and well-being. These and other determinants of health contribute to up to 60 percent of deaths in the United States,⁷² yet less than 5 percent of health expenditures target prevention.⁷³

The NQF health and well-being portfolio includes 47 measures, which cover areas such as health-related behaviors to promote healthy living; community-level indicators of health and disease; modifiable social, economic, and environmental determinants of health; primary prevention and/or screening; and oral health.

In 2017, NQF's Health and Well-Being Standing Committee evaluated 12 new measures and 11 measures undergoing maintenance review. The 2017 project was the third phase of NQF's work to review measures focused primarily on primary prevention and/or screening. Ultimately, 13 measures were endorsed, one measure received inactive endorsement with reserve status, and six measures were not endorsed. Three eMeasures assessing hepatitis C screening for at-risk patients, as well as appropriate follow-up, were approved for trial use. The trial use designation allows the eMeasures that are ready for implementation to undergo the reliability and validity testing necessary for full endorsement consideration by using clinical data in electronic health records (EHRs). Measures approved for trial use may be submitted for endorsement review within three years. NQF's health and well-being project concluded in April 2017.

Infectious Disease 2016-2017

Each year, the nation spends more than \$120 billion to treat infectious diseases and \$5 billion to treat antibiotic resistant bacteria.⁷⁴ Infectious diseases account for 3.9 million hospital visits per year and are a leading cause of death in the United States.⁷⁵ Septicemia is the most expensive condition treated in U.S. hospitals, costing \$20.3 billion in 2011.⁷⁶

The NQF infectious disease portfolio includes nine measures. In its 2017 work, NQF's Infectious Disease Standing Committee evaluated measures that address infectious diseases, such as HIV/AIDS and sepsis, and made recommendations for measure endorsement. The project built on NQF's earlier work to set performance measurement standards for HIV/AIDS and other sexually transmitted infections, hepatitis, adult and pediatric respiratory infections, and sepsis.

The Committee evaluated four new measures and five measures undergoing maintenance review. All nine measures were endorsed. This project concluded in August 2017.

Musculoskeletal

Musculoskeletal disorders (MSDs) are a leading cause of disability in the United States, with increasing prevalence and cost associated with musculoskeletal diseases in an aging population.⁷⁷ In addition to the morbidity associated with musculoskeletal disorders, there has been a significant increase in costs to treat musculoskeletal disorders.⁷⁸ Low back pain is among the most common reasons for visits to physicians and a major reason for work-related disability. Because of the burden of these disorders, there is a critical need for nationally recognized musculoskeletal care measures.

The NQF musculoskeletal portfolio includes 29 measures. In its 2016-2017 work, NQF's Musculoskeletal Standing Committee evaluated two measures undergoing maintenance review. Neither measure was endorsed. This project concluded in July 2017.

Palliative and End-of-Life Care

Improving both access to, and quality of, palliative and end-of-life care is becoming increasingly important due to the aging of the U.S. population; the projected increases in the number of Americans with chronic illnesses, disabilities, and functional limitations; and the growth in ethnic and cultural diversity, which has intensified the need for individualized, person-centered care.⁷⁹

The NQF palliative and end-of-life portfolio includes 59 measures. In 2017, NQF's Palliative and End-of-Life Standing Committee evaluated a new composite measure assessing whether hospices perform seven critical care processes upon admission of adult patients. Seven individual NQF-endorsed quality measures—which are currently implemented in the CMS Hospice Quality Reporting Program—will provide the source data for this comprehensive assessment measure. The measure was endorsed.

The Standing Committee in 2017 also made several refinements to NQF's measurement framework for palliative and end-of-life care. For example, the Standing Committee differentiated curative palliative care, which is provided alongside curative treatment, and chronic palliative care, which is provided to individuals with noncurable conditions who are not near the end of life. The Standing Committee also emphasized the need for measurement focused on the caregiver, among other recommendations. This project concluded in September 2017.

Patient Safety

Errors and adverse events associated with healthcare cause hundreds of thousands of preventable deaths each year in the United States.⁸⁰ Patient safety-related events occur across healthcare settings from hospitals to clinics to nursing homes and include healthcare-associated infections (HAIs),

medication errors, falls, and other potentially avoidable occurrences. The societal costs are tremendous. These costs include higher use of hospital and other services, higher insurance premiums, higher taxes, lost work time and wages, and reduced quality of life.

NQF-endorsed patient safety measures are important tools for tracking and improving patient safety performance in U.S. healthcare. NQF's patient safety portfolio includes 73 measures, including measures of medication safety, healthcare-associated infection, falls, pressure ulcers, and other safety concerns. These measures are used in many quality improvement, public reporting, and accountability programs across the country. Federal programs using measures from NQF's patient safety portfolio include CMS' Physician Quality Reporting System (PQRS), and the Hospital Inpatient Quality Reporting (IQR) Program, Hospital Value-Based Purchasing (VBP) Program, and the Hospital-Acquired Condition Reduction Program (HACRP).

In a project that concluded in March 2017, NQF's Patient Safety Standing Committee evaluated 13 new measures and two measures undergoing maintenance review. Eleven measures were endorsed and two measures were not endorsed. The endorsement decision for one measure undergoing maintenance review was deferred. In addition, one eMeasure to assess the quality of blood samples in the emergency department was approved for trial use. The endorsed measures include three measures to address the prescription of opiolds at high doses or from multiple providers, with appropriate exclusions, including cancer patients. These are the first NQF-endorsed measures intended to address the nation's devastating—and growing—opioid epidemic.

In a separate project that concluded in July 2017, the Committee evaluated the deferred measure from its March 2017 work, as well as six new measures. The deferred measure, which is part of the Healthcare Effectiveness Data and Information Set (HEDIS) and assesses whether or not older adults were dispensed a high-risk medication, was endorsed. The Committee evaluated the six new measures, which were intended to assess potentially avoidable complications for patients with certain conditions. The measure developer withdrew the measures from further consideration before NQF made a final endorsement decision.

Pediatric

Approximately 74 million children under 18 years of age live in the United States, representing 23.3 percent of the population.⁸¹ The number of children and adolescents diagnosed with chronic medical conditions has risen consistently over the last decades.⁸² Although the number of NQF-endorsed pediatric measures to evaluate and improve care of children and adolescents is growing, expanding the availability of evidence-based pediatric measures for public and private use is a priority.

The Children's Health Insurance Reauthorization Act of 2009 (CHIPRA) accelerated interest in pediatric quality measurement and provided an unprecedented opportunity to Improve the healthcare quality and outcomes of the nation's children, especially the nearly 36 million children enrolled in Medicaid and/or CHIP.⁸³ CHIPRA mandates that CMS develop and update a core set of performance measures for voluntary use by states to assess the quality of care provided to children enrolled in Medicaid and CHIP—the Child Core Set—and requires annual recommended updates to the set.

NQF's pediatrics portfolio includes 102 measures, of which 39 are specific to the pediatric population and 63 include both the pediatric and adult populations. Many of the measures in the pediatric portfolio are in use in at least one federal program. Seventeen NQF-endorsed measures were included in the 2017 Core Set of Children's Health Care Quality Measures for Medicaid and CHIP (Child Core Set).⁸⁴

For this project, which concluded in August 2017, NQF's Pediatric Standing Committee evaluated 11 new measures. Four measures were endorsed, including a new facility-level outcome measure of preventable adverse events among pediatric inpatients, as well as an outcome measure to examine public insurance participation rates and measure continuity of enrollment among vulnerable children. Seven measures were not endorsed.

Person- and Family-Centered Care

Ensuring that patients and their families are engaged partners in care is one of the core priorities of the NQS and is a focus of significant healthcare efforts. NQF's person- and family-centered care (PFCC) portfolio has 62 measures, most of which are outcome measures. The portfolio includes measures focused on quality of life, functional status, experience of care, shared decision making, symptom/symptom burden, and communication.

In the phase of PFCC work that concluded in January 2017, NQF's PFCC Standing Committee evaluated 12 new measures and one measure undergoing maintenance review. All 13 measures were endorsed, including patient-reported outcome (PRO) performance measures.

Renal

Renal disease is a leading cause of death and morbidity in the United States. Millions of Americans have chronic kidney disease (CKD), and over half a million Americans have received a diagnosis of end-stage renal disease (ESRD), the only chronic disease covered by Medicare for people under the age of 65.⁸⁵

NQF's renal portfolio currently contains 21 measures. For this project, which began in 2015 and concluded in February 2017, NQF's Renal Standing Committee evaluated three new measures and three measures undergoing maintenance review. Five measures were endorsed, including measures to assess hemodialysis patients. One measure was not endorsed. Of the five endorsed measures, one was endorsed with adjustment for social risk.

Surgery

The rate of surgical procedures continues to increase annually, and ambulatory surgery centers are the fastest growing provider type participating in Medicare.⁸⁶ Performance measurement and reporting provide an opportunity to further improve the safety and quality of surgical care.

NQF's surgery measure portfolio is one of its largest, with 62 measures. It addresses cardiac, vascular, orthopedic, urologic, and gynecologic surgeries, and includes measures for adult and child surgeries as well as surgeries for congenital anomalies. The portfolio also includes measures of perioperative safety, care coordination, and a range of other clinical or procedural subtopics. Many of the measures in the portfolio are used in public- and/or private-sector accountability and quality improvement programs. However, while significant strides have been made in some areas, measure gaps remain for some types

of procedures and additional, effective measures are needed to evaluate and improve overall surgical quality, shared accountability, and patient-centered care.

During the 2015-2017 phase of work, NQF's Surgery Standing Committee evaluated 10 new measures, including five new eMeasures, and 13 measures undergoing maintenance review. Fifteen measures were endorsed, three were not endorsed, and the five eMeasures were not approved for trial use.

New Projects in 2017

In September 2017, NQF began work to review measures in 14 topic areas. This work will be completed under NQF's new, compressed endorsement process which now allows for two measure review cycles annually. Measure developers may submit measures for endorsement review for the cycle initiated in September 2017 or in the next cycle scheduled for April 2018. Reflecting another improvement from NQF's 2017 Consensus Development Process redesign, scientific review of complex measures in these topic areas will be conducted by the Scientific Methods Panel, and NQF staff will review will review noncomplex measures. This input will be shared with the standing committees in their consideration of measures for endorsement. Furthermore, all standing committees will apply the NQF measure prioritization criteria in their new work.

All-Cause Admissions and Readmissions

Despite the healthcare industry's focus in recent years on reducing preventable readmissions, challenges persist, especially for patients who suffer from chronic and comorbid conditions. Measuring critical factors that affect the quality of patient care can provide valuable information to help providers better address patients' health needs after hospitalization and keep them from unnecessarily returning to the hospital.

Reducing avoidable readmissions is a national priority. NQF will review measures related to admissions and readmissions, both all-cause and those specific to certain conditions, such as heart failure. No measures were submitted for this project for the September 2017 cycle. Measures are expected for the April 2018 cycle.

Behavioral Health and Substance Use

Behavioral health encompasses a range of treatments and services for individuals who are at risk or suffering from mental, behavioral, and/or addictive disorders. These may include substance abuse, post-traumatic stress disorder, and anxiety, or depression. Behavioral health disorders are a leading cause of disability, and treatment continues to be a source of rising healthcare costs in the United States.⁸⁷

NQF will review measures that can help achieve better behavioral health and healthcare, with a focus on attention deficit/hyperactivity disorder (ADHD), depression, and substance abuse screening, primary care, and treatment. Better measures of the quality of behavioral healthcare services can help ensure that people receive timely, coordinated, and effective care that ultimately leads to better outcomes and improved overall health. Five measures were submitted for this project for the September 2017 cycle.

Cancer

Cancer takes the lives of more than 1,600 Americans each day.⁸⁸ More and more people are also surviving cancer: nearly 14.5 million Americans with a history of cancer were alive in 2014, and it is estimated that the number of cancer survivors in the United States will increase to almost 19 million by 2024.⁸⁹ In addition, according to the Agency for Healthcare and Research Quality (AHRQ), the cost of cancer care in the United States has more than doubled in the 10 years from 2001 to 2011. Quality measures are needed to ensure effectiveness, value, and efficiency of cancer care for patients and their families.

NQF will review measures to assess the quality of care for breast, colon, prostate, esophageal, lung, and other cancers. Since cancer care is complex and provided in multiple settings by multiple providers, high-quality measures that capture the complexity of this care as well care coordination are essential. NQF seeks to endorse measures focused on cancer screening and treatment. Five measures were submitted for this project for the September 2017 cycle.

Cardiovascular

More than 800,000 Americans die every year from heart disease and many people living with heart disease are seriously ill and disabled.⁹⁰ Heart disease is also a tremendous financial burden, accounting for approximately \$300 billion in annual U.S. healthcare expenditures.⁹¹ By improving measurement of heart disease treatment, interventions, and outcomes, NQF aims to improve the quality of care and health outcomes for the millions of Americans affected by heart disease.

NQF will review measures for heart conditions such as hypertension, coronary artery disease, acute myocardial infarction, percutaneous coronary intervention, heart failure, and atrial fibrillation. Measures may assess outcomes, treatments, diagnostic studies, interventions, or procedures associated with these conditions. Six measures were submitted for this project for the September 2017 cycle.

Cost and Efficiency

Healthcare spending in the United States is unmatched by any country in the world, without a corresponding increase in better outcomes or overall value.⁹² According to CMS, national healthcare expenditures rose 5.8 percent to \$3.2 trillion in 2015, or \$9,990 per person.⁹³ Additionally, estimates suggest that as much as 30 percent of all healthcare spending is wasted on unnecessary or ineffective services.⁹⁴ Improving efficiency within the healthcare system holds the potential both to reduce the rate of cost growth and improve the quality of care provided.

To help understand how and where healthcare dollars are spent, NQF will review measures focused on the cost of care, payment, and efficiency for all conditions. Measures may, for example, evaluate total care costs for individual patients, as well as look at specific treatment costs for any condition. No measures were submitted for this project for the September 2017 cycle. Measures are expected for the April 2018 cycle.

Geriatrics and Palliative Care

Improving both access to, and the quality of, geriatric and palliative care in all healthcare settings is becoming increasingly important. About 48 million Americans are age 65 and older, and that number is

projected to grow to over 88 million by 2050.⁹⁵ Increasingly, older Americans are living with multiple chronic conditions that can lead to gradual and prolonged functional decline. Palliative care has been shown to improve quality of life, enhance information and communication, lower costs of care, and even help some patients live longer. However, the quality and accessibility of palliative care are highly variable in hospital and outpatient settings, and many patients who receive end-of-life palliative care through hospice enroll too late to benefit fully from this care. Consensus on endorsed measures that capture the important structures, processes, and outcomes of palliative and geriatric care will help to improve these services across care settings.

NQF will reconvene its Palliative and End-of-Life Care Standing Committee as the Geriatrics and Palliative Care Committee to review measures focused on experience with care, care planning, management of pain or difficulty breathing, care preferences, and quality of care at the end of life. No measures were submitted for this project for the September 2017 cycle. Measures are expected for the April 2018 cycle.

Neurology

Neurological conditions can be severe, affecting the normal function of both the spinal cord and the brain by impeding muscle function, lung function, swallowing, and even breathing. With more than 600 neurologic diseases, neurological conditions are a leading cause of death in the United States and a major contributor to healthcare costs. According to the U.S. Centers for Disease Control and Prevention, 1 in 26 people will develop epilepsy during their life. In addition, nearly 800,000 Americans suffer a stroke each year, making stroke the fifth leading cause of death in the nation.⁹⁶ The Alzheimer's Association estimates that more than 5 million Americans are living with Alzheimer's disease. The estimated cost of care for people with dementia was \$230 billion in 2016.⁹⁷

To help guide improved treatment and care for millions of Americans with neurological disorders, NQF will review measures in key areas, including stroke, epilepsy, multiple sclerosis, dementia and Alzheimer's disease, Parkinson's disease, and traumatic brain injury. No measures were submitted for this project for the September 2017 cycle. Measures are expected for the April 2018 cycle.

Patient Experience and Function

High-quality performance measures are essential to provide information and insight on how providers are responding to the needs and preferences of patients and families. Measures that address how healthcare organizations can create effective care practices that support positive patient experiences and improved function are vital to improving the quality of care.

NQF's patient experience and function work encompasses quality measures previously designated to NQF's Person- and Family-Centered Care and Care Coordination Standing Committees. In this consolidated area of work, NQF will review measures that assess health-related quality of life, patient and family engagement in care, functional status, symptoms and symptom burden, experience with care, and care coordination. Eight measures were submitted for this project for the September 2017 cycle.

Patient Safety

Despite significant achievements in measuring and addressing patient harms, tens of thousands of preventable injuries to patients still occur each year, and many of these harms have dire consequences. For example, an estimated 5 to 10 percent of hospitalized patients acquire healthcare-associated infections each year, resulting in 99,000 deaths and \$20 billion annually in healthcare costs.⁹⁸

In this new work, NQF will review measures focused on pressure ulcers, healthcare-acquired conditions, sepsis, medication management, and mortality rates. One measure was submitted for this project for the September 2017 cycle.

Perinatal and Women's Health

The United States spends more on perinatal healthcare than any other health sector (\$111 billion in 2010),⁹⁹ but ranks last in maternal outcomes among all industrialized nations.¹⁰⁰ With nearly 4 million U.S. births in 2015,¹⁰¹ and great disparities in care and outcomes among different racial and ethnic groups, reproductive and perinatal healthcare is a major concern for women, mothers, babies, and the providers who care for them, and accordingly, is important for quality measurement.¹⁰²

NQF will reconvene the multistakeholder Perinatal and Reproductive Health Standing Committee as the Perinatal and Women's Health Standing Committee to review measures focused on reproductive health, pregnancy, prenatal care, labor and delivery, post-partum care for newborns, and childbirth-related issues for women. One measure was submitted for this project for the September 2017 cycle.

Prevention and Population Health

The United States ranks lower than many other developed nations on health outcomes, yet spends more on healthcare than any other nation,¹⁰³ and continues to struggle with significant disparities in health and healthcare. In addition, social risk factors contribute to up to 60 percent of deaths in the United States. However, most U.S. healthcare dollars are spent on treatment rather than social and other services that can help prevent disease.¹⁰⁴ Improving population health requires a commitment to sustained prevention efforts, including adopting healthy behaviors, increased screening for disease, reducing harmful environmental exposures, and mitigating the effects of social risk factors (e.g., economic, geographic, and race/ethnicity) on health.

Performance measures can help to monitor the success of population health improvement initiatives and help focus future health improvement efforts on proven, effective strategies. NQF will reconvene the Health and Well-Being Standing Committee as the Prevention and Population Health Standing Committee to review measures focused on smoking, diet, disease incidence and prevalence, prevention and screening, practices to promote healthy living, community interventions, and modifiable social, economic, and environmental determinants of health with a demonstrable relationship to prevention and population health. Eight measures were submitted for this project for the September 2017 cycle.

Primary Care and Chronic Illness

Primary care has a central role in improving the health of people and populations. Primary care practitioners manage the uniqueness and complexities of each patient. In this setting, the diagnosis and treatment of the patient focus on the health of the entire patient and not a single disease. Chronic

illnesses are long-lasting or persistent health conditions or diseases that patients and providers must manage on an ongoing basis. The incidence, impact, and cost of chronic disease is increasing in the United States. It is essential to better understand the scope of two of the most common and most expensive chronic diseases confronting the nation: diabetes, which affects at least 29 million Americans,¹⁰⁵ and asthma, which affects 25 million Americans.¹⁰⁶

High-quality performance measurement that captures the complexity of primary care and chronic illnesses is essential to improve diagnosis, treatment, and management of conditions. NQF will review measures in these important healthcare areas under a consolidated measure portfolio that reflects the importance of caring for chronic illness in primary care settings. Measures may focus on nonsurgical eye or ear, nose, and throat conditions, diabetes care, osteoporosis, HIV, rheumatoid arthritis, gout, back pain, asthma, chronic obstructive pulmonary disease (COPD), and acute bronchitis. No measures were submitted for this project for the September 2017 cycle. Measures are expected for the April 2018 cycle.

Renal

Renal disease is widespread in the United States. An estimated 30 million American adults (15 percent of the population) have chronic kidney disease (CKD), which is associated with premature mortality, decreased quality of life, and increased healthcare costs. Left untreated, CKD can result in ESRD, which afflicts over half a million people in the United States.¹⁰⁷ Measures can help ensure that people with renal disease receive high-quality care.

NQF will review measures that address conditions, treatments, interventions, or procedures relating to ESRD, CKD, and other renal conditions, for accountability and quality improvement. No measures were submitted for this project for the September 2017 cycle. Measures are expected for the April 2018 cycle.

Surgery

In 2010, 51.4 million inpatient procedures and 53.3 million surgical and nonsurgical procedures were performed in ambulatory surgery centers.¹⁰⁸ Ambulatory surgery centers are the fastest growing provider type participating in Medicare.¹⁰⁹ In 2012, 28 percent of hospital stays (excluding maternal and neonatal stays) involved operating room procedures and accounted for nearly half of total hospital costs.¹¹⁰ Consumers are increasingly turning to public reports of quality measures to make decisions about surgical care, looking specifically at the likelihood of surgical success, i.e., the surgery achieving its intended outcome and avoiding complications. Despite advances in improving surgical care and given the increasing rates of surgical procedures and associated costs, gaps persist in performance measurement and reporting that impair efforts to improve the safety and quality of surgical care.

While significant strides have been made to make surgery safer and improve outcomes, patientcentered measures that assess shared accountability and overall surgical quality are still needed. In this new work, NQF will review measures that assess pre- and post-surgical care, timing of prophylactic antibiotics, and adverse surgical outcomes. Seven measures were submitted for this project for the September 2017 cycle.

IV. Stakeholder Recommendations on Quality and Efficiency Measures

Section 1890(b)(5)(A)(vi) of the Social Security Act requires the CBE to include in this report a description of matters related to multistakeholder group input on the selection of quality and efficiency measures from among: (I) measures that have been endorsed by the entity; and (II) such measures that have not been considered for endorsement by such entity but are used or proposed to be used by the Secretary for the collection or reporting of quality and efficiency measures.

Measure Applications Partnership

Under section 1890A of the Act, HHS is required to establish a pre-rulemaking process under which a consensus-based entity (currently NQF) would convene multistakeholder groups to provide input to the Secretary on the selection of quality and efficiency measures for use in certain federal programs. The list of quality and efficiency measures HHS is considering for selection is to be publicly published no later than December 1 of each year. No later than February 1 of each year, the consensus-based entity is to report the input of the multistakeholder groups, which will be considered by HHS in the selection of quality and efficiency measures.¹¹¹

First convened in 2011, NQF's MAP recommends performance measures for use in federal healthcare quality programs. The MAP pre-rulemaking process enables a unique multistakeholder dialogue about priorities for measurement in these programs. It provides private- and public-sector stakeholders across the care continuum—including patients, clinicians, providers, purchasers, and payers—with the opportunity to identify and recommend the highest-value measures for each program as well as to provide strategic guidance across programs. Throughout its six years of annual review, MAP has worked toward the goal of lowering costs while improving quality, making measurement meaningful for improvement while reducing unnecessary administrative burden, and ensuring that patients and consumers get the information they need to support their healthcare decision making.

MAP convenes the Rural Health Workgroup and three setting-specific workgroups (Hospital, Clinician, and Post-Acute/Long-Term Care), as well as the Coordinating Committee, an overarching body that provides strategic direction and synchronization among the workgroups. More than 150 healthcare leaders from 90 organizations who regularly use measures and measurement information serve on MAP and participate in its discussions. The annual list of measures under consideration (MUC) for use in federal programs and MAP's deliberations on these measures are transparent and open for public comment. Each MAP workgroup considers public comment in its review of measures. For detailed information regarding MAP representatives, criteria for selection to MAP, and rosters, please see <u>Appendix E</u> and <u>Appendix G</u>.

MAP's efforts help to facilitate the alignment or use of the same measures across multiple federal programs. Alignment of measures helps providers better identify key areas in which to improve quality; reduces burdensome data collection that could distract hospitals, physicians, and nurses from their care delivery work; and helps to curb the proliferation of redundant measures, which could confuse patients and payers. MAP strives to offer recommendations that apply to and are coordinated across settings of care; federal, state, and private programs; levels of attribution and measurement analysis; and payer types. Although MAP provides recommendations to HHS, many are also adopted by the private sector.

New in 2017, MAP's Rural Health Workgroup will provide guidance on measures specific to the needs and challenges of rural providers and residents.

2017 Pre-Rulemaking Input

MAP completed its deliberations for the 2016-2017 pre-rulemaking cycle with the publication of its annual reports in February and March 2017, marking MAP's sixth review of measures for HHS programs. MAP reviewed 71 unique performance measures under consideration for use in 16 federal quality reporting and value-based payment programs (see <u>Appendix F</u>) covering clinician, hospital, and post-acute/long-term care settings.

The MAP Measure Selection Criteria guides the review process for the measures under consideration (see <u>Appendix E</u>). Over the course of the review process, MAP promotes alignment of measures across HHS programs and with private-sector efforts. MAP also incorporates measure use and performance information into its decision making to provide HHS with specific recommendations about the best use of available measures as well as filling measure gaps.

Guidance on Measures Currently in Use

Currently, there are a total of 634 measures used in programs that MAP reviews. In its 2017 guidance, MAP conducted a holistic review of the current measure sets used in federal programs and recommended significant improvements to reduce measure burden.

Other Process Improvements

In addition to providing guidance on measures currently in use in federal programs, MAP also made process improvements to address the challenge of reviewing measures early in their lifecycle. MAP is committed to the scientific integrity of the measures used in accountability programs but historically has had limited information about the reliability and validity of the measures under consideration. Some of the measures under consideration in a given year may not yet have been reviewed for NQF endorsement, and some measures under consideration may still be in development or testing.

MAP now reviews all measures using the same decision categories, with the addition of a new category in 2016-2017, Refine and Resubmit Prior to Rulemaking. The other categories include Support for Rulemaking, Conditional Support for Rulemaking, and Do Not Support for Rulemaking. MAP added the Refine and Resubmit category after it determined that all measures under consideration should be reviewed using the same process and that measures still in development would not be reviewed separately. MAP created this decision category to preserve its ability to support the concept of a measure under consideration and encourage its continued development, while noting that significant changes may be needed prior to its implementation. The Refine and Resubmit category differs from the Conditional Support for Rulemaking category by signaling that a larger change is needed to the measure under consideration or that the measure under consideration has not completed development and testing. A measure may receive this designation if MAP determines it is not an efficient use of measurement resources, it may not be feasible to report, it may not be reliable and valid for the setting and level of analysis for which it is being considered, or if implementation issues have been identified. The intent of this category was that measures receiving this designation would be brought back to MAP



prior to implementation. However, the HHS Secretary has statutory authority to propose measures after considering MAP's recommendations.

In 2017, MAP also completed improvements to integrate the MAP and NQF measure endorsement processes to provide MAP members and the public better information about the endorsement status of measures under consideration. For example, if a measure under consideration has undergone measure endorsement review, MAP members received the results of that review in the preliminary analysis and the discussion guide about the measure. MAP recommendations are also provided to the relevant NQF standing committee if and when a measure under consideration for use in federal programs is reviewed for endorsement.

MAP members have expressed a desire to understand more about what happens to a measure under consideration after MAP's review, particularly when MAP recommends potential improvements to the measure or the measure has not yet completed testing. Through the addition of the Refine and Resubmit Prior to Rulemaking category, MAP has established a pathway to receive feedback from CMS and measure developers on how its recommendations have been addressed.

NQF piloted a feedback loop process in the 2016-2017 pre-rulemaking cycle for CMS to provide the PAC/LTC Workgroup with updates on the development and endorsement of selected measures included on previous lists of measures under consideration. This review was not intended to allow for a change in MAP's recommendations about a measure; rather, it provided an opportunity for MAP members to better understand whether or how their suggested refinements and conditions of support have been met. The feedback loop process was well received by the PAC/LTC Workgroup. MAP members appreciated the opportunity to better understand how CMS implemented their input on measures under consideration. CMS also noted the value of the feedback loop to build relationships and better inform stakeholders. NQF plans to implement the feedback loop process across MAP for the 2017-2018 pre-rulemaking cycle.

MAP Clinician Workgroup

In its 2016-2017 cycle, MAP reviewed clinician-level measures under consideration for the following programs:

- Merit-Based Incentive Payment System (MIPS). MIPS is one of two tracks in the Quality Payment Program (QPP).
- Medicare Shared Savings Program. The Shared Savings Program is designed to create incentives for healthcare providers to work together voluntarily to coordinate care and improve quality for their patient population.

MIPS was established by section 101(c)of MACRA.¹¹² MIPS consolidates aspects of three existing Medicare quality reporting and value-based purchasing programs for clinicians. MIPS applies positive and negative payment adjustments for MIPS eligible clinicians (ECs) based on performance in four categories:

 Quality: replaces the Physician Quality Reporting System (PQRS) program and Value-Based Payment Modifier (VM) programs

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- Cost: replaces the VM program
- Advancing Care Information: replaces the Electronic Health Records Incentive Program for eligible professionals
- Improvement Activities: new performance category

MAP reviewed 18 measures for the MIPS. MAP supported two measures and conditionally supported seven measures, including three patient-reported outcome-based performance measures pending the completion of measure testing that supports variation in performance at the individual clinician level and the receipt of NQF endorsement. MAP recommended that eight measures under consideration be refined and resubmitted prior to rulemaking. The Committee noted that the measures addressed promising concepts for measurement (e.g., in population health and appropriate use) but stressed the need for further testing to be completed prior to implementation in the MIPS. MAP suggested refinements to one measure of smoking prevalence that was under consideration for both the MIPS and the Shared Savings Program, raising concerns about performance goals and attribution, as a clinician would be held accountable for the county-level smoking rate.

MAP recognized that MIPS includes a large number of measures across a wide range of specialties and the majority of measures may not be applicable to all or most specialties. Therefore, a larger number of measures is needed to ensure all eligible clinicians can participate. MAP also noted that the design of the program, where clinicians choose which measures to report, can influence whether or not there is still an opportunity to improve performance on a measure, as some measures are reported by a smaller number of clinicians. These factors make it challenging to streamline the MIPS measure set.

Measures for MIPS on the 2016 MUC list were under consideration for potential implementation in 2018 affecting the payment year 2020 measure set and future years.

The Medicare Shared Savings Program was established by Section 3022 of the Affordable Care Act (ACA).¹¹³ Eligible providers and suppliers may participate in the Shared Savings Program by creating or participating in an Accountable Care Organization (ACO). ACOs that meet the program requirements and quality performance standards are eligible to share in savings. There are three participation options: (1) one-sided risk model (sharing of savings only for all three years, (2) two-sided risk model (sharing of savings and losses for all three years) with preliminary prospective assignment with retrospective reconciliation, and (3) two-sided risk model (sharing of savings and losses for all three years) with prospective assignment.

MAP also considered the local smoking prevalence measure that was under consideration for MIPS for the Shared Savings Program. MAP agreed with the importance of reducing smoking rates but recommended the measure be refined and resubmitted, noting concerns about fairly comparing ACOs as smoking rates can vary significantly in different areas of the country. MAP recommended ensuring that the measure is properly risk adjusted and suggested measuring the change in rates rather than comparing rates across the country, noting concerns about risk adjustment and variation in smoking prevalence in different geographic regions.

An overarching theme of MAP's pre-rulemaking recommendations for measures in the MIPS and the Shared Savings Program is that high-value measures are needed in both programs. MAP emphasized moving beyond the process measures that make up the majority of the current measures. MAP has identified the following measure types as high-value:

- Outcome measures (e.g., mortality, adverse events, functional status, patient safety, complications, or intermediate outcomes)
- Patient-reported outcomes where the patients provide the data about the results of their treatment, level of function, and health status
- Measures addressing patient experience, care coordination, population health, quality of life, or impact on equity
- Appropriateness, overuse, efficiency, and cost-of-care measures
- Composite measures
- Process measures with a strong evidence-based link to patient outcomes

However, MAP members recognized the associated complexities of developing, testing, and properly attributing outcome measures at the clinician level. MAP members requested that CMS and specialty societies work together to create a suite of high-impact measures that are actionable by the individual clinician and demonstrate the ability to improve quality.

MAP Hospital Workgroup

The MAP Hospital Workgroup reviewed measures under consideration for seven hospital and settingspecific programs, making the following recommendations.

End-Stage Renal Disease Quality Incentive Program. The End-Stage Renal Disease Quality Incentive Program (ESRD QIP) is a value-based purchasing program that links a portion of an end-stage renal facility's payment under the ESRD PPS to its performance on quality measures. This program was established to promote the provision of high-quality renal dialysis services by dialysis facilities.

MAP reviewed three measures under consideration for the ERSD QIP program, supporting two and recommending that one be refined and resubmitted prior to rulemaking.

PPS-Exempt Cancer Hospital Quality Reporting Program. The Prospective Payment System (PPS)-Exempt Cancer Hospital Quality Reporting (PCHQR) program is a quality reporting program for PPSexempt cancer hospitals.¹¹⁴ The program's goal is to provide information to the public about the quality of care that is furnished in the 11 cancer hospitals that are exempt from payment under the Medicare Inpatient Prospective Payment System (IPPS).

MAP reviewed five measures under consideration for the PCHQR program, recommending four and not supporting one.

Ambulatory Surgery Center Quality Reporting Program. The Ambulatory Surgical Center Quality Reporting (ASCQR) program is a pay-for-reporting program.¹¹⁵ Ambulatory Surgical Centers (ASCs) that fail to meet program requirements receive a 2 percent reduction to their annual payment increase. The ASC program was established to provide information about the quality of care provided at ASCs. MAP reviewed three measures under consideration for the ASCQR program, conditionally supporting three and recommending that two be refined and resubmitted prior to rulemaking.

Inpatient Psychiatric Facility Quality Reporting Program. The Inpatient Psychiatric Facility Quality Reporting (IPFQR) Program¹¹⁶ is a pay-for-reporting program that requires inpatient psychiatric facilities (IPFs) to meet program requirements, including submitting data on measures, to avoid receiving a 2 percent reduction in their annual update to a standard federal rate for discharges for the IPF occurring during a particular year. The IPFQR program provides information about the quality of care in inpatient psychiatric facilities.

MAP reviewed three measures under consideration for the IPFQR program, recommending that all three be refined and resubmitted prior to rulemaking.

Hospital Outpatient Quality Reporting Program. The Hospital Outpatient Quality Reporting (OQR) Program (OQR) is a pay-for-reporting program.¹¹⁷ Subsection (d) hospitals that fail to meet program requirements receive a 2.0 percentage point reduction to their OPD fee schedule increase factor. This program established a system for collecting and providing quality data about hospital outpatient services.

MAP reviewed three measures under consideration for the Hospital OQR Program, supporting one, conditionally supporting another, and recommending that one be refined and resubmitted prior to rulemaking.

Hospital Readmissions Reduction Program. The Hospital Readmissions Reduction Program (HRRP) is similar to the hospital value-based purchasing program¹¹⁸; it aims to reduce readmissions to Medicare subsection (d) hospitals, defined as a general, acute case, short-term hospitals. Psychiatric hospitals, rehabilitation hospitals, long-term care hospitals, children's hospitals, cancer hospitals, and critical access hospitals are exempt from the program. Diagnosis-related group (DRG) payment rates are reduced based on a hospital's ratio of actual to expected readmissions.

There were no measures under consideration for the HRRP in the 2016-2017 pre-rulemaking deliberations. However, MAP reviewed the current set of six measures and raised concerns that safetynet hospitals may be disproportionately penalized by the HRRP, as the measures are not currently risk adjusted for social risk factors. MAP recommended that CMS consider the recommendations of the Assistant Secretary for Planning and Evaluation (ASPE) in the *Report to Congress: Social Risk Factors and Performance Under Medicare's Value-Based Purchasing Programs*¹¹⁹ to mitigate the impact of the HRRP on safety net hospitals.

Hospital Inpatient Quality Reporting Program/Medicare and Medicaid EHR Incentive Program for Eligible Hospitals and Critical Access Hospitals (Meaningful Use). The Hospital Inpatient Quality Reporting (IQR) Program is a pay-for-reporting program that addresses the quality of care furnished by hospitals and requires subsection (d) hospitals to meet program requirements or be subject to a onequarter reduction to their applicable percentage increase.

MAP reviewed 15 measures under consideration for the Hospital IQR Program and/or EHR Incentive Programs, conditionally supporting one, suggesting refinements to nine, and not supporting five.

When reviewing the current measure set for Hospital IQR Program, MAP highlighted the need for alignment across hospital programs. In particular, MAP members noted the 21st Century Cures Act provisions that require consideration of the proportion of dually eligible patients served by facilities participating in the HRRP. MAP recommended that CMS explore ways to align the readmissions measures used both for the Hospital IQR Program and HRRP to ensure consistency in the information provided to both hospitals and consumers. In addition, MAP suggested that CMS consider ASPE's recommendations in its report on social risk factors in value-based purchasing programs, as some measures used in the IQR program also are used in the Hospital Value-Based Purchasing Program (VBP) and the HRRP.

Hospital Value-Based Purchasing Program. The Hospital VBP program is a value-based purchasing program¹²⁰ designed to improve the quality of hospital inpatient services by linking a portion of a hospital's Medicare payment under the IPPS to its performance on quality measures. Hospitals are eligible to receive incentive payments based either on how well they perform compared with other hospitals or how much their performance has improved over time.

MAP reviewed one measure under consideration for the Hospital VBP Program and did not support it. MAP also reviewed the 21 current measures in the program and suggested opportunities for improvement. First, MAP recommended that CMS review ASPE's recommendations and consider ways to mitigate the effect of the Hospital VBP Program on safety-net hospitals, as social risk may influence the efficiency and mortality measures currently included in the program. Secondly, MAP raised concerns about the reliability, actionability, and usability of the PSI-90 measure used in the program and urged CMS to develop new patient safety measures, such as measures addressing all-cause harm. Finally, MAP noted concerns about the potential overlap among the efficiency measures used in the program. For example, MAP noted that the Medicare Spending per Beneficiary Measure would include episodes captured in the risk-standardized payment associated with the 30 day-episode of care measures for acute myocardial infarction and heart failure and that including both measures would lead to a hospital being rewarded or penalized twice for the same patient case.

Hospital-Acquired Condition Reduction Program. The Hospital-Acquired Condition Reduction Program (HACRP) is a value-based purchasing program; it penalizes hospitals for occurrences of hospital-acquired conditions (HACs).¹²¹ Hospitals with the highest rates of HACs will have their Medicare payments reduced by 1 percent. Hospitals are currently scored on measures in two domains: PSI-90 and National Healthcare Safety Network measures. The domain scores are used to calculate the Total HAC Score. Hospitals above the 75th percentile for their Total HAC Score are subject to the payment reduction. There were no measures under consideration for the HACRP in the 2016-2017 pre-rulemaking deliberations. However, MAP reviewed the measures currently used in the program and recommended that HHS develop new safety measures to replace PSI-90 in the HACRP as MAP had concerns about the actionability and reliability of this measure.

The MAP Hospital Workgroup identified the need for high-value measures across programs. Such measures would address key areas where measure development is needed, including measures to evaluate the appropriate use of health interventions and testing; measures of care transitions, which are pivotal to improving healthcare quality, especially after hospitalization; and measures of patient-

reported outcomes. MAP also emphasized the need for measures that will drive improvement and foster more consistent performance among providers. MAP looked to the potential use of eMeasures to reduce collection and administrative burden on providers, noting that decisions to select a measure should weigh the burden to report on the measure against its potential to improve care quality.

MAP PAC/LTC Workgroup

The Measure Applications Partnership (MAP) reviewed measures under consideration for five settingspecific federal programs addressing post-acute care (PAC) and long-term care (LTC). MAP provided feedback on the current measure sets for these programs and identified several overarching themes, including: (1) implementation of the Improving Medicare Post-Acute Care Transformation (IMPACT) Act and (2) continued opportunities to address quality. MAP also discussed the current measure set of a sixth program for which no new measures were submitted.

Inpatient Rehabilitation Facility Quality Reporting Program. The Inpatient Rehabilitation Facility Quality Reporting Program (IRF QRP) is a pay-for-reporting program that addresses the quality of care furnished by IRFs to Medicare beneficiaries.¹²² This program applies to IRFs that are paid by Medicare under the IRF prospective payment system (PPS), including freestanding IRFs and inpatient rehabilitation units of hospitals or critical care access hospitals (CAHs).

MAP reviewed three measures under consideration for the IRF QRP, conditionally supporting one and recommending two others to be refined and resubmitted prior to rulemaking. MAP also reviewed the measures currently in the program and noted the need for measures that address issues such as patient and family engagement, and nutrition.

Long-Term Care Hospital Quality Reporting Program. The Long-Term Care Hospital Quality Reporting Program (LTCH QRP) is a pay-for-reporting program¹²³ that addresses the quality of care furnished by LTCHs to Medicare beneficiaries. This program applies to all hospitals certified by Medicare as LTCHs.

MAP reviewed three measures under consideration for the LTCH QRP, conditionally supporting one and recommending that two others be refined and resubmitted prior to rulemaking. MAP also reviewed the measures currently used in the program, noting that LTCH measurement could be improved, for example, by replacing measures of specific infections with a measure of all facility-acquired infections. MAP also identified gaps in the measure set, including the need for measures addressing the transfer of information between attending clinicians, and not just between settings. MAP also recommended adding an LTCH-specific Consumer Assessment of Healthcare Providers and Systems (CAHPS) survey to assess patient experience with care.

Skilled Nursing Facility Quality Reporting Program. The Skilled Nursing Facility Quality Reporting Program (SNF QRP) is a pay-for-reporting program¹²⁴ that addresses the quality of care furnished by SNFs to Medicare beneficiaries. This program applies to freestanding SNFs, SNFs affiliated with acute care facilities, and all non-SNF swing-bed rural hospitals. Beginning with fiscal year 2018, SNFs that do not submit data as required under the SNF QRP for a fiscal year will receive a 2 percentage reduction to their annual market basket percentage that would otherwise apply for that fiscal year.

MAP reviewed three measures under consideration for the SNF QRP, conditionally supporting one and recommending that the two others be refined and resubmitted prior to rulemaking. MAP reviewed the measures currently in the program and suggested that the measure set could be improved by taking a person-centered focus to measurement that addresses advance directives and additional aspects of care coordination, such as the efficacy of transfers from acute care hospitals to skilled nursing facilities, the transfer of information between facilities and attending clinicians, and the patient's experience.

Skilled Nursing Facility Value-Based Purchasing Program (SNF VBP). The Skilled Nursing Facility Value-Based Purchasing Program (SNF VBP) is a value-based purchasing program¹²⁵ that links Medicare payments to SNFs under the SNF PPS to their performance on a measure of all-cause all-condition hospital readmission rates.

MAP identified opportunities to clarify measure specifications for the program to ensure alignment with program goals.

Home Health Quality Reporting Program. The Home Health Quality Reporting Program (HH QRP)¹²⁶ is a pay-for-reporting program established in accordance with section 1895(b)(3)(B)(v)(II) of the Social Security Act, and it aims to improve the quality of care provided to home health patients. Home health agencies (HHAs) that do not comply with the program's incentive structure are subject to a 2 percent reduction in their annual home health market basket percentage increase applicable to the HHA for such year. These data are made publicly available through the Home Health Compare website to provide national ratings on the quality of HHAs.

MAP reviewed five measures under consideration for the HH QRP, conditionally supporting three and recommending that the two others be refined and resubmitted prior to rulemaking. In reviewing the measures currently in the program, MAP affirmed the need for a streamlined measure set to reduce the burden on providers while ensuring that consumers and other stakeholders have the information they need to support their decision making.

Hospice Quality Reporting Program. The Hospice Quality Reporting Program (HQRP) is a pay-forreporting program¹²⁷ established by Section 3004 of the Affordable Care Act. The HQRP applies to all hospices, regardless of setting. Failure to submit quality data will result in a 2 percent reduction to a hospice's annual payment update.

MAP reviewed eight measures under consideration for the HQRP and supported all of them. MAP reviewed the measures currently in the program, noting several measurement gaps to be addressed in future rulemaking cycles. These gaps include measures of medication management at the end of life, the provision of bereavement services, patient care preferences, and measures that address symptom management for other conditions besides cancer, particularly dementia. MAP also noted the need to include outcome measures in the Hospice QRP set. Finally, MAP emphasized the importance of publicly reporting measure results to help guide patient decision making.

V. Gaps on Endorsed Quality and Efficiency Measures Across HHS Programs

Under section 1890(b)(5)(A)(iv) of the Act, the entity is required to describe in the annual report gaps in endorsed quality and efficiency measures, including measures within priority areas identified by HHS under the agency's National Quality Strategy, and where quality and efficiency measures are unavailable or inadequate to identify or address such gaps.

NQF is committed to measurement that drives meaningful improvement in the healthcare system. In addition to endorsing high-value measures and recommending measures for use in federal programs, NQF standing committees, its Measure Applications Partnership, and Medicaid workgroups also identify measure gaps—areas in healthcare where high-value measures are too few or nonexistent—to drive improvement.

During their 2017 deliberations, NQF standing committees that reviewed measures for endorsement or conducted other activities related to improving NQF's measure portfolios discussed and identified more than 100 measurement gaps. NQF's self-funded initial measure prioritization efforts surfaced important measurement gaps in palliative and end-of-life care. Standing committees also identified a large number of measure gaps in behavioral health, pediatric, and patient safety topical areas. These gaps are included in <u>Appendix H</u>.

The Measure Applications Partnership provided feedback on measure gaps across and within federal programs, guided by CMS input in the Program Specific Measure Priorities and Needs document on high-priority domains.¹²⁸ Medicare measure gaps identified by MAP are included in <u>Appendix I</u>. In addition, NQF's Medicaid Task Forces and Dual Eligible Beneficiaries Workgroup also identified gaps in the Adult and Child Core Sets and the Dual Eligible Beneficiaries Family of Measures. These gaps are included in <u>Appendix J</u>.

VI. Gaps in Evidence and Targeted Research Needs

Under section 1890(b)(5)(A)(v) of the Act, the entity is required to describe areas in which evidence is insufficient to support endorsement of quality and efficiency measures in priority areas identified by the Secretary under the National Quality Strategy and where targeted research may address such gaps.

Several NQF projects completed in 2017, as well as one that is underway, create needed strategic approaches, or frameworks, to measure quality in areas critical to improving health and healthcare for the nation but for which quality measures are too few, are under developed, or non-existent.

A measurement framework is a conceptual model for organizing ideas that are important to measure for a topic area and for describing how measurement should take place (i.e., whose performance should be measured, care settings where measurement is needed, when measurement should occur, or which individuals should be included in measurement). Frameworks provide a structure for organizing currently available measures, areas where gaps exist, and prioritization for future measure development.

NQF's foundational frameworks identify and address measurement gaps in important healthcare areas, underpin future efforts to improve quality through metrics, and ensure safer, patient-centered, costeffective care that reflects current science and evidence.

NQF completed projects to create strategic measurement frameworks for assessing the quality of telehealth, diagnostic quality and accuracy, and transitions of care into and out of emergency departments. NQF also developed a measurement structure for assessing progress toward interoperability, an important area for advancing care that continues to present significant challenges to healthcare organizations. In other work, NQF continued its efforts to support structured reporting of patient safety events in hospitals and other care settings. NQF also began a new project to identify measure concepts that can improve the quality and safety of care in ambulatory care settings.

Telehealth

Telehealth offers the potential to transform the healthcare delivery system by providing technological methods of care delivery that overcome geographical distance, enhance access to care, and create greater efficiencies in the delivery of care. Services provided through telehealth are expected to increase due to new reimbursement strategies for Medicare providers who offer these services as part of MACRA.

The Health Resources and Services Administration (HRSA) defines telehealth as "the use of electronic information and telecommunications technologies to support and promote clinical healthcare, patient and professional health-related education, public health, and health administration."¹²⁹ Although it does not represent all existing definitions for this important area of health IT across both the private and public sectors, ¹³⁰ there is general consensus that telehealth supports a range of clinical activities, including:

- Enhancing interactions among providers to improve patient care (for example, consultation with distant specialists by the direct care provider);
- Supporting provider-to-provider training;
- Enhancing service capacity and quality (for example, small rural hospital emergency departments and pharmacy services);
- Enabling direct patient-provider interaction (such as follow-up for diabetes or hypertension, or urgent care services);
- Managing patients with multiple chronic conditions from a distance; and
- Monitoring patient health and activities (for example, home monitoring equipment linked to a distant provider).¹³¹

These activities are especially useful in communities where access to appropriate healthcare services is limited. Compared to residents of urban communities, residents of rural and frontier communities are more likely to be older and to have more risk factors associated with their health conditions. The supply of healthcare professionals to treat certain conditions, such as mental and behavioral health disorders and chronic disease, can be scarce in many of these areas, and existing providers may have limited training in specialized areas of care. To address these challenges, some rural hospitals and other healthcare settings have adopted telehealth, including video communication between providers and the

sharing of information, such as radiological and imaging reports.¹³² Similar strategies have been adopted in urban and suburban settings, especially for specialties with significant workforce shortages and/or maldistribution (e.g., dermatology and psychiatry), or where long delays to schedule new patient appointments may occur.

In a one-year project that concluded in August 2017, NQF's Telehealth Committee was charged with developing a measurement framework that identifies critical areas where measurement can effectively assess the quality and impact of telehealth services and serves as a conceptual foundation for new measures, where needed. The Committee recommended measuring the quality of telehealth in four broad categories: patients' access to care, financial impact to patients and their care team, patient and clinician experience, and effectiveness of clinical and operational systems. Within these categories, NQF identified six key areas as having the highest priority for measurement in telehealth, including travel, timeliness of care, actionable information, added value of telehealth to provide evidence-based practices, patient empowerment, and care coordination.

The Committee identified 16 NQF-endorsed measures that can be used initially to measure telehealth quality. These measures span a variety of conditions, ranging from mental and behavioral health to care coordination. The Committee noted that existing quality measures must be widely accepted and impactful to evaluate the effectiveness and benefits of telehealth. While a number of measures were identified through this work, the Committee acknowledged it is difficult to ascertain which would suffice to assess whether telehealth is comparable to, or an improvement over, in-person care. The report and conceptual framework for measuring telehealth serve as the foundation for future efforts by measure developers, researchers, analysts, and others in the healthcare community to advance quality measurement for telehealth.

Interoperability

Interoperability is the electronic sharing of health information and how that information is used. True interoperability is a significant challenge to healthcare organizations for various reasons, including the lack of a common, standard framework that reconciles the differences in data as well as the varying data types. Additionally, healthcare organizations maintain incompatible products and systems, which are unable to exchange the appropriate data within the organization and with partners in its community.

In 2017, NQF concluded a foundational, one-year project to develop a measurement structure and ideas for measures to address current measurement gaps in interoperability. As a first step in developing this framework, NQF conducted an environmental scan of references and research that provided insight into the use of data to facilitate interoperability and the different methods of exchanging information, including papers that focus on the use, effectiveness, or outcomes of health information exchange (HIE). Key findings from the scan included:

- Interoperability facilitates the exchange of data across numerous systems to support areas such as public health, care coordination, patient engagement, and innovation
- The availability of data with electronic health records (EHRs) and other systems, such as clinical data registries, help support interoperability

- Facilitating greater interoperability supports decision making by providers and patients by
 integrating data from various sources to present a unified view to facilitate data exchange as
 well as establishing common formats for care coordination, quality reporting, and collaborative
 care
- Interoperability has a significant impact on the accuracy of quality measurement in areas such as cancer research, chronic disease management, and heart failure, as well as quality reporting by using common data models and application programming interfaces.

NQF supplemented the findings of the environmental scan with key informant interviews with candidates from payer organizations, health information exchanges, integrated delivery systems, health information exchange vendors, EHR/HIE vendors, informatics, and patient advocacy groups. These interviews helped identify examples of the current realities of interoperability and exchange of data across disparate systems; availability of data to facilitate interoperability; use of interoperability to facilitate decision making; and the impact of interoperability on health/health-related outcomes and processes.

NQF convened the multistakeholder Interoperability Committee to provide input and help guide the creation of a framework. The committee developed a set of guiding principles to define key criteria for measuring interoperability, including:

Interoperability is more than EHR to EHR. That is, the focus of interoperability within a measurement structure must extend beyond the concept of data exchange between two EHRs into one that encompasses the diversity of data sources that capture patient and population data.

Stakeholder involvement. A broadly accessible, interoperable system that incorporates data from various sources would potentially enable diverse stakeholders to participate actively in using this data. However, the impact of interoperable data affects various stakeholders in different ways, including patients, providers, payers, and government.

Use of "outside data." The Committee clarifies that its concept of interoperability does not focus on the ability of systems to gather outside data, but instead on the ability of systems to obtain and exchange data accurately, effectively, efficiently, and in a usable form.

Differences due to setting and maturity. The use of interoperable data may also vary depending on the setting (e.g., clinical, nonclinical) and its individualized needs, so measure concepts should be selected to fit the setting. For example, measure concepts selected for nonclinical providers and settings that are working to exchange health information electronically with community-based settings such as social services might focus on the interoperability of social and environmental determinants of health data.

Various data types. Specifically, it will be critical for interoperability measures and measure concepts to account for data that come from nonclinical sources that reside in multiple systems and in some cases cannot yet be exchanged into an EHR or other clinical information system without compromising their content and meaning.

Based on the findings of the environmental scan, the key informant interviews, and its guiding principles, the Committee ultimately proposed measuring key interoperability elements in four broad categories (domains) and 15 subcategories (subdomains). These include:

- 1. Exchange of electronic health information
 - Availability of electronic health information
 - Quality of data content
 - Method of exchange
- 2. Usability of exchanged electronic health information
 - Relevance
 - Accessibility
 - Comprehensibility
- 3. Application of exchanged electronic health information
 - Human use
 - Computable
- 4. Impact of interoperability
 - Patient safety costs
 - Productivity
 - Care coordination
 - Improved processes and health outcomes
 - Patient and caregiver engagement
 - Patient and caregiver experience

NQF's interoperability project lays the groundwork for addressing the current gaps in the measurement of interoperability, and is an important step in accomplishing national priorities for interoperability, access, and use of health data.

Emergency Department Transitions of Care

Nearly 1 in 12 patients return to the emergency department (ED) or are hospitalized within three days of an initial ED visit, and a third of those "revisits" occur at a different institution, according to a recent study of 58 million patients discharged from EDs in six states. The study found that the revisit rate grew from 2.7 percent within one day of discharge to 8.2 percent within three days of discharge and to 20 percent within 30 days of discharge.¹³³

Unclear, incomplete, or missing information during ED transitions in care between providers and settings may lead to patient anxiety and uncertainty, avoidable resource use, or a worsening in the patient's condition and potential harm. In addition, variability in communication during transitions from one care setting to another may contribute to confusion among clinicians about the patient's severity of condition and near-term care needs, duplicative tests, inconsistent patient monitoring, medication errors, delays in diagnosis, and lack of follow through on referrals.¹³⁴



Currently, few measures address the quality of transitions of care into and out of an emergency department (ED). However, ED visits often represent a critical juncture for a patient, and management of these transitions is important to improve person-centered care, value, and cost efficiency.

To address the measurement gap, in 2016, NQF convened the multistakeholder Emergency Department Quality of Transitions of Care Expert Panel to develop a measurement framework to prioritize measures and measure concepts, as well as a set of guiding recommendations to help providers better manage transitions of care. In a final report issued in August 2017, NQF recommended four domains, or broad conceptual areas, and 11 subdomains, for measuring the quality of ED transitions. The four domains include:

- Provider information exchange. Communication and transfer of information between providers that occurs during transitions of care into and out of the ED
- Patient, family, and caregiver information exchange. Interactive and bidirectional communication between patients (and their families, caregivers, or health proxies) and a multidisciplinary, healthcare team (e.g., case manager, nurse, primary care physician)
- Engagement of the broader community. The extent to which the broader community's
 organizations, services, and information technology infrastructures are available and engaged to
 support a quality transition of care into and out of the ED.
- Achievement of outcomes. The extent to which quality, patient-centered ED transition of care
 outcomes occur across patient episodes of acute care and within systems of care.

The Panel identified a set of priority measures and concepts that improve transitions for both patients and providers, promote structures and processes to link clinical and nonclinical settings more effectively, and measure outcomes to help monitor the development and implementation of systems to optimize transitions.

The Panel also developed recommendations to promote policy change in support of measure recommendations. For example, they suggest that EDs should expand infrastructure to support patient-centered ED transitions, such as by investing in ED-based care managers and social workers. Other recommendations include enhancing health IT to enable data sharing, facilitating improvement through payment models and other levers, and encouraging research to understand better patients who are at highest risk for poor ED transition guality as well as poor outcomes related to these transitions.

Improving Diagnostic Quality and Safety

Diagnostic errors are the failure to establish or communicate an accurate and timely assessment of the patient's health problem.¹³⁵ In the United States, at least 5 percent of adults seeking outpatient care experience a diagnostic error.¹³⁶ These errors contribute to nearly 10 percent of deaths annually, and up to 17 percent of adverse hospital events.¹³⁷ Diagnostic errors persist across all healthcare settings and can result in physical, psychological, or financial repercussions for the patient.

To assist in reducing diagnostic harm, NQF in 2016 convened a multistakeholder expert Committee to develop a structure for measuring diagnostic quality and safety and identify priorities for future measure development. With guidance from the Committee, NQF staff conducted an environmental scan to

identify measures related to diagnostic quality and safety and to inform the development of the measurement framework. In a final report issued in September 2017, NQF recommends three domains and 11 subdomains for the measurement of diagnostic quality and safety. These include:

- Patients, families, and caregivers: patient experience and patient engagement
- The diagnostic process: information gathering and documentation, information integration, information interpretation, diagnostic efficiency, diagnostic accuracy, and follow-up
- Organizational and policy opportunities: diagnostic quality improvement activities, access to care and diagnostic services, workforce (e.g., the availability of appropriate staff)

The framework is intended to facilitate systematic identification and prioritization of measure gaps and to help guide efforts to fill those gaps through measure development and endorsement.

The Committee identified high-priority areas where measures are needed, including timeliness of diagnosis, timeliness of test result follow-up, patient experience of diagnostic care, and communication and hand-offs in transitions of care.

The report shares nonmeasurement guidance from the Committee on issues that affect the ability of the field to make improvements in diagnostic quality. For example, diagnostic accuracy can be advanced significantly if EHRs are able to collect key diagnostic data and are interoperable within and across systems. The Committee suggested engaging with medical specialty societies for input on measures for conditions that are frequently misdiagnosed. The Committee also suggested that diagnostic safety and quality become an important component of professional education.

Common Formats for Patient Safety

In 2008, AHRQ first released Common Formats to support structured reporting of safety events in hospitals. These reporting techniques standardize the collection of patient safety event information using common language, definitions, and reporting formats. Use of common data fields for event reporting ensures that information shared with Patient Safety Organizations (PSOs) is consistent across healthcare providers and can be aggregated to provide population-level insights into trends in adverse events.

The public has an opportunity to comment on all elements of the Common Formats modules using commenting tools developed and maintained by NQF. An NQF Expert Panel reviews the public comments and provides AHRQ feedback with the goal of improving the Common Formats modules.

In 2017, NQF continued to collect comments on all elements of the Common Formats, including the most recent release, Hospital Common Formats Version 2.0. The NQF Expert Panel received updates from AHRQ about ongoing development of new Common Formats, and AHRQ has signaled that it expects to release an updated version of the Common Formats for Hospital Surveillance in early 2018. NQF will post this new module for comments, which will then be reviewed by the Expert Panel for feedback to AHRQ.

Ambulatory Care Patient Safety

According to the Centers for Disease Control and Prevention, more than 83 percent of U.S. adults use ambulatory care services annually through visits to primary care physicians, urgent care centers, dialysis centers, and other outpatient providers. Although there has been tremendous research on patient safety in inpatient settings, much less is known about effectively addressing safety issues in ambulatory care. The 1999 Institute of Medicine publication, *To Err is Human*, raised awareness of the critical importance of improving patient safety across the healthcare continuum and spurred a national call to measure the quality of care across settings. With the increasing number of individuals seeking outpatient care, it has never been more important to ensure patient safety in ambulatory care settings.

Building on NQF's body of work to improve quality and safety, including earlier work to set measurement standards for ambulatory care,¹³⁸ NQF has convened an advisory group to identify measures and measure concepts for ambulatory care patient safety. This one-year project, funded by the Agency for Healthcare Research and Quality (AHRQ), will inform the development of priority measures to improve patient safety across ambulatory care settings for nonelderly patients (under age 65), and will help make care safer and more effective for millions of Americans. A report is expected in September 2018.

VII. Coordination with Measurement Initiatives by Other Payers

Section1890(b)(5)(A)(i) of the Social Security Act mandates that the Annual Report to Congress and the Secretary include a description of the implementation of quality and efficiency measurement initiatives under this Act and the coordination of such initiatives with quality and efficiency initiatives implemented by other payers.

Quality Measurement Support for the Medicaid Innovation Accelerator Program

Adding to NQF's efforts to improve healthcare for adults and children enrolled in Medicaid, NQF in September 2017 issued its first measure recommendations specifically for four high-cost, high-need areas of care for the Medicaid population. These recommendations aim to support federal efforts to help states tie payments—which totaled \$553 billion in 2016—to improved value.

State Medicaid programs have faced numerous challenges in finding and using standardized measures to evaluate quality within states and in comparing care delivered across states. The decentralized nature of state quality programs has led to a proliferation of measures across states, contributing to a lack of alignment and increased reporting burden for providers. Benchmarking also can be difficult, as similar measures used in states may have different specifications.

The Medicaid Innovation Accelerator Program (IAP) supports states' ongoing efforts related to payment and delivery reforms through targeted technical assistance to state Medicaid agencies across four overlapping and interrelated areas of focus: reducing substance use disorders, improving care for beneficiaries with complex needs and high costs, promoting community integration through long-term services and supports, and supporting physical and mental health integration. In addition, the program works with states around key delivery system reform efforts in four functional areas: quality measurement, performance improvement, data analytics, and payment modeling and financial simulations.¹³⁹

In 2016, under contract with CMS, NQF convened the multistakeholder Innovation Accelerator Project Coordinating Committee and four Technical Expert Panels to identify and recommend measures that address key quality issues in each of the IAP's four areas of focus. In a final report issued in September 2017, the Committee made the following measure recommendations to:

- Reduce substance abuse disorders. 24 measures and five measure concepts, such as screening and brief intervention, medication-assisted treatment, and continuity of care
- Improve care for beneficiaries with complex care needs and high costs. 18 measures and one measure concept, such as care utilization, follow-up care, and medication reconciliation
- Promote community integration through long-term services and supports. 10 measures and four measure concepts, such as quality of services, access to care, and medication reconciliation
- Support physical and mental health integration. 30 measures and one measure concept, such as coordination of treatment among providers, screening for physical and mental health conditions, and care follow-up

The recommended measures and measure concepts are available for use by all state Medicaid agencies and stakeholders to begin leveraging them for better, more efficient care regardless of participation in the IAP.

Core Quality Measures Collaborative – Private and Public Alignment

Adding to NQF's efforts to encourage the use of more meaningful measures and reduce measure burden on providers, NQF has provided technical assistance to the Core Quality Measures Collaborative (CQMC) for several years. This initiative—led by the America's Health Insurance Plans (AHIP) and its member plans' chief medical officers, and also involving CMS—brought together private- and public-sector payers to reach consensus on core performance measures.³⁴⁰ Representatives from national physician organizations, employers, and consumer groups also participated in this effort. NQF self-funded its participation in the CQMC.

The alignment of measure sets across payers will aid in:

- Promotion of measurement that is evidence-based and can generate valuable information for quality improvement;
- Consumer decision making;
- Value-based purchasing;
- Reduction in the variability in measure selection; and
- Decreasing providers' collection burden and costs.

Focusing initially on clinician-level measures used in the ambulatory care settings, the Collaborative in 2016 issued seven core measure sets in the following areas:

- ACOs, PCMH, and primary care
- Cardiology

- Gastroenterology
- HIV and hepatitis C
- Medical oncology
- Obstetrics and gynecology
- Orthopedics

CMS is already using measures from each of these core sets.¹⁴¹ In July 2017, the Collaborative published an additional pediatrics core measure set consisting of nine measures intended for use at the provider level for individual clinicians or group practices.^{142,143} Seven of the nine measures in the CQMC pediatric set are also included in the Medicaid and CHIP Child Core Set,¹⁴⁴ for which NQF makes annual recommendations. Although the CQMC pediatric set is intended for measurement at the healthcare provider and group practice levels, measure alignment may help facilitate state-level Child Core Set reporting and quality improvement initiatives, according to CMS.¹⁴⁵

VIII. Conclusion

NQF's work to improve health and healthcare is closely aligned with the national priorities of making care safer, strengthening person and family engagement, promoting effective communication, promoting effective prevention and treatment of chronic disease, working with communities to promote best practices of healthy living, and making care affordable in partnership with public and private healthcare stakeholders across the country.

In 2017, NQF completed or began work in key areas of importance to these national priorities. This work includes projects to improve measurement of care quality in rural settings, reduce healthcare disparities, address social determinants of health, and improve ways that the quality and outcomes of a patient's care are accurately and fairly attributed to the responsible physician or other provider. Additional projects provided national guidance on measurement structures to assess the quality of telehealth, further progress toward interoperability, improve transitions of care from emergency departments, and advance the quality and safety of clinical diagnoses.

Working with multistakeholder committees to build consensus on key strategies for performance measurement and quality improvement, NQF's annual review and endorsement of healthcare performance measures ultimately provides clinicians, hospitals, and other providers with the tools they need to understand whether the care they provide their patients is optimal, and appropriate, and if not, where to focus improvement efforts. NQF-endorsed measures serve to enhance healthcare value by ensuring that consistent, high-quality performance data are available, which allows for comparisons across providers as well as the ability to benchmark performance.

NQF's measure portfolio contains high-value measures across a variety of clinical and cross-cutting topic areas. Forty-two percent of the measures in NQF's portfolio are outcomes measures. With continued focus on high-value measures, NQF initiated efforts to prioritize meaningful measures and further refined its measure portfolio, endorsing 120 new measures and removing endorsement for 109 measures across 18 quality measure endorsement projects in 2017.

NQF's commitment to make measure endorsement more efficient, foster innovation, and enable greater access to NQF's technical assistance was manifested in the significant improvements made in 2017 to its measure review and endorsement process. Importantly, these efforts will reduce the measure endorsement process to seven months, allow for two measure review cycles every year, and enhance transparency through an expanded 15+ week opportunity for public comment for each endorsement project. NQF also established a Scientific Methods Panel to provide methodological analyses of complex measures.

NQF's Measure Applications Partnership (MAP) is a forum for the private and public sectors across the care continuum where patients, clinicians, providers, purchasers, payers, and other stakeholders identify and recommend the highest-value measures for federal program and provide strategic guidance across these programs. Throughout its six years of annual review, MAP has worked toward the goal of lowering costs while improving quality, making measurement meaningful for improvement while reducing unnecessary administrative burden, and ensuring that patients and consumers get the information they need to support their healthcare decision making. Importantly, in 2017, MAP constituted a new workgroup to address the specific needs and challenges of rural providers and residents. MAP's 2017 work included a review of 71 unique performance measures under consideration for use in 16 federal quality reporting and value-based payment programs covering clinician, hospital, and post-acute/long-term care settings. In its 2017 guidance, MAP conducted a holistic review of the current measure sets used in federal programs and recommended significant improvements to reduce measure burden.

During their 2017 deliberations, NQF standing committees that reviewed measures for endorsement or conducted other activities related to improving NQF's measure portfolios discussed and identified more than 100 measure gaps—areas in healthcare where high-value measures are too few or nonexistent—to drive improvement. NQF's standing committees surfaced important measurement gaps in areas such as palliative and end-of-life care, behavioral health, pediatric care, and patient safety. MAP also identified measure gaps to assess care and improvement in federal healthcare programs, and NQF's Medicaid Task Forces and Workgroup noted gaps in the core measure sets that states use to assess care for adults and children on Medicaid.

In 2018, NQF looks forward to continuing work that drives increased use of high-value quality measurement across settings of care, improves the usability and implementation of eMeasures, and furthers a portfolio of effective and impactful measures that public and private payers, providers, and patients can rely upon to improve health and healthcare value.

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IX. References

¹ Throughout this report, the relevant statutory language appears in italicized text.

² Contract with a consensus-based entity regarding performance measurement. 42 USC 1395aaa(b)(1) (2014).

³ HHS. *Report to Congress: National Strategy for Quality Improvement in Health Care*. Washington, DC: HHS; 2011. Available at <u>http://www.ahrq.gov/workingforquality/ngs/ngs2011annirpt.pdf</u>. Last accessed October 2016.

⁴ Census Bureau. 2010 Census urban and rural classification and urban area criteria website. <u>https://www.census.gov/geo/reference/ua/urban-rural-2010.html</u>. Last accessed January 2018.

⁵ Department of Agriculture. State fact sheets website. https://data.ers.usda.gov/reports.aspx?ID=17854. Last accessed June 2017.

⁶ Rural Health Research Gateway. The 2014 update of the rural-urban chartbook webinar website. <u>https://www.ruralhealthresearch.org/webinars/rural-urban-chartbook</u>. Last assessed June 2017.

⁷ Health Resources & Services Administration. Shortage designation website. <u>https://bhw.hrsa.gov/shortage-designation/hpsas</u>. Last accessed January 2018.

⁸ Wishner J, Solleveld P, Rudowitz R, et al. *A Look at Rural Hospital Closures and Implications for Access to Care: Three Case Studies.* Washington, DC: Henry J. Kaiser Family Foundation, Kaiser Commission on Medicaid and the Uninsured; 2016. Available at <u>https://www.kff.org/report-section/a-look-at-rural-hospital-closures-and-implications-for-access-to-care-three-case-studies-issue-brief/</u>. Last accessed January 2018.

⁹ NQF. *Performance Measurement for Rural Low-Volume Providers*. Washington, DC: NQF; 2015. Available at <u>https://www.qualityforum.org/Publications/2015/09/Rural Health Final Report.aspx</u>. Last accessed February 2018.

¹⁰ NQF. Measuring and Improving the Performance of Rural Healthcare Providers. Washington, DC: NQF; 2016. Available at

http://public.qualityforum.org/Chart%20Graphics/Measuring%20and%20Improving%20the%20Perform ance%20of%20Rural%20Healthcare%20Providers.pdf. Last accessed January 2018.

¹¹ National Academies of Sciences, Engineering, and Medicine. Accounting for Social Risk Factors in Medicare Payment: Identifying Social Risk Factors. Washington, DC: National Academies Press; 2016. Available at https://www.nap.edu/catalog/21858/accounting-for-social-risk-factors-in-medicarepayment-identifying-social. Last accessed January 2018.

¹² NQF. *Disparities in Healthcare and Health Outcomes in Selected Conditions*. Washington, DC: NQF; 2017. Available at

http://www.qualityforum.org/Publications/2017/01/Disparities in Healthcare and Health Outcomes in Selected Conditions.aspx. Last accessed January 2018.

¹³ Agency for Healthcare Research and Quality (AHRQ). 2016 National Healthcare Quality and Disparities Report. Rockville, MD; AHRQ; 2016. Available at

https://www.ahrg.gov/research/findings/nhgrdr/nhgdr16/summary.html. Last accessed January 2018.

¹⁴ NQF. Effective Interventions in Reducing Disparities in Healthcare and Health Outcomes in Selected Conditions. Washington, DC: NQF; 2017. Available at

https://www.qualityforum.org/Publications/2017/03/Effective_Interventions_in_Reducing_Disparities_i n_Healthcare_and_Health_Outcomes_in_Selected_Conditions.aspx. Last accessed January 2018.

¹⁵ NQF. An Environmental Scan of Health Equity Measures and Framework for Measure Development. Washington, DC: NQF; 2017. Available at

https://www.qualityforum.org/Publications/2017/06/An Environmental Scan of Health Equity Meas ures and a Conceptual Framework for Measure Development.aspx. Last accessed January 2018.

¹⁶ NQF. A Roadmap for Promoting Health Equity and Eliminating Disparities: The Four I's for Health Equity. Washington, DC: NQF; 2017. Available at

https://www.gualityforum.org/Publications/2017/09/A Roadmap for Promoting Health Equity and Eliminating Disparities The Four I s for Health Equity.aspx. Last accessed January 2018.

¹⁷ Center for Health Care Strategies, Inc. (CHCS). Measuring social determinants of health among lowincome populations: early insights from state initiatives website. <u>https://www.chcs.org/resource/measuring-social-determinants-health-among-low-income-populations-</u> early-insights-state-initiatives/. Last accessed November 2017.

¹⁸ Spencer A, Fredo B, McGinnis T. Measuring Social Determinants of Health among Medicaid Beneficiaries: Early State Lessons. Hamilton, NJ: CHCS; 2016. Available at <u>https://www.chcs.org/media/CHCS-SDOH-Measures-Brief</u> 120716 FINAL.pdf. Last accessed November 2017.

¹⁹ Crawford M, Houston R. *State Payment and Financing Models to Promote Health and Social Service Integration*. Hamilton, NJ: CHCS; 2015. Available at <u>https://www.chcs.org/resource/state-payment-financing-models-promote-health-social-service-integration/</u>. Last accessed November 2017.

²⁰ Heiman HJ, Artiga S. Beyond Health Care: The Role of Social Determinants in Promoting Health and Health Equity. Washington, DC: Henry J. Kaiser Family Foundation; 2015. Available at <u>https://www.kff.org/disparities-policy/issue-brief/beyond-health-care-the-role-of-social-determinantsin-promoting-health-and-health-equity/</u>. Last accessed January 2018.

²¹ Gates A, Rudowitz R, Guyer J. *An Overview of Delivery System Reform Incentive Payment (DSRIP) Waivers*. Washington, DC: Henry J. Kaiser Family Foundation; 2014. Available at <u>http://files.kff.org/attachment/an-overview-of-dsrip</u>. Last accessed December 2017.

²² Taylor L, Hyatt A, Sandel M. Defining the health care system's role in addressing social determinants and population health. *Health Affairs Blog*. November 17, 2016. <u>https://www.healthaffairs.org/do/10.1377/hblog20161117.057601/full/</u>. Last accessed November 2017.

²³ Gottlieb LM, Fichtenberg C, Adler NE. Social determinants of health: What's a health care system to do? 2017; manuscript under review.

²⁴ Centers for Medicare & Medicaid Services (CMS). October 2017 Medicaid and CHIP enrollment data highlights website. <u>https://www.medicaid.gov/medicaid/program-information/medicaid-and-chipenrollment-data/report-highlights/index.html</u>. Last accessed January 2018.

²⁵ CMS. October 2017 Medicaid and CHIP enrollment data website. <u>https://www.medicaid.gov/medicaid/program-information/medicaid-and-chip-enrollment-data/report-highlights/index.html</u>. Last accessed January 2018.

²⁶ CMS. People Enrolled in Medicare and Medicaid Fact Sheet. Baltimore, MD: CMS, Medicare-Medicaid Coordination Office; 2017. Available at <u>https://www.cms.gov/Medicare-Medicaid-Coordination/Medicare-and-Medicaid-Coordination/Medicare-Medicaid-Coordination-Office/Downloads/MMCO_Factsheet.pdf</u>. Last accessed April 2017.

²⁷ CMS. Improving care for Medicaid beneficiaries with complex care needs and high costs website. <u>https://www.medicaid.gov/state-resource-center/innovation-accelerator-program/beneficiaries-with-complex-needs/beneficiaries-with-complex-needs.html</u>. Last accessed January 2018.

²⁸ CMS. Medicaid & CHIP. Strengthening Coverage, Improving Health. Baltimore, MD: CMS; 2017. Available at <u>https://www.medicaid.gov/medicaid/program-information/downloads/accomplishments-report.pdf</u>. Last accessed January 2018.

²⁹ NQF. Strengthening the Core Set of Healthcare Quality Measures for Adults Enrolled in Medicaid, 2017. Washington, DC: NQF; 2017. Available at

https://www.gualityforum.org/Publications/2017/08/Strengthening the Core Set of Healthcare Qual ity Measures for Adults Enrolled in Medicaid, 2017.aspx. Last accessed January 2018.

³⁰ Musumeci M, Poindexter D. *Medicaid Restructuring under the American Health Care Act and Children with Special Health Care Needs. Issue Brief.* Washington, DC: Kaiser Family Foundation (KFF); 2017. Available at http://www.kff.org/medicaid/issue-brief/medicaid-and-children-with-special-health-care-needs/. Last accessed June 2017.

³¹ Tyler ET, Hulkower RL, Kaminski JW. *Behavioral Health Integration in Pediatric Primary Care: Considerations and Opportunities for Policymakers, Planners and Providers*. New York, NY: Milbank Memorial Fund; 2017. Available at <u>https://www.milbank.org/wp-</u> <u>content/uploads/2017/03/MMF_BHI_REPORT_FINAL.pdf</u>. Last accessed June 2017.

³² Mathematica Policy Research. Moving Medicaid data forward: understanding T-MSIS reports website. <u>https://www.mathematica-mpr.com/search</u>. Last accessed January 2018.

³³ Mathematica. FFY 2013 Adult core set reporting in CARTS, FFY 2013 child core set reporting in CARTS website. <u>https://www.mathematica-mpr.com/search</u>. Last accessed January 2018.

³⁴ NQF. Strengthening the Core Set of Healthcare Quality Measures for Adults Enrolled in Medicaid, 2017. Washington, DC: NQF; 2017. Available at

http://www.qualityforum.org/Publications/2017/08/Strengthening the Core Set of Healthcare Quality Measures for Children Enrolled in Medicaid, 2017.aspx. Last accessed January 2018.

³⁵ Mathematica. MACPro reports and Form CMS-416 reports for the FFY 2015 reporting cycle.

³⁷ NQF. Promoting Integrated and Coordinate Care that Addresses Social Risk for the Dual Eligible Beneficiary Population, 2017. Washington, DC: NQF; 2017. Available at http://www.qualityforum.org/Publications/2017/08/Promoting Integrated and Coordinated Care tha t Addresses Social Risk for the Dual Eligible Beneficiary Population, 2017.aspx. Last accessed January 2018.

³⁸ CMS. People Enrolled in Medicare and Medicaid Fact Sheet. Baltimore, MD: CMS, Medicare-Medicaid Coordination Office; 2017. Available at <u>https://www.cms.gov/Medicare-Medicaid-Coordination/Medicare-Medicaid-Coo</u>

³⁹ Medicare Payment Advisory Commission (MedPAC), Medicaid and CHIP Payment and Access Commission (MACPAC). *Data Book: Beneficiaries Dually Eligible for Medicare and Medicaid*. Washington, DC: MACPAC; 2017. Available at <u>https://www.macpac.gov/wp-</u> content/uploads/2017/01/Jan17_MedPAC_MACPAC_DualsDataBook.pdf. Last accessed April 2017.

⁴⁰ Contract with a consensus-based entity regarding performance measurement. 42 USC 1395aaa(b)(2)(3) (2014).

⁴¹ NQF. 2017 Consensus Development Process (CDP) Redesign. Washington, DC: NQF; 2017.

⁴² NQF. Measure evaluation criteria website.

http://www.qualityforum.org/Measuring_Performance/Submitting_Standards/Measure_Evaluation_Cri teria.aspx. Last accessed January 2018.

⁴³ NQF. Consensus standards approval committee.

http://www.gualityforum.org/About NQF/CSAC/Consensus Standards Approval Committee.aspx. Last accessed January 2018.

⁴⁴ CMS. Better care. Smarter spending. Healthier people paying providers for value, not volume fact sheet website. <u>https://www.cms.gov/Newsroom/MediaReleaseDatabase/Fact-sheets/2015-Fact-sheets-items/2015-01-26-3.html</u>. Last accessed January 2018.

⁴⁵ NQF. *Risk Adjustment for Socioeconomic Status or Other Sociodemographic Factors*. Washington, DC: NQF; 2014. Available at

http://www.qualityforum.org/Publications/2014/08/Risk Adjustment for Socioeconomic Status or O ther Sociodemographic Factors.aspx. Last accessed January 2018.

⁴⁶ National Academies of Sciences, Engineering, and Medicine. Accounting for Social Risk Factors in Medicare Payment: Identifying Social Risk Factors. Washington, DC: National Academies Press; 2016. Available at <u>https://www.nap.edu/catalog/21858/accounting-for-social-risk-factors-in-medicarepayment-identifying-social</u>. Last accessed January 2018.

⁴⁷ HHS. Report to Congress: Social Risk Factors and Performance Under Medicare's Value-Based Purchasing Programs. Washington, DC: Office of the Assistant Secretary for Planning and Evaluation (ASPE); 2016. Available at <u>https://aspe.hhs.gov/pdf-report/report/congress-social-risk-factors-andperformance-under-medicares-value-based-purchasing-programs</u>. Last accessed January 2018. ⁴⁸ NQF. Social Risk Trial Final Report. Washington, DC: NQF; 2017. Available at <u>https://www.qualityforum.org/Publications/2017/07/Social Risk Trial Final Report.aspx</u>. Last accessed January 2018.

⁴⁹ NQF. Scientific Methods Panel website.

https://www.gualityforum.org/Measuring Performance/Scientific Methods Panel.aspx. Last accessed January 2018.

⁵⁰ NQF standing committees are comparable to the expert advisory committees typically convened by federal agencies.

⁵¹ NQF. *Measure Evaluation Criteria and Guidance for Evaluating Measures for Endorsement*. Washington, DC: NQF; 2017. Available at

http://www.qualityforum.org/WorkArea/linkit.aspx?LinkIdentifier=id&ItemID=86084. Last accessed January 2018.

⁵² MedPAC. Refining the Hospital Readmissions Reduction Program. In: *Report to the Congress: Medicare and the Health Care Delivery System.* Washington, DC: MedPAC; 2013:91-114. Available at http://medpac.gov/docs/default-source/reports/jun13 entirereport.pdf. Last accessed March 2017.

⁵³ Boccuti C, Casillas G. Aiming for Fewer Hospital U-turns: The Medicare Hospital Readmission Reduction Program. Washington, DC: Kaiser Family Foundation (KFF); 2017. Issue Brief. Available at http://kff.org/medicare/issue-brief/aiming-for-fewer-hospital-u-turns-the-medicare-hospitalreadmission-reduction-program/. Last accessed March 2017.

⁵⁴ McCarthy D, Cohen A, Johnson MB. *Gaining Ground: Care Management Programs to Reduce Hospital Admissions and Readmissions among Chronically III and Vulnerable Patients*. Washington, DC: Commonwealth Fund; 2013. Commonwealth Fund pub. 1658. Available at <u>https://www.pcpcc.org/sites/default/files/1658_McCarthy_care_transitions_synthesis_v2.pdf</u>. Last accessed July 2017.

⁵⁵ National Institute of Mental Health (NIMH). Any mental illness (AMI) among U.S. adults website. . <u>https://www.nimh.nih.gov/health/statistics/prevalence/any-mental-illness-ami-among-us-adults.shtml</u>. Last accessed March 2017.

⁵⁶ Substance Abuse and Mental Health Services Administration (SAMHSA). Behavioral Health Trends in the United States: Results from the 2014 National Survey on Drug Use and Health. Rockville, Maryland: SAMHSA; 2015. Available at <u>https://www.samhsa.gov/data/sites/default/files/NSDUH-FRR1-</u> 2014/NSDUH-FRR1-2014.pdf. Last accessed March 2017.

⁵⁷ Roehrig C. Mental disorders top the list of the most costly conditions in the United States: \$201 Billion. *Health Aff (Millwood)*. 2016;35(6):1130-5. Available at <u>https://www.healthaffairs.org/doi/abs/10.1377/hlthaff.2015.1659</u>. Last accessed March 2017.

⁵⁸ American Cancer Society (ACS). Economic impact of cancer website. <u>http://www.cancer.org/cancer/cancerbasics/economic-impact-of-cancer.</u> Last accessed June 2016.

⁵⁹ National Cancer Institute (NCI). Cancer statistics website. <u>https://www.cancer.gov/about-</u> <u>cancer/understanding/statistics</u>. Updated March 2016. Last accessed January 2017.

⁶⁰ ACS. Cancer Facts & Figures 2016. Atlanta, GA: American Cancer Society; 2016. Available at <u>https://www.cancer.org/research/cancer-facts-statistics/all-cancer-facts-figures/cancer-facts-figures-2016.html</u>. Last accessed June 2016.

⁶¹ NCI. Cancer prevalence and cost of care projections website. <u>https://costprojections.cancer.gov/</u>. Last accessed January 2018.

⁶² Agency for Healthcare Research and Quality (AHRQ) 2015 National Healthcare Quality and Disparities Report and 5th Anniversary Update on the National Quality Strategy. Rockville, MD: AHRQ; 2016. Available at <u>http://www.ahrq.gov/research/findings/nhqrdr/nhqdr15/index.html</u>. Last accessed January 2018.

⁶³ Agency for Healthcare Research & Quality (AHRQ). *AHRQ Research to Reduce Cost and Improve the Quality of Health Care*. Rockville, MD: AHRQ; 2015. Available at

https://www.ahrq.gov/research/findings/factsheets/costs/costqual/index.html. Last accessed January 2018.

⁶⁴ Torio CM, Elixhauser A, Andrews RM. *Trends in Potentially Preventable Admissions among Adults and Children, 2005-2010*. Rockville, MD: Agency for Healthcare Research & Quality (AHRQ); 2013. Healthcare Cost and Utilization Project (HCUP) Statistical Brief #151. Available at https://www.hcup-us.ahrq.gov/reports/statbriefs/sb151.pdf. Last accessed March 2017.

⁶⁵ Martin AB, Hartman M, Washington B, et al. National health spending: faster growth in 2015 as coverage expands and utilization increases. *Health Aff (Millwood)*. 2017;36(1):166-176.

⁶⁶ Squires D, Anderson C. U.S. Health Care from a Global Perspective: Spending, Use of Services, Prices, and Health in 13 Countries. Issues in International Health Policy. New York: Commonwealth Fund; 2015. Available at <u>http://www.commonwealthfund.org/~/media/files/publications/issuebrief/2015/oct/1819 squires us hlt care global perspective oecd intl brief v3.pdf</u>. Last accessed March 2017.

⁶⁷ Davis K, Stremikis K, Squires D, et al. *Mirror, Mirror on the Wall, How the Performance of the U.S. Health Care System Compares Internationally*. New York: The Commonwealth Fund; 2014. Available at <u>http://www.commonwealthfund.org/~/media/files/publications/fund-report/2014/jun/1755_davis_mirror_2014.pdf</u>. Last accessed March 2017.

⁶⁸ CDC. Improving the Nation's Vision Health: A Coordinated Public Health Approach. Atlanta, GA; 2007. Available at <u>http://www.cdc.gov/visionhealth/publications/vhi_report.htm</u>. Last accessed February 2017.

⁶⁹ Wittenborn J, Rein D. Cost of Vision Problems: The Economic Burden of Vision Loss and Eye Disorders in the United States. Chicago, IL: NORC at the University of Chicago; 2013. Available at <u>http://www.preventblindness.org/sites/default/files/national/documents/Economic%20Burden%20of%</u> 20Vision%20Final%20Report 130611.pdf. Last accessed December 2016.

⁷⁰ CDC. National Ambulatory Medical Care Survey Factsheet for Otolaryngology. Atlanta, GA: CDC: 2010. Available at <u>http://www.cdc.gov/nchs/data/ahcd/NAMCS_2010_factsheet_otolaryngology.pdf</u>. Last accessed February 2017.

⁷¹ Eggleston EM, Finkelstein JA. Finding the role of health care in population health. *JAMA*. 2014;311(8):797-798.

⁷² Kindig DA, Asada Y, Booske B. A population health framework for setting national and state health goals. *JAMA*. 2008;299(17):2081-2083.

⁷³ Bipartisan Policy Center. Lots to Lose: How America's Health and Obesity Crisis Threatens Our Economic Future. Washington, DC: Bipartisan Policy Center; 2012.

⁷⁴ Research America. Investment in Research Saves Lives and Money #15 Facts about infectious diseases. Alexandria, VA: Research America; 2015. Available at

http://www.researchamerica.org/sites/default/files/uploads/factsheet15infectiousdiseases.pdf. Last accessed April 2017.

⁷⁵ CDC. National Center for Health Statistics FastStats infectious disease website. <u>http://www.cdc.gov/nchs/fastats/infectious-disease.htm</u>. Last accessed April 2017.

⁷⁶ Tono CM, Andrews RM. National Inpatient Hospital Costs: The Most Expensive Conditions by Payer, 2011. Rockville, MD: AHRQ; 2013. Healthcare Cost and Utilization Project (HCUP) Statistical Brief #160. Available at <u>https://www.hcup-us.ahrq.gov/reports/statbriefs/sb160.pdf</u>. Last accessed April 2017.

⁷⁷ United States Bone and Joint Initiative. Health Care Utilization and Economic Cost of Musculoskeletal Diseases. In: *The Burden of Musculoskeletal Diseases in the United States*. 2nd ed. Rosemont, IL: American Academy of Orthopaedic Surgeons; 2011:219-252.

⁷⁸ The Burden of Musculoskeletal Diseases in the United States. Economic cost by age website. <u>http://www.boneandjointburden.org/2014-report/xd23/age</u>. Last accessed January 2018.

⁷⁹ Institute of Medicine (IOM). Dying in America: Improving Quality and Honoring Individual Preferences near the End of Life. Washington, DC: National Academies Press; 2014. Available at <u>http://www.nationalacademies.org/hmd/Reports/2014/Dying-In-America-Improving-Quality-and-Honoring-Individual-Preferences-Near-the-End-of-Life.aspx</u>.

⁸⁰ James JT. A new, evidence-based estimate of patient harms associated with hospital care. *J Patient Saf.* 2013;9(3):122-128.

⁸¹ Colby SL, Ortman JM. *Projections of the Size and Composition of the U.S. Population: 2014 to 2060.* Washington, DC: U.S. Census Bureau; 2014. Current Population Reports Series P25-1145. Available at <u>https://www.census.gov/content/dam/Census/library/publications/2015/demo/p25-1143.pdf</u>. Last accessed January 2018.

³² McGrady ME, Hommel KA. Medication adherence and health care utilization in pediatric chronic illness: a systematic review. *Pediatrics*. 2013;132(4):730-740.

⁸³ CMS. October 2017 Medicaid and CHIP enrollment data highlights website. <u>https://www.medicaid.gov/medicaid/program-information/medicaid-and-chip-enrollment-data/report-highlights/index.html</u>. Last accessed January 2018.

⁸⁴ CMS. 2017 Core Set of Children's Health Care Quality Measures for Medicaid and CHIP (Child Core Set) Baltimore, MD: 2017. Available at <u>https://www.medicaid.gov/medicaid/quality-of-</u> <u>care/downloads/2017-child-core-set.pdf</u>. Last accessed March 2017.

⁸⁵ U.S. Renal Data System. USRDS 2010 Annual Data Report: Atlas of Chronic Kidney Disease and End-Stage Renal Disease in the United States. Bethesda, MD: National Institutes of Health, National Institute of Diabetes and Digestive and Kidney Diseases; 2010. Available at <u>https://www.usrds.org/atlas10.aspx</u>. Last accessed June 2016. ³⁶ Cullen KA, Hall MJ, Golosinskiy A. Ambulatory surgery in the United States, 2006. *Natl Health Stat Report*. 2009;28(11):1-25. Available at <u>http://www.cdc.gov/nchs/data/nhsr/nhsr011.pdf</u>. Last accessed August 2016.

⁸⁷ SAMHSA. Projections of National Expenditures for Treatment of Mental and Substance Use Disorders, 2010-2020. Rockville, MD: SAMHSA; 2014. Available at <u>https://store.samhsa.gov/shin/content/SMA14-4883/SMA14-4883.pdf</u>.

⁸⁸ ACS. Economic impact of cancer website. <u>https://www.cancer.org/cancer/cancer-basics/economic-impact-of-cancer.html</u>. Last accessed January 2018.

⁸⁹ National Cancer Institute. Cancer statistics website. <u>https://www.cancer.gov/about-cancer/understanding/statistics</u>. Last accessed January 2018.

⁹⁰ HHS. Million hearts costs & consequences website. <u>https://millionhearts.hhs.gov/learn-prevent/cost-consequences.html</u>. Last accessed January 2018.

⁹³ CMS. National health expenditure data NHE fact sheet website. <u>https://www.cms.gov/research-statistics-data-and-systems/statistics-trends-and-reports/nationalhealthexpenddata/nhe-fact-sheet.html</u>. Last accessed January 2018.

⁹² CMS. National health expenditure data NHE fact sheet website. <u>https://www.cms.gov/research-statistics-data-and-systems/statistics-trends-and-reports/nationalhealthexpenddata/nhe-fact-sheet.html</u>. Last accessed January 2018.

⁹³ CMS. National health expenditure data NHE fact sheet website. <u>https://www.cms.gov/research-statistics-data-and-systems/statistics-trends-and-reports/nationalhealthexpenddata/nhe-fact-sheet.html</u>. Last accessed January 2018.

⁹⁴ IOM. Best Care at Lower Cost: the Path to Continuously Learning Health Care in America. Washington, DC: National Academies Press; 2013.

⁹⁵ He W, Goodkind D, Kowal P. *An Aging World: 2015*. Washington, DC: Census Bureau; 2016. Available at <u>https://www.census.gov/content/dam/Census/library/publications/2016/demo/p95-16-1.pdf</u>. Last accessed January 2018.

⁹⁶ CDC. Stroke facts website. https://www.cdc.gov/stroke/facts.htm. Last accessed January 2018.

⁹⁷ Alzheimer's Association. 2017 Alzheimer's disease facts and figures website. https://www.alz.org/facts/overview.asp. Last accessed January 2018.

⁹⁸ CDC. Healthcare-associated infections (HAI) website. <u>http://www.cdc.gov/hai/</u>. Last accessed January 2018.

⁹⁹ Childbirth Connection. United States maternity care fact and figures website. <u>http://transform.childbirthconnection.org/resources/datacenter/factsandfigures/</u>. Last accessed January 2018.

¹⁰⁰ Robeznieks A. U.S. has highest maternal death rate among developed countries. *Modern Healthcare*. May 6, 2015. <u>http://www.modernhealthcare.com/article/20150506/NEWS/150509941</u>. Last accessed January 2018.

Tavernise S. Maternal mortality rate in U.S. rises, defying global trend, study finds. *New York Times*. September 21, 2016. <u>https://www.nytimes.com/2016/09/22/health/maternal-mortality.html</u>. Last accessed January 2018.

Welch A. How the U.S. ranks in maternal and child health. *CBS News*. May 4, 2015. <u>https://www.cbsnews.com/news/us-ranks-worse-than-other-developed-nation-in-maternal-health/</u>. Last accessed January 2018.

¹⁰¹ CDC. Births and natality website. <u>https://www.cdc.gov/nchs/fastats/births.htm</u>. Last accessed January 2018.

¹⁰² Dehlendorf C, Rodriguez MI, Levy K, et al. Disparities in family planning. *American J Obstet Gynecol*. 2010;202(3):214-220. Available at <u>http://www.ncbi.nlm.nih.gov/pmc/articles/PMC2835625/</u>. Last accessed October 2015.

CDC. Pregnancy mortality surveillance system website. http://www.cdc.gov/reproductivehealth/maternalinfanthealth/pmss.html. Last accessed October 2015.

¹⁰³ Davis K, Stremikis K, Schoen D, et al. *Mirror, Mirror on the Wall, 2014 Update: How the U.S. Health Care System Compares Internationally*. Washington, DC: The Commonwealth Fund; 2014. Available at <u>http://www.commonwealthfund.org/publications/fund-reports/2014/jun/mirror-mirror</u>. Last accessed October 2016.

¹⁰⁴ Bipartisan Policy Center. Lots to Lose: How America's Health and Obesity Crisis Threatens Our Economic Future. Washington, DC: Bipartisan Policy Center; 2012.

¹⁰⁵ CDC. More than 29 million Americans have diabetes; 1 in 4 doesn't know website. <u>https://www.cdc.gov/media/releases/2014/p0610-diabetes-report.html</u>. Last accessed January 2018.

¹⁰⁶ CDC. Asthma in the US website. <u>https://www.cdc.gov/vitalsigns/asthma/index.html</u>. Last accessed January 2018.

¹⁰⁷ U.S. Renal Data System (USRDS). USRDS 2010 Annual Data Report: Atlas of Chronic Kidney Disease and End-Stage Renal Disease in the United States. Bethesda, MD: National Institutes of Health, National Institute of Diabetes and Digestive and Kidney Diseases; 2010. Available at <u>https://www.usrds.org/atlas10.aspx</u>. Last accessed June 2016.

¹⁰⁸ CDC, NCHS. Number of all-listed procedures for discharges from short-stay hospitals, by procedure category and age: United States, 2010. National Hospital Discharge Survey. Atlanta, GA: CDC; 2011. Available at http://www.cdc.gov/nchs/data/nhds/4procedures/2010pro4_numberprocedureage.pdf. Last accessed February 2018.

¹⁰⁹ Fingar KR, Stocks C, Weiss AJ, et al. *Most Frequent Operating Room Procedures Performed in U.S. Hospitals, 2003-2012. HCUP Statistical Brief 186.* Rockville, MD: AHRQ; 2014. Available at https://hcupus.ahrq.gov/reports/statbriefs/sb186-Operating-Room-Procedures-United-States-2012.jsp. Last accessed February 2018.

¹¹⁰ Agency for Healthcare Research and Quality (AHRQ). *Most Frequent Operating Room Procedures Performed in U.S. Hospitals, 2003-2012.* HCUP Statistical Brief #186. Rockville, MD: AHRQ; 2014.

¹¹¹ Contract with a consensus-based entity regarding performance measurement. 42 USC 1395aaa(b)(5)(A) (2014).

¹¹² CMS. MIPS overview website. <u>https://qpp.cms.gov/mips/overview</u>. Last accessed January 2018.

³¹³ CMS. Shared savings program website. <u>https://www.cms.gov/Medicare/Medicare-Fee-for-Service-</u> Payment/sharedsavingsprogram/index.html. Last accessed January 2018.

³¹⁴ CMS. PPS-exempt cancer hospital quality reporting (PCHQR) program website. https://www.cms.gov/Medicare/Quality-Initiatives-Patient-Assessment-Instruments/HospitalQualityInits/PCHQR.html. Last accessed January 2018.

¹¹⁵ CMS. Ambulatory surgical center quality reporting (ASCQR) program website. <u>https://www.cms.gov/Medicare/Quality-Initiatives-Patient-Assessment-Instruments/ASC-Quality-Reporting/index.html</u>. Last accessed January 2018.

¹¹⁶ CMS. Inpatient psychiatric facility quality reporting (IPFQR) Program website. <u>https://www.cms.gov/Medicare/Quality-Initiatives-Patient-Assessment-</u> Instruments/HospitalQualityInits/IPFQR.html. Last accessed January 2018.

¹¹⁷ CMS. Hospital outpatient quality reporting program website. <u>https://www.cms.gov/Medicare/Quality-Initiatives-Patient-Assessment-Instruments/HospitalQualityInits/hospitalQutpatientQualityReportingProgram.html</u>. Last accessed January 2018.

¹¹⁸ CMS. The Hospital readmissions reduction (HRR) program website. <u>https://www.cms.gov/Medicare/Quality-Initiatives-Patient-Assessment-Instruments/Value-Based-Programs/HRRP/Hospital-Readmission-Reduction-Program.html</u>. Last accessed January 2018.

¹¹⁹ HHS, Office of the Assistant Secretary for Planning and Evaluation (ASPE). *Report to Congress: Social Risk Factors and Performance Under Medicare's Value-Based Purchasing Programs*. Washington, DC: HHS, ASPE; 2016. Available at <u>https://aspe.hhs.gov/pdf-report/report/congress-social-risk-factors-and-performance-under-medicares-value-based-purchasing-programs</u>. Last accessed July 2017.

¹²⁰ CMS. The hospital value-based purchasing (VBP) program website. https://www.cms.gov/Medicare/Quality-Initiatives-Patient-Assessment-Instruments/Value-Based-Programs/HVBP/Hospital-Value-Based-Purchasing.html. Last accessed January 2018.

¹²¹ CMS. Hospital-acquired condition reduction program (HACRP) website. <u>https://www.cms.gov/Medicare/Medicare-Fee-for-Service-Payment/AcuteInpatientPPS/HAC-Reduction-Program.html</u>. Last accessed January 2018.

¹²² CMS. Inpatient rehabilitation facilities (IRF) quality reporting program (QRP) website. <u>https://www.cms.gov/Medicare/Quality-Initiatives-Patient-Assessment-Instruments/IRF-Quality-Reporting/</u>. Last accessed January 2018.

¹²³ CMS. Long-term care hospital (LTCH) quality reporting (QRP) website. <u>https://www.cms.gov/medicare/quality-initiatives-patient-assessment-instruments/ltch-quality-reporting/</u>. Last accessed January 2018.

¹²⁴ CMS. Skilled nursing facility (SNF) quality reporting program measures and technical information website. <u>https://www.cms.gov/Medicare/Quality-Initiatives-Patient-Assessment-</u> <u>Instruments/NursingHomeQualityInits/Skilled-Nursing-Facility-Quality-Reporting-Program/SNF-Quality-Reporting-Program-Measures-and-Technical-Information.html</u>. Last accessed January 2018.

¹²⁵ CMS. The skilled nursing facility value-based purchasing program (SNF VBP) website. <u>https://www.cms.gov/Medicare/Quality-Initiatives-Patient-Assessment-Instruments/Value-Based-Programs/Other-VBPs/SNF-VBP.html</u>. Last accessed January 2018.

¹²⁶ CMS. Home health quality reporting requirements website. <u>https://www.cms.gov/Medicare/Quality-Initiatives-Patient-Assessment-Instruments/HomeHealthQualityInits/Home-Health-Quality-Reporting-Requirements.html</u>. Last accessed January 2018.

¹²⁷ CMS. Hospice quality reporting website. <u>https://www.cms.gov/Medicare/Quality-Initiatives-Patient-Assessment-Instruments/Hospice-Quality-Reporting/</u>. Last accessed January 2018.

¹²⁸ CMS. Center for Clinical Standards and Quality. *2016 Measures under Consideration List. Program Specific Measure Priorities and Needs.* Baltimore, MD: CMS; 2016:25-26. Available at https://www.cms.gov/Medicare/Quality-Initiatives-Patient-Assessment-linstruments/QualityMeasures/Downloads/Program-Specific-Measure-Priorities-and-Needs.pdf. Last accessed December 2017.

¹²⁹ HHS, Health Resources and Services Administration (HRSA). Telehealth programs website. <u>https://www.hrsa.gov/ruralhealth/telehealth/index.html</u>. Last accessed May 2017.

¹³⁰ Doarn CR, Pruitt S, Jacobs J, et al. Federal efforts to define and advanced telehealth—a work in progress. *Telemed J E Health*. 2014;20(5):409-418.

¹³¹ Smith AC, Bensink M, Armfield N, et al. Telemedicine and rural health care applications. *J Postgrad Med.* 2005;51(4):286-293.

¹³² Black AD, Car J, Pagliari C, et al. The impact of eHealth on the quality and safety of healthcare: a systematic overview. *PLoS Med.* 2011;8(1):e1000387.

¹³³ Duseja R, Bardach NS, Lin GA, et al. Revisit rates and associated costs after an emergency department encounter: a multistate analysis. *Ann Intern Med.* 2015; 162(11):750-756.

¹³⁴ National Transitions of Care Coalition (NTCC). Improving Transitions of Care: Findings and Considerations of the "Vision of the National Transitions of Care Coalition". Little Rock, AR: NTCC; 2010. Available at <u>http://www.ntocc.org/portals/0/pdf/resources/ntoccissuebriefs.pdf</u>. Last accessed May 2017.

¹³⁵ IOM. Improving Diagnosis in Health Care. Washington, DC: National Academies Press; 2015.

¹³⁶ Singh H, Meyer AND, Thomas EJ. The frequency of diagnostic errors in outpatient care: estimations from three large observational studies involving US adult populations. *BMJ Qual Saf.* 2014;23(9):727-731.

¹³⁷ Singh H, Meyer AND, Thomas EJ. The frequency of diagnostic errors in outpatient care: estimations from three large observational studies involving US adult populations. *BMJ Qual Saf.* 2014;23(9):727-731.

¹³⁸ NQF. Ambulatory care overview 2005-2009 website. <u>http://www.qualityforum.org/Projects/a-b/Ambulatory Care, Standardizing (2004)/Ambulatory Care Overview 2005-2009.aspx</u>. Last accessed January 2018

¹³⁹ CMS. Medicaid innovation accelerator program (IAP) website. <u>https://www.medicaid.gov/state-resource-center/innovation-accelerator-program/innovation-accelerator-program.html</u>. Last accessed February 2017.

¹⁴⁰ CMS. Core measures: overview website. <u>https://www.cms.gov/Medicare/Quality-initiatives-patient-</u> assessment-instruments/qualitymeasures/core-measures.html. Last accessed February 2017.

¹⁴¹ CMS. Release of core quality measures collaborative pediatric core measure set factsheet website. <u>https://www.cms.gov/Newsroom/MediaReleaseDatabase/Fact-sheets/2017-Fact-Sheet-items/2017-07-28.html</u>. Last accessed January 2018.

¹⁴² CMS. Core measures: overview website. <u>https://www.cms.gov/Medicare/Quality-initiatives-patient-assessment-instruments/qualitymeasures/core-measures.html</u>. Last accessed February 2017.

¹⁴³ CMS. Release of core quality measures collaborative pediatric core measure set factsheet website. <u>https://www.cms.gov/Newsroom/MediaReleaseDatabase/Fact-sheets/2017-Fact-Sheet-items/2017-07-28.html</u>, Last accessed January 2018.

¹⁴⁴ CMS. Children's health care quality measures website. <u>https://www.medicaid.gov/medicaid/quality-of-care/performance-measurement/child-core-set/index.html</u>. Last accessed January 2017.

¹⁴⁵ CMS. Release of core quality measures collaborative pediatric core measure set factsheet website. <u>https://www.cms.gov/Newsroom/MediaReleaseDatabase/Fact-sheets/2017-Fact-Sheet-items/2017-07-28.html</u>, Last accessed January 2018. -

Appendix A: 2017 Activities Performed Under Contract with HHS

1. Recommendations on the National Quality Strategy and Priorities

Description	Output	Status	Notes/Scheduled or Actual Completion Date
Eliminating healthcare disparities and achieving health equity	Roadmap for reducing health and healthcare disparities through policy levers	Completed	Final report published September 2017
Food Insecurity and Housing Instability A framework for Medicaid programs to address social determinants of health	Guidance for state Medicaid programs to make strategic investments in the collection and use of social determinants of health data	Completed	Final report completed December 2017
Annual review and update of quality measures for adults enrolled in Medicaid	Annual input on the Core Set of Health Care Quality Measures for Adults Enrolled in Medicaid	Completed	Completed August 2017
Annual review and update of quality measures for children enrolled in Medicaid	Annual input on the Core Set of Health Care Quality Measures for Children enrolled in Medicaid.	Completed	Completed August 2017
Annual review and update of quality measures for the dual- eligible (Medicare-Medicaid) population	Annual input on the Dual Eligible Beneficiaries Family of Measures.	Completed	Completed August 2017

2. Quality and Efficiency Measurement Initiatives Completed in 2017

Description	Output	Status	Notes/Scheduled or Actual Completion Date
All-Cause Admissions and Readmissions 2015-2017	Set of endorsed measures for all-cause admissions and readmissions	2015-2017 completed	Final report published April 2017
All Cause Admissions and Readmissions 2017	Set of endorsed measures for all-cause admissions and readmissions	2017 completed	Final report published September 2017
Behavioral Health 2016-2017	Set of endorsed measures for behavioral health	2016-2017 completed	Final report published August 2017
Cancer 2015-2017	Set of endorsed measures for cancer care	2015-2017 completed	Final report published January 2017
Cardiovascular Conditions 2016- 2017	Set of endorsed measures for cardiovascular conditions	2016-2017 completed	Final report published February 2017
Care Coordination Measures 2016-2017	Set of endorsed measures for care coordination	2016-2017 completed	Final report published August 2017
Cost and Resource Use 2016- 2017	Set of endorsed measures for cost and resource use	2016-2017 completed	Final report published August 2017
Eye Care and Ear, Nose, and Throat Conditions Off-Cycle Measure Review 2017	Endorsed measure for ear condition	2017 completed	Final report published September 2017
Health and Well-Being 2015-2017	Set of endorsed measures for health and well-being	2015-2017 completed	Final report published April 2017
Infectious Disease 2016-2017	Set of endorsed measures for infectious disease	2016-2017 completed	Final report published August 2017

Description	Output	Status	Notes/Scheduled or Actual Completion Date
Musculoskeletal Off-Cycle Measure Review 2017	No measures for musculoskeletal conditions endorsed	2017 completed	Final report published July 2017
Palliative and EOL Care Off-Cycle Measure Review 2017	One measure endorsed for palliative and end-of-life care	2017 completed	Final report published September 2017
Patient- and Family-Centered Care 2015-2016	Set of endorsed measures for patient- and family-centered care	2015-2016 completed	Final report published January 2017
Patient Safety 2016	Set of endorsed measures for patient safety	2016 completed	Final report published March 2017
Patient Safety Off-Cycle Measure Review 2017	Measures considered but not endorsed	2017 completed	Final report published July 2017
Pediatric Performance Measures 2017	Set of endorsed measures for pediatrics	2017 completed	Final report published August 2017
Renal Conditions 2015-2017	Set of endorsed measures for renal conditions	2015-2017 completed	Final report published February 2017
Surgical Procedures 2015-2017	Set of endorsed measures for surgical procedures	2015-2017 completed	Final report published April 2017

Started in 2017

Description	Output	Status	Notes/Scheduled or Actual Completion Date
All-Cause Admissions and Readmissions	Set of endorsed measures for all-cause admissions and readmissions	In progress	Final report expected July 2018
Behavioral Health and Substance Use	Set of endorsed measures for behavioral health	In progress	Final report expected July 2018
Cancer	Set of endorsed measures for cancer care	In progress	Final report expected July 2018
Cardiovascular	Set of endorsed measures for cardiovascular conditions	In progress	Final report expected July 2018
Cost and Efficiency	Set of endorsed measures for cost and resource use	In progress	Final report expected July 2018
Geriatric and Palliative Care	Set of endorsed measures for geriatric and palliative care	In progress	Final report expected July 2018
Neurology	Set of endorsed measures for neurological conditions	In progress	Final report expected July 2018
Patient Experience and Function	Set of endorsed measures for patient experience and function	In progress	Final report expected July 2018
Patient Safety	Set of endorsed measures for patient safety	In progress	Final report expected July 2018
Perinatal and Women's Health	Set of endorsed measures for perinatal and women's health	In progress	Final report expected July 2018
Prevention and Population Health	Set of endorsed measures for prevention and population health	In progress	Final report expected July 2018
Primary Care and Chronic Illness	Set of endorsed measures for primary care and chronic illness	In progress	Final report expected July 2018
Renal	Set of endorsed measures for renal conditions	In progress	Final report expected July 2018
Surgery	Set of endorsed measures for surgical procedures	In progress	Final report expected July 2018

3. Stakeholder Re	commendations on Quality	and Efficiency Measures an	d National Priorities
			at a fait of a start of a

Description	Output	Status	Notes/Scheduled or Actual Completion Date
Recommendations for measures to be implemented through the federal rulemaking process for public reporting and payment	Measure Applications Partnership pre- rulemaking recommendations on measures under consideration by HHS for 2017 rulemaking	Completed	Completed February 2017

Appendix B: Medicaid Task Forces and Workgroup Rosters

Adult Task Force

CHAIR (VOTING) Harold Pincus, MD

ORGANIZATIONAL MEMBERS (VOTING)

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Centene Corporation

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Centers for Medicare & Medicaid Services (CMS) Marsha Smith, MD

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Amy Richardson, MD, MBA

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Rachel La Croix, PhD

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Joe Baker, JD

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National Association of Social Workers Joan Levy Zlotnik, PhD, ACSW

New Jersey Hospital Association Aline Holmes, DNP, MSN, RN

SNP Alliance Richard Bringewatt

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K. Charlie Lakin, PhD

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Kimberly Rask, MD, PhD

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CMS Medicare-Medicaid Coordination Office

Stacey Lytle, MPH

Office of the Assistant Secretary for Planning and Evaluation D.E.B. Potter, MS

Appendix C: Scientific Methods Panel Roster

Chairs

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Members

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Assistant Professor, Armstrong Institute for Patient Safety and Quality at Johns Hopkins Medicine

Bijan Borah, MSc, PhD Associate Professor, Mayo Clinic

John Bott, MBA, MSSW

Manager, Healthcare Ratings, Consumer Reports

Lacy Fabian, PhD

Lead Healthcare Evaluation Specialist, The MITRE Corporation

Marybeth Farquhar, PhD, MSN, RN

Vice President, Quality, Research & Measurement, URAC

Jeffrey Geppert, EdM, JD

Senior Research Leader, Battelle Memorial Institute

Paul Gerrard, BS, MD

Associate Medical Director Physical Medicine and Rehabilitation, New England Rehabilitation Hospitals of Portland (HealthSouth, Inc.)

Laurent Glance, MD

Professor and Vice-Chair for Research, University of Rochester School of Medicine and Dentistry

Stephen Horner, RN, BSN, MBA Vice President Clinical Analytics, HCA, Inc.

Sherrie Kaplan, PhD, MPH

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Joseph Kunisch, PhD, RN-BC, CPHQ

Enterprise Director of Clinical Quality Informatics, Memorial Hermann Health System

Paul Kurlansky, MD

Associate Professor of Surgery / Associate Director, Center for Innovation and Outcomes Research / Director of Research, Recruitment and CQI, Columbia University, College of Physicians and Surgeons / Columbia HeartSource

Zhengiu Lin, PhD

Director of Data Management and Analytics, Yale-New Haven Hospital

Jack Needleman, PhD

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David Nerenz, PhD

Director, Center for Health Policy and Health Services Research, Henry Ford Health System

Eugene Nuccio, PhD

Assistant Professor, University of Colorado, Anschutz Medical Campus

Jennifer Perloff, PhD

Scientist and Deputy Director at the Institute of Healthcare Systems, Brandeis University

Sam Simon, PhD

Senior Researcher, Mathematica Policy Research

Michael Stoto, PhD

Professor of Health Systems Administration and Population Health, Georgetown University

Christie Teigland, PhD

Vice President, Advanced Analytics, Avalere Health

Ronald Walters, MD, MBA, MHA, MS

Associate Vice President of Medical Operations and Informatics, University of Texas MD Anderson Cancer Center

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Susan White, PhD, RHIA, CHDA Administrator - Analytics, The James Cancer Hospital at The Ohio State University Wexner Medical Center

NQF #	Title	Variable Included
0076	Optimal Vascular Care	Insurance product
0275	Chronic Obstructive Pulmonary Disease (COPD) or Asthma in Older Adults Admission Rate (PQI 05)	Percent of households under the federal poverty level
0283	Asthma in Younger Adults Admission Rate (PQI 15)	Percent of households under the federal poverty level
0369	Standardized Mortality Ratio for Dialysis Facilities	Race, ethnicity
2651	CAHPS [®] Hospice Survey (experience with care)	Payer Respondent education Variable indicating survey language and respondent's home language
2827	PointRight [®] Pro Long Stay(TM) Hospitalization Measure	Medicaid beneficiary status
2842	Family Experiences with Coordination of Care (FECC)-1: Has Care Coordinator	Respondent education
2843	Family Experiences with Coordination of Care (FECC)-3: Care coordinator helped to obtain community services	Respondent education
2844	Family Experiences with Coordination of Care (FECC)-5: Care coordinator asked about concerns and health	Respondent education
2845	Family Experiences with Coordination of Care (FECC)-7: Care coordinator assisted with specialist service referrals	Respondent education
2846	Family Experiences with Coordination of Care (FECC)-8: Care coordinator was knowledgeable, supportive and advocated for child's needs	Respondent education
2847	Family Experiences with Coordination of Care (FECC)-9: Appropriate written visit summary content	Respondent education
2849	Family Experiences with Coordination of Care (FECC)-15: Caregiver has access to medical interpreter when needed	Respondent education
2850	Family Experiences with Coordination of Care (FECC)-16: Child has shared care plan	Respondent education
2858	Discharge to Community	Marital status
2967	CAHPS® Home- and Community-Based Services Measures	Whether respondent lives alone
3188	30-Day Unplanned Readmissions for Cancer Patients (Phase 3)	Dual eligible status

Appendix D: NQF-Endorsed Measures Adjusted for Social Risk

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Appendix E: MAP Measure Selection Criteria

The Measure Selection Criteria (MSC) are intended to assist MAP with identifying characteristics that are associated with ideal measure sets used for public reporting and payment programs. The MSC are not absolute rules; rather, they are meant to provide general guidance on measure selection decisions and to complement program-specific statutory and regulatory requirements. Central focus should be on the selection of high-quality measures that optimally address the National Quality Strategy's three aims, fill critical measurement gaps, and increase alignment. Although competing priorities often need to be weighed against one another, the MSC can be used as a reference when evaluating the relative strengths and weaknesses of a program measure set, and how the addition of an individual measure would contribute to the set. The MSC have evolved over time to reflect the input of a wide variety of stakeholders.

To determine whether a measure should be considered for a specified program, the MAP evaluates the measures under consideration against the MSC. MAP members are expected to familiarize themselves with the criteria and use them to indicate their support for a measure under consideration.

1. NQF-endorsed measures are required for program measure sets, unless no relevant endorsed measures are available to achieve a critical program objective

Demonstrated by a program measure set that contains measures that meet the NQF endorsement criteria, including importance to measure and report, scientific acceptability of measure properties, feasibility, usability and use, and harmonization of competing and related measures

Subcriterion 1.1	Measures that are not NQF-endorsed should be submitted for endorsement if selected to meet a specific program need
Subcriterion 1.2	Measures that have had endorsement removed or have been submitted for endorsement and were not endorsed should be removed from programs
Subcriterion 1.3	Measures that are in reserve status (i.e., topped out) should be considered for removal from programs

2. Program measure set adequately addresses each of the National Quality Strategy's three aims

Demonstrated by a program measure set that addresses each of the National Quality Strategy (NQS) aims and corresponding priorities. The NQS provides a common framework for focusing efforts of diverse stakeholders on:

Subcriterion 2.1	Better care, demonstrated by patient- and family-centeredness, care
	coordination, safety, and effective treatment
Subcriterion 2.2	Healthy people/healthy communities, demonstrated by prevention and well- being
Subcriterion 2.3	Affordable care



3. Program measure set is responsive to specific program goals and requirements

Demonstrated by a program measure set that is "fit for purpose" for the particular program

Subcriterion 3.1	Program measure set includes measures that are applicable to and appropriately tested for the program's intended care setting(s), level(s) of analysis, and population(s)
Subcriterion 3.2	Measure sets for public reporting programs should be meaningful for consumers and purchasers
Subcriterion 3.3	Measure sets for payment incentive programs should contain measures for which there is broad experience demonstrating usability and usefulness (Note: For some Medicare payment programs, statute requires that measures must first be implemented in a public reporting program for a designated period)
Subcriterion 3.4	Avoid selection of measures that are likely to create significant adverse consequences when used in a specific program
Subcriterion 3.5	Emphasize inclusion of endorsed measures that have eCQM specifications available

4. Program measure set includes an appropriate mix of measure types

Demonstrated by a program measure set that includes an appropriate mix of process, outcome, experience of care, cost/resource use/appropriateness, composite, and structural measures necessary for the specific program

Subcriterion 4.1	In general, preference should be given to measure types that address specific program needs
Subcriterion 4.2	Public reporting of program measure sets should emphasize outcomes that matter to patients, including patient- and caregiver-reported outcomes
Subcriterion 4.3	Payment program measure sets should include outcome measures linked to cost measures to capture value

5. Program measure set enables measurement of person- and family-centered care and services

Demonstrated by a program measure set that addresses access, choice, self-determination, and community integration

Subcriterion 5.1	Measure set addresses patient/family/caregiver experience, including aspects of communication and care coordination
Subcriterion 5.2	Measure set addresses shared decision making, such as for care and service planning and establishing advance directives
Subcriterion 5.3	Measure set enables assessment of the person's care and services across providers, settings, and time

6. Program measure set includes considerations for healthcare disparities and cultural competency

Demonstrated by a program measure set that promotes equitable access and treatment by considering healthcare disparities. Factors include addressing race, ethnicity, socioeconomic status, language, gender, sexual orientation, age, or geographical considerations (e.g., urban vs. rural). Program measure set also can address populations at risk for healthcare disparities (e.g., people with behavioral/mental illness).

Subcriterion 6.1	Program measure set includes measures that directly assess healthcare
	disparities (e.g., interpreter services)

Subcriterion 6.2 Program measure set includes measures that are sensitive to disparities measurement (e.g., beta blocker treatment after a heart attack), and that facilitate stratification of results to better understand differences among vulnerable populations

7. Program measure set promotes parsimony and alignment

Demonstrated by a program measure set that supports efficient use of resources for data collection and reporting, and supports alignment across programs. The program measure set should balance the degree of effort associated with measurement and its opportunity to improve quality.

 Subcriterion 7.1
 Program measure set demonstrates efficiency (i.e., minimum number of measures and the least burdensome measures that achieve program goals)

 Subcriterion 7.2
 Program measure set places strong emphasis on measures that can be used

across multiple programs or applications (e.g., Physician Quality Reporting System, Meaningful Use for Eligible Professionals, Physician Compare)

Appendix F: Federal Quality Reporting and Performance-Based Payment Programs Considered by MAP

- 1. Ambulatory Surgical Center Quality Reporting
- 2. End-Stage Renal Disease Quality Improvement Program
- 3. Home Health Quality Reporting
- 4. Hospice Quality Reporting
- 5. Hospital Acquired Condition Payment Reduction (ACA 3008)
- 6. Hospital Inpatient Quality Reporting (IQR) Program
- 7. Hospital Outpatient Quality Reporting (OQR) Program
- 8. Hospital Readmission Reduction Program
- 9. Hospital Value-Based Purchasing
- 10. Inpatient Psychiatric Facility Quality Reporting Program
- 11. Inpatient Rehabilitation Facility Quality Reporting
- 12. Long-Term Care Hospital Quality Reporting
- 13. Medicaid Adult and Child Core Measure Sets
- 14. Medicare Shared Savings Program
- 15. Merit-Based Incentive Payment System
- 16. Prospective Payment System (PPS)-Exempt Cancer Hospital Quality Reporting
- 17. Skilled Nursing Facility Quality Reporting Program
- 18. Skilled Nursing Facility Value-Based Purchasing Program

Appendix G: MAP Structure, Members, Criteria for Service, and Rosters

MAP operates through a two-tiered structure. Guided by the priorities and goals of HHS's National Quality Strategy, the MAP Coordinating Committee provides direction and direct input to HHS. MAP's workgroups advise the Coordinating Committee on measures needed for specific care settings, care providers, and patient populations. Time-limited task forces consider more focused topics, such as developing "families of measures"—related measures that cross settings and populations—and provide further information to the MAP Coordinating Committee and workgroups. Each multistakeholder group includes individuals with content expertise and organizations particularly affected by the work.

MAP's members are selected based on NQF Board-adopted selection criteria, through an annual nominations process and an open public commenting period. Balance among stakeholder groups is paramount. Due to the complexity of MAP's tasks, individual subject matter experts are included in the groups. Federal government *ex officio* members are nonvoting because federal officials cannot advise themselves. MAP members serve staggered three-year terms.

MAP Coordinating Committee

COMMITTEE CO-CHAIRS (VOTING) Charles Kahn, III, MPH Federation of American Hospitals Harold Pincus, MD New York Presbyterian/Columbia University

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MAP Post-Acute Care/Long-Term Care Workgroup

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Appendix H: Identified Gaps by NQF Measure Portfolio

In 2017, NQF's standing committees identified the following measure gaps—where high-value measures are too few or non-existent to drive improvement—across topical areas for which measures were reviewed for endorsement.

Behavioral Health

- Outcome measures for psychotic disorders, including schizophrenia
- Overprescription of opiates
- Setting-specific measures (e.g., jails)
- Proximal outcome measures
- · Measures that focus on substance use disorders in the primary care setting
- Composite measures that incorporate myriad mental illnesses (e.g., bipolar disorder, depression, and schizophrenia) rather than separate screening measures for each illness
- Patient-reported outcome measures
- Measures that encompass multiple settings to better assist in the push towards integrated behavioral health and physical health
- Measures that examine the period of time between screening and remission
- · Measures that address access to behavioral health facilities, or lack thereof
- · Measures that focus not only on treatment and prevention but also on recovery

Cancer

- Prostate and thoracic cancer measures that range from screening to advanced disease
- Oral chemotherapy compliance measures
- Outcome measures including risk-adjusted morbidity and mortality measures

Care Coordination

- Linkages and synchronization of care and services
- A comprehensive assessment process that incorporates the perspective of a care recipient and
 his care team
- Shared accountability within a care team
- Measures that evaluate "system-ness" rather than measures that address care within silos
- Outcome measures
- Capturing data and documenting linkages between a patient's need/goal and relevant interventions in a standardized way and linked to relevant outcomes
- Measures that are evidence-based

Cost and Resource Use

- Total per capita cost measure for Medicare patients
- Measures for post-acute care settings, including home health, skilled nursing facilities, and longterm acute care
- Measures that examine spending for high-cost, high-risk acute patients, including patients with multiple chronic diseases
- Measures that examine resource use across the patient episode of care—spanning across care settings, providers, and time

Health and Well-Being

 Measures that detect differences in quality across institutions or in relation to certain benchmarks, but also differences in quality among populations or social groups.

- 35414
- Measures that assess access to care
- Measures that assess environmental factors
- Measures that address food insecurity
- Measures that address language and literacy
- Measures that address health literacy
- Measures that address social cohesion

Infectious Disease

- Measures that underscore the value of infectious disease (ID) consultation, which studies have shown to improve outcomes. For example, the rate of ID consults in those with Staphylococcus aureus bacteremia, cryptococcal infection, and HIV patients on ART.
- HPV screening in females with HIV

Palliative and End of Life Care

- Screening for depression, anxiety, etc.
- Access to nutritional support
- Use of decisional conflict scale
- Dying in preferred site of death
- Assessment of psychosocial and spiritual issues/needs
- Provider Orders for Life-Sustaining Treatment (POLST) form completion according to patient values
- Assessing family/caregivers for risk (e.g., depression, complicated bereavement, etc.)
- Preservation of functional status
- Total pain (including spiritual pain)
- Psychosocial health
- Unmet need (e.g., through Integrated Palliative Care Outcome Scale (iPOS) instrument)
- Quality of life (e.g., through single item self-report of quality of life as in McGill Quality of Life Survey)
- Goal-concordance
- Shared decision making
- Comfort with decisions that are made (e.g., less decisional conflict)
- Patient/family engagement
- Values conversation that elicits goals of care
- Good communication (e.g., prognosis, health literacy, clarity of goals for all parties)
- Unwanted care/care that is not goal-concordant
- Symptomatology due to use of excess/poor value medications/ interventions
- Unmet psychosocial and spiritual need
- Medication reconciliation
- Safe medication use
- Safe medication disposal
- Feeding tube placement in dementia patients
- Discussion about and potential discontinuation of available interventions in terminal patients (e.g., statin, aspirin, multivitamins, memory drugs, ICDs, CPR, chemo in last 2 weeks)
- Caregiver support
- Caregiver stress
- Good communication (early, open/shared).

- Basic caregiver skills training provided (e.g., how to lift patient without injury to caregiver's back, changing sheets when patient is bedridden, etc.)
- Potentially avoidable ED visits and hospitalizations
- Proportion of elderly chronic kidney disease patients with multiple comorbidities who were started on dialysis
- Proportion of dialysis patients admitted to ICU in last 30 days of life
- Percentage of elderly patients with chronic kidney disease and multiple comorbidities admitted to an "active medical management without dialysis" pathway of care
- · Geographic access to hospice and palliative care (both hospital and community)
- Access to home and community-based services
- Time to palliative care consult or timeliness of palliative care consultation (>48 hours prior to death)
- Access to specialty palliative care team
- Nursing load or chaplain load
- Number of patients in a hospice or palliative care program who are getting chaplain visits
- Standard/minimum service offerings
- Materials offered at appropriate education levels/languages

Patient Safety

- Interoperability of health information technology
- Transitions in care
- Safety in ambulatory surgical centers
- Measurement focused on episodes of care across and within settings
- Outcome measures related to medical errors and complications
- · Greater focus on ambulatory, outpatient, and post-acute care
- Assessment of workforce performance
- Patient-reported outcomes

Pediatric Performance Measures

- Additional pediatric patient safety measures, such as measures related to dosing errors for pediatric patients, pediatric diagnostic errors, and patient safety for outpatient pediatric services
- Measures pertaining to pediatric patients living with intellectual and/or developmental disabilities, including measures for children with dual diagnoses of intellectual/developmental disability and mental illness
- Measures of coordination of care for children with chronic disease
- Measures of quality for foster children, in particular, measures of foster care/ out-of-home placement rates for substance-exposed newborns, and measures evaluating the time substanceexposed children spend in biologic-home settings versus foster care
- Measures of how much time substance-exposed newborns spend in the acute care hospital, NICU, rehabilitation, or children's specialty hospitals
- Measures of quality evaluating abuse and mistreatment, including measures specifically focused on children with special needs
- Measures that capture social determinants of health screening, including food and housing insecurity
- Measures evaluating cost as it relates to children with special healthcare needs that are technologically dependent

- · Measures defining parental strengths and needs within a practice site
- Measures to capture the identification of a team to work together to plan and test improvements in eliciting parental strengths and needs within a practice site
- Measures on integrating tools (e.g., process flows, prompts, and reminders) into practice flow to support the engagement of parents
- Clinic-/systems-level measures that offer more specificity about appropriate antibiotic prophylaxis in children with sickle cell anemia

Person and Family Centered Care

- Pediatric measures, especially for shared decision making
- Measures derived from shorter versions of the CAHPS surveys
- The next level of functional measures: measures not tied to traditional inpatient settings, and that focus on functional restoration, becoming independent, and nonmedical outcomes (e.g., return to employment)
- Setting-specific measures that ensure issues and outcomes specific to that site are measured, for example, measures for ventilator care, which would only happen in Long Term Acute Care (LTAC) Facilities and would not apply to Skilled Nursing Facilities (SNF) or Inpatient Rehabilitation Facilities (IRFs)
- Measures for partnerships between large health systems and community-based agencies, to help health systems partner with high-quality community agencies
- Additional measures of informed and shared decision making to ensure people are effective
 advocates for their healthcare, including, how to choose and change a provider, how to use the
 healthcare system to best advantage, how to use technology to benefit the patient, and how to
 interpret quality data
- Measures across the continuum of care, starting in primary care or emergency departments, through the completion of all services for the patient
- The medical neighborhood extending past the medical home and into other areas of the community where care is received
- Measures that specifically address eliciting and aligning patient goals with the plan of care

Renal

- Patient-reported outcomes
- Patient experience of care and engagement
- Care for comorbid conditions
- Palliative dialvsis
- Vascular Access
- Young dialysis patients' preparedness for transition from pediatric facilities to adult facilities
- Rehabilitation of people who are working age
- Harmonization and improvement of measuring bloodstream infections across dialysis and other facilities

Surgery

- Outcome measures
- Specialty areas that are still in early stages of quality measurement, including orthopedic surgery, bariatric surgery, neurosurgery, obstetrics, gynecology, and smaller specialties (MAP also identified gynecology and genitourinary measurement as gaps)
- Pediatric (<18 years of age), including morbidity and mortality, either added to existing measures or specific to pediatric populations



- Adult and pediatric morbidity and mortality related to frequently performed cardiac procedures
 beyond measures now available
- Postsurgical functional status, including neurodevelopmental morbidity following pediatric and congenital heart surgery
- Surgery-related infections
- Patient-centered approach to decision making including determination to forego treatment
- Aggregated picture of episodes of care, including short- and long-term morbidity and patientreported outcomes, to include measures that cross organizational borders
- Discharge coordination
- Shared accountability

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Appendix I: Medicare Measure Gaps Identified by NQF's Measure Applications Partnership

During its 2016-2017 deliberations, MAP identified the following measure gaps—where high-value measures are too few or nonexistent to drive improvement—for Medicare programs for hospitals and hospital settings, post-acute care/long-term care settings, and clinicians.

Program	Measure Gaps			
End-Stage Renal Disease Quality Incentive Program (ESRD QIP)	 Assessment of quality of pediatric dialysis Management of comorbid conditions (e.g., congestive heart failure, diabetes, and hypertension) Patient-reported outcomes such as functional status, quality of life, and symptom management 			
PPS-Exempt Cancer Hospital Quality Reporting (PCHQR) Program	 Measures that assess safety events broadly (i.e. a measure of global harm) Quality of patients' informed consent process and assessment of patient understanding of potential risks and benefits of treatment 			
Ambulatory Surgery Center Quality Reporting (ASCQR) Program	 Site infections Complications Patient and family engagement Appropriate pre-operative testing 			
Inpatient Psychiatric Facility Quality Reporting Program (IPF QRP)	 Medical comorbidities Quality of psychiatric care provided in the emergency department for patients not admitted to the hospital Discharge planning Condition-specific readmission measures Access to inpatient psychiatric services, especially in rural areas 			
Hospital Outpatient Quality Reporting (OQR) Program	Use of evidence-based practices Communication and care coordination Falls Accurate diagnosis			
Hospital Inpatient Quality Reporting (IQR) Program and Medicare and Medicaid EHR Incentive Programs for Eligible Hospitals and Critical Access Hospitals (CAHs)	 Patient-reported outcomes Dementia 			
Hospital Readmissions Reduction Program (HRRP)	None discussed			
Hospital Value-Based Purchasing Program. (VBP)	Reliable and actionable safety measures			
Hospital-Acquired Condition Reduction Program (HACRP)	Reliable and actionable safety measures			

Program	Measure Gaps		
Merit-Based Incentive Payment System (MIPS)	 Outcome measures (e.g., episode-based as well as patient-reported outcomes) Improved process measures (e.g., composite measures, measures tied to outcomes most important to patients) 		
Medicare Shared Savings Program (MSSP)	 Care coordination (e.g., communication and timeliness of care) Avoidable emergency department use Person and family engagement 		
Inpatient Rehabilitation Facility Quality Reporting Program (IRF QRP)	 Experience of care measures related to patient and family engagement 		
Long-Term Care Hospital Quality Reporting Program (LTCH QRP)	 LTCH-specific CAHPS survey to assess experience of care Nutritional status measures Transfer of information between clinicians 		
Skilled Nursing Facility Quality Reporting Program (SNF QRP)	 Experience of care Efficacy of transfers from acute care hospitals to SNFs Transfer of information between clinicians 		
Skilled Nursing Facility Value-Based Purchasing Program (SNF VBP)	None discussed		
Home Health Quality Reporting Program (HH QRP)	 Measures to drive adoption of congestive heart failure care plans 		
Hospice Quality Reporting Program (HQRP)	 Medication management at the end of life Provision of bereavement services Patient care preferences Symptom management for conditions other than cancer, particularly dementia 		

Appendix J: Medicaid Measure Gaps Identified by NQF's Medicaid Task Force and the Dual Eligible Beneficiaries Workgroup

In 2017, NQF's Medicaid Task Forces and Dual Eligible Beneficiaries Workgroup identified the following high-priority measure gaps for the Medicaid Adult and Child Core Sets of measures and the Dual Eligible Beneficiaries Family of Measures.

Medicaid Measure Set High-Priority Measure Gap Areas	
Adult Core Set	 Behavioral health (integration and coordination with primary and acute settings and outcomes) Assessing and addressing social determinants of health Maternal/reproductive health (e.g., inter-conception care and poor birth outcomes, access to obstetric care in the rural community, and postpartum complications) Long-term care-related supports and services (e.g., home and community-based services, nursing home care) New chronic opiate use
Child Core Set	 Substance abuse Care coordination (e.g., care integration, social services coordination, cross-sector measures, and care coordination for conditions requiring community linkages) Mental health Overuse and medically unnecessary care as well as underuse Cost and resource use measures
Dual Eligible Beneficiaries Family of Measures	 Goal-directed, person-centered care planning and implementation Shared decision making Systems to coordinate acute care, long-term services and supports (LTSS), and nonmedical community resources Beneficiary sense of control/autonomy/self-determination Psychosocial needs Community integration/inclusion and participation Optimal functioning Home and community-based services (HCBS) Affordable and cost-effective care

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